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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[TD 10006]

RIN 1545-BQ29

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AC11

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 146 and 147

[CMS-9902-F]

RIN 0938-AU93

Requirements Related to the Mental Health Parity and Addiction Equity Act

AGENCY: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: This document sets forth final rules amending regulations implementing the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) and adding new regulations implementing the nonquantitative treatment limitation

(NQTL) comparative analyses requirements under MHPAEA, as amended by the Consolidated Appropriations Act, 2021 (CAA, 2021). Specifically, these final rules amend the existing NQTL standard to prohibit group health plans and health insurance issuers offering group or individual health insurance coverage from using NQTLs that place greater restrictions on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. As part of these changes, these final rules require plans and issuers to collect and evaluate relevant data in a manner reasonably designed to assess the impact of NQTLs on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and to take reasonable action, as necessary, to address material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits. These final rules also amend existing examples and add new examples on the application of the rules for NQTLs to clarify and illustrate the requirements of MHPAEA. Additionally, these final rules set forth the content requirements for NQTL comparative analyses and specify how plans and issuers must make these comparative analyses available to the Department of the Treasury (Treasury), the Department of Labor (DOL), and the Department of Health and Human Services (HHS) (collectively, the Departments), as well as to an applicable State authority, and to participants, beneficiaries, and enrollees. Finally, HHS finalizes regulatory amendments to implement the sunset provision for self-funded non-Federal governmental plan elections to opt out of compliance with MHPAEA, as adopted in the Consolidated Appropriations Act, 2023 (CAA, 2023).

DATES:

Effective date. These regulations are effective on **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

Applicability date. See the SUPPLEMENTARY INFORMATION section for information on the applicability dates.

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SUPPLEMENTARY INFORMATION:

I. Background

America continues to experience a mental health and substance use disorder crisis affecting people across all demographics, with marginalized communities disproportionately impacted.¹ The COVID-19 pandemic exacerbated the crisis, but its effects have continued post-pandemic.² From August 19, 2020, to February 1, 2021, the percentage of adults exhibiting symptoms of an anxiety or a depressive disorder rose from 36.4 percent to 41.5 percent.³ In 2022, there were an estimated 15.4 million adults aged 18 or older in the United States with a serious mental illness and nearly one in four adults (59.3 million) living with any mental illness.⁴

Additionally, in 2022, nearly 54.6 million people aged 12 or older were classified as needing treatment for substance use, but only about 24 percent of those people received any treatment, according to the Substance Abuse and Mental Health Services Administration's (SAMHSA) National Survey on Drug Use and Health (NSDUH).⁵ The unmet need for treatment for substance use disorders has been even greater among racial minorities and other marginalized

¹ Kaiser Family Foundation (2022), Five key findings on mental health and substance use disorders by race/ethnicity, <https://www.kff.org/mental-health/issue-brief/five-key-findings-on-mental-health-and-substance-use-disorders-by-race-ethnicity/>.

² American Psychological Association (2023), Stress in America™ 2023: A nation grappling with psychological impacts of collective trauma, <https://www.apa.org/news/press/releases/2023/11/psychological-impacts-collective-trauma>.

³ Vahratian, A., Blumberg, S.J., Terlizzi, E.P., Schiller, J.S. (2021), Symptoms of Anxiety or Depressive Disorder and Use of Mental Health Care Among Adults During the COVID-19 Pandemic — United States, Aug. 2020–Feb. 2021, *MMWR Morb Mortal Wkly Rep* 2021;70:490–494, <https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e2.htm>.

⁴ SAMHSA (2023), Key substance use and mental health indicators in the United States: Results from the 2022 National Survey on Drug Use and Health (HHS Publication No. PEP23-07-01-006, NSDUH Series H-58), <https://www.samhsa.gov/data/report/2022-nsduh-annual-national-report>.

⁵ *Ibid.*

communities. Between 2019 and 2021, median monthly overdose deaths among persons aged 10–19 years increased 109 percent; and deaths involving illicitly manufactured fentanyl increased 182 percent.⁶ In 2021, American Indian and Alaskan Native men aged 15-34 had an age-adjusted death rate caused by drug overdoses of 42 per 100,000 people, compared to 20.5 age-adjusted deaths per 100,000 people during the same time period in 2018.⁷ Non-Hispanic Black or African American men aged 35-64 had an age-adjusted death rate caused by drug overdoses of 61.2 per 100,000 people; an increase from 30.6 deaths per 100,000 people during the same time period in 2018.⁸

Following the COVID-19 pandemic, employers highlighted that they have responded to the impact of the pandemic on the mental health and substance use disorder crisis by offering more comprehensive benefits, including mental health support. According to a report published in 2021, “about three in four large employers and two in four small/medium employers report that they offer at least one type of mental health support for employees.”⁹ In a recent survey, 87 percent of large employers stated that access to mental health care was a top priority, and another survey found that “the number of in-network behavioral health providers has increased by an average of 48 percent in 3 years among commercial health plans.”¹⁰ Group health plans and health insurance issuers have taken steps to ensure mental health parity is reflected in their

⁶ Tanz, L.J., Dinwiddie, A.T., Mattson, C.L., O’Donnell, J., Davis, N.L. (2022), Drug Overdose Deaths Among Persons Aged 10–19 Years — United States, July 2019–Dec. 2021. *MMWR Morb Mortal Wkly Rep* 2022;71:1576–1582, <https://www.cdc.gov/mmwr/volumes/71/wr/mm7150a2.htm>.

⁷ Han, B., Einstein, E.B., Jones, C.M., Cotto, J., Compton, W.M., Volkow, N.D. (2022), Racial and Ethnic Disparities in Drug Overdose Deaths in the US During the COVID-19 Pandemic, *JAMA Netw Open*, 5(9):e2232314, DOI:10.1001/jamanetworkopen.2022.32314, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9490498/>. Age-adjusted death rates are death rates that control for the effects of differences in population age distributions.

⁸ *Ibid.*

⁹ Coe, E., Cordina, J., Enomoto, K., Mandel, A., Stueland, J. (2021), National Surveys Reveal Disconnect Between Employees and Employers Around Mental Health Need, McKinsey & Company, <https://www.mckinsey.com/industries/healthcare/our-insights/national-surveys-reveal-disconnect-between-employees-and-employers-around-mental-health-need>.

¹⁰ America’s Health Insurance Plans (AHIP), Health Insurance Providers Facilitate Broad Access to Mental Health Support (Aug. 2022), <https://ahiporg-production.s3.amazonaws.com/documents/Mental-Health-Survey-July-2022-FINAL.pdf>.

benefit designs and to educate participants, beneficiaries, and enrollees¹¹ about MHPAEA's requirements, by reaching out to members, expanding telehealth availability, expanding behavioral health provider networks, integrating behavioral health with physical health care, and working to reduce stigmatization of seeking treatment.

Despite these efforts, disparities in coverage between mental health and substance use disorder benefits and medical/surgical benefits have grown. In the preamble to the proposed rules,¹² the Departments cited a 2019 Milliman report¹³ that found a growing disparity in the utilization of out-of-network behavioral health care providers relative to out-of-network medical/surgical care providers. A recent study by RTI International¹⁴ found that out-of-network use was 3.5 times higher for all behavioral health clinician office visits than for all out-of-network medical/surgical clinician office visits; in addition, the study noted that these disparities in out-of-network use for behavioral health office visits compared to medical/surgical office visits have remained large and, according to the study, are not fully attributable to behavioral health provider shortages. The study concluded that these results demonstrate the need for more robust parity enforcement.

¹¹ Consistent with the proposed rules, these final rules apply directly to group health plans or health insurance coverage offered by an issuer in connection with a group health plan, and apply to individual health insurance coverage by cross-reference through 45 CFR 147.160, which currently provides that the requirements of 45 CFR 146.136 apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner and to the same extent as to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market. As noted later in this preamble, HHS is finalizing an amendment to 45 CFR 147.160 to also include a cross-reference to 45 CFR 146.137 to similarly extend the new comparative analysis requirements to individual health insurance coverage in the same manner and to the same extent as group health insurance coverage. For simplicity, this preamble generally refers only to the applicability to group health plans and health insurance coverage offered in connection with a group health plan and to participants and beneficiaries enrolled in such a plan or coverage, but references to participants and beneficiaries should also be considered to include enrollees in the individual market, unless otherwise specified.

¹² 88 FR 51552, 51554 (Aug. 3, 2023).

¹³ Melek, S., Davenport, S., Gray, T.J. (2019), *Addiction and mental health vs. physical health: Widening disparities in network use and provider reimbursement*, Milliman, 6, https://assets.milliman.com/ektron/Addiction_and_mental_health_vs_physical_health_Widening_disparities_in_network_use_and_provider_reimbursement.pdf.

¹⁴ Mark, T.L., Parish, W. (2024), *Behavioral health parity – Pervasive disparities in access to in-network care continue*, RTI International, <https://dpjh8al9zd3a4.cloudfront.net/publication/behavioral-health-parity-pervasive-disparities-access-network-care-continue/fulltext.pdf>.

RTI concluded that its analyses of the most recent, comprehensive private insurance claims data

reveal material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, as reflected in much greater use of out-of-network providers.... These disparities indicate that behavioral health networks are clearly inadequate and signal potential noncompliance with the NQTL requirements of MHPAEA.¹⁵

These final rules aim to strengthen consumer protections consistent with MHPAEA’s fundamental purpose – to ensure that individuals in group health plans or with group or individual health insurance coverage who seek treatment for covered mental health conditions or substance use disorders do not face greater burdens on access to benefits for those conditions or disorders than they would face when seeking coverage for the treatment of a medical condition or a surgical procedure.¹⁶ As highlighted in the preamble to the proposed rules,¹⁷ such barriers are particularly problematic when the benefits that the plan or issuer purports to make available and that individuals reasonably expect to be covered are not in fact covered. To the extent these barriers disproportionately limit access to mental health or substance use disorder benefits, such practices contravene MHPAEA’s statutory language, which requires that the financial requirements and treatment limitations applicable to mental health or substance use disorder benefits be “no more restrictive” than the predominant requirements and limitations applicable to substantially all medical/surgical benefits.¹⁸ The Departments’ enforcement efforts have shown

¹⁵ *Id.* at 46.

¹⁶ In a floor statement, Representative Patrick Kennedy (D-RI), one of the chief architects of MHPAEA, made the case for its passage on the grounds that “access to mental health services is one of the most important and most neglected civil rights issues facing the Nation. For too long, persons living with mental disorders have suffered from discriminatory treatment at all levels of society.” 153 Cong. Rec. S1864-5 (daily ed. Feb. 12, 2007). Cf. H. Rept. 110-374, part 3 (Mar. 4, 2008), <https://www.congress.gov/congressional-report/110th-congress/house-report/374> (“The purpose of H.R. 1424, the ‘Paul Wellstone Mental Health and Addiction Equity Act of 2007’ is to have fairness and equity in the coverage of mental health and substance-related disorders vis-a-vis coverage for medical and surgical disorders.”).

¹⁷ 88 FR 51552 (Aug. 3, 2023).

¹⁸ Internal Revenue Code (Code) section 9812(a)(3)(A), Employee Retirement Income Security Act of 1974 (ERISA) section 712(a)(3)(A), and Public Health Service Act (PHS Act) section 2726(a)(3)(A).

that such barriers persist more than 15 years after MHPAEA’s enactment.¹⁹ These final rules are critical to addressing barriers to access to mental health and substance use disorder benefits.

The problems persist notwithstanding the Departments’ unprecedented commitment to advance parity for mental health and substance use disorder benefits in recent years, as reflected through increased enforcement efforts and the Departments’ work with interested parties to help them understand and comply with MHPAEA’s requirements.²⁰ To promote compliance, the Departments have provided extensive guidance and compliance assistance materials, especially with respect to NQTLs,²¹ yet disparities still persist.

In 1996, Congress enacted the Mental Health Parity Act of 1996 (MHPA 1996), which required parity in aggregate lifetime and annual dollar limits for mental health benefits and medical/surgical benefits for group health plans and health insurance coverage offered in connection with such plans.²² These mental health parity provisions were codified in Code section 9812, ERISA section 712, and PHS Act section 2705.²³ Congress expanded on these efforts in 2008 with the enactment of MHPAEA,²⁴ which amended Code section 9812, ERISA section 712, and PHS Act section 2705 by adding requirements for plans and issuers related to financial requirements and treatment limitations and made further amendments to the existing

¹⁹ See, e.g., 2022 MHPAEA Report to Congress (Jan. 2022), <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf>; 2023 MHPAEA Comparative Analysis Report to Congress (July 2023), <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf>.

²⁰ More information on the Departments’ enforcement efforts and guidance issued under MHPAEA is available at <https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/mental-health-and-substance-use-disorder-parity/tools-and-resources> and <https://www.cms.gov/marketplace/private-health-insurance/mental-health-parity-addiction-equity>.

²¹ As discussed in more detail later in this preamble, NQTLs are generally non-numerical limits on the scope or duration of treatment, such as prior authorization requirements, step therapy, and standards related to network composition.

²² Pub. L. 104–204, 110 Stat. 2874 (Sept. 26, 1996). The Departments published interim final rules implementing MHPA 1996 at 62 FR 66932 (Dec. 22, 1997).

²³ The Departments published interim final rules implementing MHPA 1996 at 62 FR 66932 (Dec. 22, 1997).

²⁴ Sections 511 and 512 of the Tax Extenders and Alternative Minimum Tax Relief Act of 2008 (Division C of Pub. L. 110-343, 122 Stat. 3765 (Oct. 3, 2008)).

mental health parity provisions, including provisions to apply the mental health parity requirements to substance use disorder benefits.

The Affordable Care Act (ACA)²⁵ reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets. The ACA added section 715(a)(1) to ERISA and section 9815(a)(1) to the Code to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The PHS Act sections incorporated by these references are sections 2701 through 2728. The ACA extended MHPAEA to apply to individual health insurance coverage and redesignated MHPAEA in the PHS Act as section 2726.²⁶ Additionally, section 1311(j) of the ACA applies PHS Act section 2726 to qualified health plans²⁷ in the same manner and to the same extent as it applies to health insurance issuers and group health plans. The ACA also included a requirement for coverage of mental health and substance use disorder services, including behavioral health treatment, as a category of essential health benefits (EHB).²⁸ HHS' EHB regulations require health insurance

²⁵ References to the Affordable Care Act or ACA include the Patient Protection and Affordable Care Act (Pub. L. 111-148, 123 Stat. 3028) enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152, 124 Stat. 1029) enacted on March 30, 2010.

²⁶ The requirements of MHPAEA generally apply to both grandfathered and non-grandfathered health plans. *See* section 1251 of the ACA and its implementing regulations at 26 CFR 54.9815-1251, 29 CFR 2590.715-1251, and 45 CFR 147.140. Under section 1251 of the ACA, grandfathered health plans are exempted only from certain ACA requirements enacted in Subtitles A and C of Title I of the ACA. The provisions extending MHPAEA requirements to individual health insurance coverage and requiring that qualified health plans comply with MHPAEA are not included in these sections. However, because MHPAEA requirements apply to health insurance coverage offered in the small group market only through the requirement to provide EHB, which does not apply to grandfathered health plans, the requirements of MHPAEA do not apply to grandfathered health plans offered in the small group market.

²⁷ A qualified health plan is a health insurance plan that is certified by a health insurance exchange that it meets certain minimum standards established under the ACA and described in subpart C of 45 CFR part 156. *See* 45 CFR 155.20.

²⁸ Section 1302 of the ACA requires non-grandfathered health plans in the individual and small group markets to cover EHB, which include items and services in the following ten benefit categories: (1) ambulatory patient services; (2) emergency services; (3) hospitalization; (4) maternity and newborn care; (5) mental health and substance use disorder services, including behavioral health treatment; (6) prescription drugs; (7) rehabilitative and habilitative services and devices; (8) laboratory services; (9) preventive and wellness services and chronic disease management; and (10) pediatric services, including oral and vision care. *See* 45 CFR 156.115 for description of the benefits a health plan must provide to provide EHB.

issuers offering non-grandfathered health insurance coverage in the individual and small group markets to comply with MHPAEA and its implementing regulations to satisfy the requirement to cover “mental health and substance use disorder services, including behavioral health treatment,” as part of EHB.²⁹

The Departments published a request for information soliciting comments on issues under MHPAEA³⁰ and subsequently issued interim final regulations to implement the requirements of MHPAEA.³¹ After considering the comments, the Departments published the 2013 final regulations.³² As detailed in the preamble to the proposed rules, in the years after the 2013 final regulations were published, the Departments provided extensive guidance and compliance assistance materials to the regulated community, State regulators, and other interested parties to facilitate the implementation and enforcement of MHPAEA, including the 2020 MHPAEA Self-Compliance Tool,³³ which provided a basic framework for plans and issuers to assess whether their NQTLs satisfy MHPAEA’s parity requirements.³⁴

The CAA, 2021 was enacted by Congress on December 27, 2020,³⁵ and amended MHPAEA, in part, by expressly requiring group health plans and health insurance issuers that provide both medical/surgical benefits and mental health or substance use disorder benefits to perform and document comparative analyses of the design and application of NQTLs that apply to mental health or substance use disorder benefits. The statute also requires plans and issuers to make their analyses available to the Departments or applicable State authorities, upon request, effective February 10, 2021. Additionally, the CAA, 2021 sets forth a process by which the

²⁹ Section 1302(b)(1)(E) of the ACA; 45 CFR 156.115(a)(3).

³⁰ 74 FR 19155 (Apr. 28, 2009).

³¹ 75 FR 5410 (Feb. 2, 2010).

³² 78 FR 68240 (Nov. 13, 2013).

³³ See Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA) (2020), <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf>.

³⁴ 88 FR 51552, 51555-56 (Aug. 2, 2023).

³⁵ Section 203 of title II of Division BB of the CAA, 2021, Pub. L. 116–260, 134 Stat. 1182 (Dec. 27, 2020).

Departments must evaluate the requested NQTL comparative analyses and enforce the comparative analyses requirements and requires the Departments to submit annually to Congress and make publicly available a report summarizing the comparative analyses requested for review by the Departments.³⁶

To help plans and issuers comply with the amendments to MHPAEA made by the CAA, 2021, the Departments issued Frequently Asked Questions (FAQs) About Mental Health and Substance Use Disorder Parity Implementation and the Consolidated Appropriations Act, 2021 Part 45 (FAQs Part 45).³⁷ As detailed in the preamble to the proposed rules, these FAQs provided initial guidance to plans and issuers on these amendments to MHPAEA.³⁸ Additionally, as required by the CAA, 2021, the Departments provided reports to Congress on the NQTL comparative analyses reviews conducted by the Departments.³⁹ These reports highlighted that nearly all of the comparative analyses reviewed by the Departments during the relevant time periods contained insufficient information to support a finding of compliance upon initial receipt and reflected common insufficiencies.

Building on the lessons learned from implementing and enforcing MHPAEA, as well as the guidance provided in FAQs Part 45, on August 3, 2023, the Departments published proposed rules to amend existing MHPAEA regulations at 26 CFR 54.9812-1, 29 CFR 2590.712, and 45 CFR 146.136;⁴⁰ to add a proposed new regulation at 26 CFR 54.9812-2, 29 CFR 2590.712-1,

³⁶ The report must state, in part, whether each plan or issuer that submitted a comparative analysis upon request submitted sufficient information to permit review; whether and why the Departments determined the plan or issuer is in compliance with MHPAEA; the specific information each plan or issuer needed to submit to allow for a review of its comparative analysis; and, for each plan or issuer the Departments determined not to be in compliance, specifications of the actions that the plan or issuer must take to come into compliance. See Code section 9812(a)(8)(B)(iv), ERISA section 712(a)(8)(B)(iv), and PHS Act section 2726(a)(8)(B)(iv).

³⁷ FAQs about Mental Health and Substance Use Disorder Parity Implementation and the Consolidated Appropriations Act, 2021 Part 45 (Apr. 2, 2021), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-45.pdf> and <https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/mhpaea-faqs-part-45.pdf>.

³⁸ 88 FR 51552, 51562 (Aug. 3, 2023).

³⁹ *Ibid.*

⁴⁰ 88 FR 51552 (Aug. 3, 2023). On July 25, 2023, DOL, in collaboration with HHS and the Treasury, also issued Technical Release 2023–01P. The Technical Release set out principles and sought public comment to inform future

and 45 CFR 146.137 in order to codify minimum standards for developing NQTL comparative analyses; and to codify HHS-only amendments to implement the sunset provision for self-funded non-Federal governmental plan elections to opt out of compliance with MHPAEA. On September 28, 2023, the Departments extended the comment period that was set to expire on October 2, 2023, by 15 days to October 17, 2023, to give interested parties additional time to review the proposed rules and submit comments.⁴¹

The Departments received 9,503 comments that were submitted during the comment period⁴² in response to the proposed rules from a wide variety of interested parties, including private citizens; consumer and advocacy organizations; employers, employee organizations, and other plan sponsors; Federal, State, and local officials; health care providers and facilities and health systems; health insurance issuers; service providers, including managed behavioral health organizations (MBHOs), third-party administrators (TPAs), and pharmacy benefit managers (PBMs); trade and professional associations; and researchers. Many commenters provided detailed feedback on multiple aspects of the proposed rules and in response to various specific comment solicitations included in the preamble to the proposed rules and the request for information.

In general, many commenters supported the proposed rules, because they would formalize and, according to these commenters, provide greater clarity on what health plans and issuers must do to comply with MHPAEA. Some commenters highlighted that the existing rules

guidance with respect to the application of the proposed data collection and evaluation requirements to NQTLs related to network composition and a potential time-limited enforcement safe harbor for plans and issuers that include data in their comparative analyses that demonstrate they meet or exceed all the thresholds identified in future guidance with respect to NQTLs related to network composition. The Departments encouraged interested parties to submit their comments consistent with the instructions contained in it separate from any comments they submitted in response to the proposed rules. The Departments are considering these comments separately and these final rules do not respond to those comments. Plans and issuers would be allowed adequate time to conform to any future guidance on the type, form, and manner of collection and evaluation for the relevant data required under the final rules.

⁴¹ 88 FR 66728 (Sept. 28, 2023).

⁴² The comment period for the proposed rules was extended by 15 days to October 17, 2023.

were insufficient and that the proposed rules were timely and necessary to strengthen MHPAEA and ensure fair access to mental health and substance use disorder care. Commenters highlighted the importance of the proposed rules to participants, beneficiaries, and enrollees, including children, teens, young adults, and others living with mental health conditions and substance use disorders. Several other commenters, however, expressed either opposition or concern regarding the proposed rules. Several commenters stated that the proposed rules would increase health plan and issuer costs and reduce treatment quality. A few commenters recommended the Departments withdraw the proposed rules and initiate a new rulemaking process after additional input from interested parties.

After reviewing the comments received during the comment period, the Departments are finalizing the proposed rules, with some changes in response to comments as described in more detail later in this preamble, to ensure that participants, beneficiaries, and enrollees can access the mental health and substance use disorder care they need without facing greater restrictions than when accessing medical and surgical care, consistent with the fundamental purpose of MHPAEA. These final rules provide additional clarity to plans and issuers on how to comply with MHPAEA's requirements and, as a result, will strengthen the protections of MHPAEA. As highlighted earlier in this preamble, since the 2013 final regulations, the Departments repeatedly sought input from interested parties on MHPAEA's requirements; therefore, the Departments decline to withdraw the proposed rules or initiate a new rulemaking process after soliciting additional input from interested parties. As explained throughout this preamble, the amendments made by these final rules are faithful to MHPAEA's parity requirements and sensitive to the flexibility plans and issuers have in designing benefits for group health plans and health insurance coverage.⁴³

⁴³ The Departments note that impacts on plan and issuer costs are discussed in more detail in the regulatory impact analysis, later in this preamble.

Among other things, these final rules:

- Make clear that MHPAEA requires that individuals will not face greater restrictions on access to mental health and substance use disorder benefits as compared to medical/surgical benefits.
- Reinforce that health plans and issuers cannot use NQTLs, such as prior authorization and other medical management techniques, standards related to network composition, or methodologies to determine out-of-network reimbursement rates, for mental health and substance use disorder benefits, that are more restrictive than the predominant NQTLs applied to substantially all medical/surgical benefits in the same classification.
- Require plans and issuers to collect and evaluate data and take reasonable action, as necessary, to address material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, where the relevant data suggest that the NQTL contributes to material differences in access.
- Codify the requirement in MHPAEA, as amended by the CAA, 2021, that health plans and issuers conduct comparative analyses to measure the impact of NQTLs. This includes evaluating standards related to network composition, out-of-network reimbursement rates, and medical management and prior authorization NQTLs.
- Prohibit plans and issuers from using discriminatory information, evidence, sources, or standards that systematically disfavor or are specifically designed to disfavor access to mental health and substance use disorder benefits when designing NQTLs.

- Implement the sunset provision for self-funded non-Federal governmental plan elections to opt out of compliance with MHPAEA.

As a result, the Departments anticipate that these final rules will result in changes in network composition and medical management techniques related to mental health and substance use disorder care, more robust mental health and substance use disorder provider networks, and fewer and less restrictive prior authorization requirements for individuals seeking mental health and substance use disorder care, as well as provide additional clarity and information needed for plans and issuers to meet their obligations under MHPAEA and for the Departments and States to enforce those obligations.

II. Overview of the Final Rules – Departments of the Treasury, Labor, and HHS

The Departments are issuing these final rules to ensure that individuals with mental health conditions and substance use disorders can benefit from the full protections afforded to them under MHPAEA, while offering clear guidance to plans and issuers on how to comply with MHPAEA's requirements. These final rules amend certain provisions of existing MHPAEA regulations at 26 CFR 54.9812-1, 29 CFR 2590.712, and 45 CFR 146.136 to incorporate new and revised definitions of key terms, as well as to specify the steps that plans and issuers must take to meet their obligations under MHPAEA. These final rules also add new regulations at 26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137 codifying minimum standards for developing NQTL comparative analyses to assess whether an NQTL, as written and in operation, complies with MHPAEA's requirements and setting forth the content elements of comparative analyses and the period for plans and issuers to respond to a request from the Departments to submit their comparative analyses. Additionally, in these final rules, HHS finalizes an amendment to 45 CFR 147.160 to specify that the final regulations at 45 CFR 146.137 apply to individual health insurance coverage offered by a health insurance issuer in the same manner and to the same extent that the regulations apply to health insurance coverage offered by a health

insurance issuer in connection with a group health plan in the large group market.⁴⁴ Consistent with the existing text at 45 CFR 147.160(a), HHS is also extending the same requirements and framework outlined in the amendments to 45 CFR 146.136 in these final rules to individual health insurance coverage in the same manner and to the same extent as the amendments that apply to group health insurance coverage. Finally, HHS is finalizing amendments to 45 CFR 146.180 to reflect the sunset of the election option for self-funded non-Federal governmental plans to opt out of compliance with MHPAEA, consistent with changes made by the CAA, 2023 to PHS Act section 2722(a)(2).⁴⁵

A. Amendments to Existing Regulations at 26 CFR 54.9812-1, 29 CFR 2590.712, and 45 CFR 146.136

1. Purpose Section - 26 CFR 54.9812-1(a)(1), 29 CFR 2590.712(a)(1), and 45 CFR 146.136(a)(1)

In the preamble to the proposed rules, the Departments stated that the fundamental purpose of the MHPAEA statute, the 2013 final regulations, and the proposed rules is to ensure that participants and beneficiaries in a group health plan or in group health insurance coverage offered by a health insurance issuer that offers mental health or substance use disorder benefits are not subject to greater restrictions when seeking those benefits than when seeking medical/surgical benefits under the terms of the plan or coverage. The Departments also stated that the fundamental purpose of MHPAEA should serve as the guiding principle for plans and issuers as they work to comply with the requirements of the law and its implementing regulations. Accordingly, the Departments proposed to add a purpose section to the regulations,

⁴⁴ Non-grandfathered health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small group market is required to comply with the requirements under PHS Act section 2726 to satisfy the requirement to provide coverage for mental health and substance use disorder services, including behavioral health treatment, as part of EHB, and as such will also be required to comply with the comparative analysis requirements finalized under 45 CFR 146.137. *See* 45 CFR 156.115(a)(3).

⁴⁵ Division FF, title I, subtitle C, chapter 3, section 1321, Pub. L. 117-328, 136 Stat. 4459 (Dec. 29, 2022).

specifying this fundamental purpose, and that MHPAEA and its implementing regulations should be interpreted in a manner that is consistent with this purpose.

Many commenters supported the addition of the purpose section and the principles it addressed, including the goal of increasing access to mental health and substance use disorder benefits, to ensure equal treatment for mental health and substance use disorder benefits and medical/surgical benefits. A few commenters expressed opposition to the proposed purpose section, arguing that its language goes beyond the intent of MHPAEA (as Congress did not direct the Departments to provide a purpose in regulations, either initially or in later amendments).

The purpose section is important to highlight the overall goals of MHPAEA and to emphasize that the provisions of the 2013 final regulations, as amended by these final rules, should be interpreted in light of these goals. Congress provided authority to the Departments to “promulgate such regulations as may be necessary or appropriate to carry out the provisions of” chapter 100 of the Code, part 7 of ERISA, and title XXVII of the PHS Act, including MHPAEA.⁴⁶ MHPAEA was enacted to address barriers to access to mental health and substance use disorder benefits as compared to medical/surgical benefits. These final rules implement MHPAEA’s requirements and provide clarifying text to promote compliance with the law. The Departments are finalizing the purpose section as proposed, with minor changes in response to comments.

Several commenters requested that the reference to “generally comparable” medical/surgical benefits in the proposed purpose section be revised to refer to the classification of benefits. These commenters noted that, consistent with the 2013 final regulations, evaluation of a plan’s or issuer’s MHPAEA compliance is assessed within the relevant classification of benefits, and that use of the term “comparable,” which is used in the 2013 final regulations and

⁴⁶ See Code section 9833, ERISA section 734, and PHS Act section 2792.

amendments made to MHPAEA by the CAA, 2021 with respect to requirements for NQTLs, is confusing and should be revised.

The Departments agree with commenters who noted that use of the term “comparable” can be confusing when used in this context, because compliance with the requirements for financial requirements, quantitative treatment limitations, and NQTLs has historically been determined within one of the six classifications of benefits.⁴⁷ Therefore, these final rules remove the reference to “generally comparable” medical/surgical benefits and instead specify that plans and issuers must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to mental health or substance use disorder benefits under the plan or coverage than they impose on access to medical/surgical benefits in the same classification of benefits. The Departments are finalizing the purpose section without any other substantive changes, but with a few minor clarifications to ensure that terms are used consistently with and accurately describe other parts of these final rules.

2. Meaning of Terms – 26 CFR 54.9812-1(a)(2), 29 CFR 2590.712(a)(2), and 45 CFR 146.136(a)(2)

a. Medical/Surgical Benefits, Mental Health Benefits, and Substance Use Disorder Benefits

Under the statute and the 2013 final regulations, the term “medical/surgical benefits” means benefits for medical or surgical services as defined under the terms of the plan or health insurance coverage but does not include mental health or substance use disorder benefits. The 2013 final regulations further provide that the term must be defined in accordance with applicable Federal and State law, and that any condition defined by the plan or coverage as being

⁴⁷ The six classifications of benefits listed at 26 CFR 54.9812-1(c)(2)(ii)(A), 29 CFR 2590.712(c)(2)(ii)(A), and 45 CFR 146.136(c)(2)(ii)(A) include inpatient, in-network; inpatient, out-of-network; outpatient, in-network; outpatient, out-of-network; emergency care, and prescription drugs. Special rules for multi-tiered prescription drug benefits, multiple network tiers, and permissible sub-classifications for office visits, separate from other outpatient services, are addressed at 26 CFR 54.9812-1(c)(3)(iii), 29 CFR 2590.712(c)(3)(iii), and 45 CFR 146.136(c)(3)(iii).

or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or State guidelines).

The proposed rules generally retained the first sentence of the 2013 final regulations' definition of "medical/surgical benefits,"⁴⁸ but amended the definition to provide that, notwithstanding this first sentence, any condition or procedure defined by the plan or coverage as being or not being a medical condition or surgical procedure must be defined consistent with generally recognized independent standards of current medical practice (for example, the most current version of the ICD). Further, the proposed rules stated that, to the extent that generally recognized independent standards of current medical practice do not address whether a condition or procedure is a medical condition or surgical procedure, plans and issuers may define the condition or procedure as medical/surgical benefits, as long as such definitions are in accordance with applicable Federal and State law. The Departments also proposed to remove the reference to State guidelines in the definition of the term in the 2013 final regulations, both to make the definitions more consistent with the statute, and to minimize situations where differences between generally recognized independent standards of current medical practice and State guidelines create conflicts and improperly limit protections under MHPAEA.

The Departments also proposed to make similar changes to the definitions of "mental health benefits" and "substance use disorder benefits" by amending the first sentence of each definition and removing the references to State guidelines, consistent with the changes described above for "medical/surgical benefits."⁴⁹ For purposes of the requirement that any condition or

⁴⁸ Under the 2013 final regulations, the term "medical/surgical benefits" means benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the plan or health insurance coverage and in accordance with applicable Federal and State law, but does not include mental health or substance use disorder benefits. 26 CFR 54.9812-1(a), 29 CFR 2590.712(a), and 45 CFR 146.136(a).

⁴⁹ Consistent with the statute and the 2013 final regulations, the Departments note that references to "mental health and substance use disorder benefits" and "mental health or substance use disorder benefits" throughout these final rules are intended to have the same meaning as the terms "mental health benefits" and "substance use disorder benefits" in combination.

disorder defined by the plan or coverage as being or not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice, the proposed rules stated that the plan's or coverage's definition must include all conditions covered under the plan or coverage, except for substance use disorders, that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed in the most current version of the American Psychiatric Association (APA) Diagnostic and Statistical Manual of Mental Disorders (DSM). Similarly, the proposed rules stated that the plan's or coverage's definition of "substance use disorder benefits" must include all disorders covered under the plan or coverage that fall under any of the diagnostic categories listed as a mental or behavioral disorder due to psychoactive substance use (or equivalent category) in the mental, behavioral and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed as a Substance-Related and Addictive Disorder (or equivalent category) in the most current version of the DSM. The proposed rules solicited comments on whether any additional clarification is needed on how State law may interact with the proposed amended definitions of "medical/surgical benefits," "mental health benefits" and "substance use disorder benefits."

In general, many commenters supported modifying these key definitions in existing MHPAEA regulations by specifying that, to be consistent with generally recognized independent standards of current medical practice, the terms of the plan or coverage must accord with appropriate chapters of the ICD or DSM. Many commenters generally supported requiring plans and issuers to follow the ICD or DSM, reasoning that both are generally accepted, peer-reviewed, nonprofit professional standards for diagnosis and descriptions of medical conditions, mental health conditions, and substance use disorders, and that following these authoritative and comprehensive diagnostic tools promotes uniform and standard application of MHPAEA to

mental health conditions and substance use disorders. Several commenters noted that these changes would significantly improve clarity and would increase access to care, especially for intellectual and neurodevelopmental disorders, including dementia and autism spectrum disorder (ASD). Another commenter recommended clarifying whether plans and issuers are required to consider both the ICD and the DSM in categorizing benefits for the purposes of the proposed rules. One commenter added that the Departments' proposal to align and clarify the definitions of "mental health benefits" and "substance use disorder benefits" would ensure parity between the relevant terms and protect the application of MHPAEA for conditions and disorders recognized under independent standards of current medical practice. Another commenter expressing support reasoned that the proposed amendments would clearly specify how mental health conditions and substance use disorders must be defined for MHPAEA compliance purposes and minimize contradictions with State guidelines that now limit MHPAEA protections. The commenter also remarked that self-insured plans frequently include language from State-level mandated benefit requirements prevalent in the plan's geographic area that may not be MHPAEA-compliant.

Several commenters supported the removal of any reference to State guidelines to prevent situations in which contradictions between Federal and State guidelines would result in a loss of protections under MHPAEA. One commenter wrote that State law definitions often predate MHPAEA, may conflict with ICD and DSM standards, and should not be the operable standard, while others stated that State guidelines should not be given precedence over Federal regulations to ensure that MHPAEA's protections are not subverted. However, one commenter urged that the Departments continue allowing plans and issuers to use State guidelines to inform the definitions of "medical/surgical benefits," "mental health benefits," and "substance use disorder benefits," regardless of whether State law is consistent with generally recognized independent standards of current medical practice. The commenter noted that independent standards of

medical practice vary and change over time and are not established with the same intents and purposes as State laws. The commenter also stated that States have been the traditional regulators of health insurance issuers when it comes to interpretive and enforcement matters, even for coverage issues subject to Federal law (such as the ACA and MHPAEA). Another commenter supported the clarification that, when the DSM or ICD does not indicate whether a condition or disorder is a mental health condition or substance use disorder, plans and issuers may define the condition or disorder in accordance with applicable Federal and State law.

In the proposed rules, the Departments noted that, to the extent applicable State law or generally recognized independent standards of current medical practice define a condition or disorder as a mental health condition or substance use disorder, plans and issuers must treat all benefits for the condition or disorder as mental health benefits or substance use disorder benefits, respectively, for purposes of analyzing parity and ensuring compliance with MHPAEA. To better understand interested parties' concerns in implementing this requirement, the Departments solicited comments on potential challenges in applying MHPAEA to all benefits for a mental health condition or substance use disorder where a specific item or service can be furnished for both medical conditions or surgical procedures and mental health conditions or substance use disorders, and whether additional clarifications or modifications to the proposed definitions are necessary.

In response to this comment solicitation, commenters identified several instances in which an individual with a mental health or substance use disorder diagnosis may need a particular treatment for that condition or disorder that may also be provided to treat a medical condition. For example, ASD⁵⁰ might be treated with speech and occupational therapy, which is also used to treat some medical conditions. Additionally, an eating disorder might require

⁵⁰ As discussed later in this preamble, the Departments stated in the proposed rules and reiterate in these final rules that ASD is a mental health condition for purposes of MHPAEA.

medical nutrition therapy, which could also be used to treat a medical condition (such as for the treatment of obesity or diabetes). Moreover, with respect to benefits for prescription drugs, a commenter noted that claims for reimbursement generally do not include diagnosis information. Some commenters explained that many specific prescription drugs are prescribed for mental health conditions and substance use disorders, as well as for medical/surgical conditions, and including diagnosis information would require a range of different entities and interested parties to change their current practice. Commenters also recommended several methods under which the rules could allow plans and issuers to characterize items and services as medical/surgical benefits, mental health benefits, or substance use disorder benefits. One commenter suggested items and services be characterized as either mental health benefits, substance use disorder benefits, or medical/surgical benefits based on the condition or disorder being treated. Similarly, another commenter suggested that items and services be characterized as mental health benefits or substance use disorder benefits when a claim’s primary diagnosis is a mental health condition or substance use disorder, respectively, as that diagnosis is driving the treatment provided. Alternatively, several commenters suggested the rules could be aligned with existing Centers for Medicare & Medicaid Services (CMS) guidance on MHPAEA compliance for Medicaid and the Children’s Health Insurance Program (CHIP) so that plans and issuers could use a “reasonable method” for defining services commonly used to treat both medical conditions and mental health conditions or substance use disorders, for example, by using the plan’s or issuer’s annual claims experience to determine its spending on the service in question.⁵¹

After reviewing comments received from interested parties, the Departments are finalizing the definitions of “medical/surgical benefits,” “mental health benefits” and “substance use disorder benefits” as proposed. While plans and issuers have some discretion in defining

⁵¹ CMS, Frequently Asked Questions: Mental Health and Substance Use Disorder Parity Final Rule for Medicaid and CHIP (Oct. 11, 2017), Q4, <https://www.medicaid.gov/federal-policy-guidance/downloads/faq101117.pdf>.

mental health benefits and substance use disorder benefits, this discretion must be exercised in a manner that comports with generally recognized independent standards of current medical practice, and the definitions in these final rules include sufficient safeguards to protect against defining a benefit in a manner that could result in limitations on access to mental health or substance use disorder benefits that are more restrictive than those applicable to medical/surgical benefits. Further, while the Departments acknowledge the concern that independent standards of current medical practice change over time and may not have been established with the same intents and purposes as State law or State guidelines, such standards better ensure that plans and issuers define mental health conditions and substance use disorders in a manner consistent with the purposes of MHPAEA. The Departments agree with one commenter's concern that some State laws, in particular, might predate MHPAEA. As a result, such State laws might not offer the same safeguards to access to mental health or substance use disorder benefits as MHPAEA. The Departments also note that plans and issuers are required to ensure that the definitions used in the plan or coverage are consistent with the appropriate chapters of the most current version of either the ICD or the DSM.

Additionally, while States generally are the traditional regulators of health insurance issuers, with respect to MHPAEA, the Departments are not persuaded that this necessitates permitting plans and issuers to use definitions of "medical/surgical benefits," "mental health benefits" and "substance use disorder benefits" that are solely tied to applicable State law or guidelines. The definitions of "medical/surgical benefits," "mental health benefits," and "substance use disorder benefits" in these final rules preserve the ability of plans and issuers to use applicable Federal and State law to inform their definitions, but only to the extent that those

laws are consistent with generally recognized independent standards of current medical practice.⁵²

These final rules do not make any changes to the proposed definitions to specifically address how plans and issuers should apply MHPAEA where a specific item or service may be used to treat both medical conditions or surgical procedures as well as mental health conditions or substance use disorders. These final rules, like the proposed rules and the 2013 final regulations, require plans and issuers to continue to characterize items and services as medical/surgical benefits, mental health benefits, or substance use disorder benefits based on the condition or disorder being treated. This interpretation is the most appropriate reading of the definitions of medical/surgical benefits, mental health benefits, and substance use disorder benefits, consistent with the statute and the purpose of MHPAEA. The Departments note that the existing CMS mental health and substance use disorder parity guidance for Medicaid and CHIP identified by several commenters addresses long-term services and supports provided through Medicaid and CHIP, not items and services covered by group health plans and health insurance coverage. The Departments reiterate that, if a plan (or coverage) defines a condition or disorder as a mental health condition or substance use disorder, plans and issuers subject to these final rules must treat all benefits for the condition or disorder as mental health benefits or substance use disorder benefits, respectively, for purposes of compliance with MHPAEA. The Departments decline to adopt the alternative methods suggested by commenters that plans and issuers might use to characterize items and services as medical/surgical benefits, mental health benefits, or substance use disorder benefits, as they may be insufficient to ensure consistency with generally recognized independent standards of current medical practice and in accordance with applicable State and Federal law. Furthermore, while the Departments acknowledge the particular

⁵² The final rules also permit plans and issuers to use applicable Federal and State law to inform their definitions to the extent generally recognized independent standards of current medical practice do not address whether a condition or disorder is a medical condition, surgical procedure, mental health condition, or substance use disorder.

challenges with respect to prescription drug benefits due to the lack of diagnostic information on claims for reimbursement, these final rules, similar to the 2013 final regulations, provide plans and issuers enough flexibility to make decisions about how to classify items and services, including prescription drugs, as either mental health benefits, substance use disorder benefits, or medical/surgical benefits.

To provide guidance to plans and issuers on how to ensure that they define benefits consistent with generally recognized independent standards of current medical practice, the proposed rules proposed separate definitions of the ICD and DSM. Specifically, the Departments proposed that the ICD would be defined as the World Health Organization's International Classification of Diseases adopted by HHS through 45 CFR 162.1002 or successor regulations, and the DSM would be defined as the APA's Diagnostic and Statistical Manual of Mental Disorders. The proposed definitions also specified, for purposes of the definition, which version of the ICD or DSM is the most current as of a particular date. This was intended to provide clarity on when a plan or issuer would be required to begin to rely on a new version of the ICD or DSM after it is released and allow sufficient time after the adoption of an updated version of the ICD or DSM for a plan or issuer to update the terms of its plan or coverage to be consistent with any changes made from the previous version. The proposed definitions stated that the most current version of the ICD or DSM, respectively, would be the version applicable no earlier than the date that is 1 year before the first day of the applicable plan year; however, the proposed rules would permit the use of an updated version before the plan or issuer is required to use it. Finally, in recognition of the fact that future versions of the ICD or DSM may include revisions to the categories of conditions or disorders or chapters listed in the proposed amended definitions for "mental health benefits" and "substance use disorder benefits," the proposed amended definitions referred to "equivalent categories" and "equivalent chapters."

The Departments received several comments on the proposed definitions of the terms “ICD” and “DSM,” with some commenters suggesting alternatives to the language identifying the most current versions of the DSM and ICD. One commenter suggested specifying that if a new version of the DSM or ICD is published in the middle of a plan year, then plans and issuers must use the updated version by the start of the next plan year. One commenter suggested that the most current version of an independent standard should encompass any version commonly in use among providers, and any version used in the most recent claims experience available to plans and issuers.

The Departments are finalizing the definition of “ICD” as proposed, with clarifications with respect to the most current version of the ICD. Specifically, under these final rules, the most current version of the ICD as of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, the effective date of these final rules, is the International Classification of Diseases, 10th Revision, Clinical Modification adopted for the period beginning on October 1, 2015, through HHS regulations at 45 CFR 162.1002 (or successor regulations).⁵³ Any subsequent version of the ICD adopted through 45 CFR 162.1002 (or successor regulations) after **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is adopted.

The Departments are also finalizing the definition of “DSM” as proposed, with similar clarifications, which note that the most current version as of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**, the effective date of these final rules, is the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition,

⁵³ These HHS regulations implement section 212 of the Protecting Access to Medicare Act of 2014 by setting compliance dates for the 10th Revision of the ICD for diagnosis and procedure coding.

Text Revision published in March 2022. A subsequent version of the DSM published after **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is published (as the DSM is published, rather than made applicable). Consistent with this clarification, if a new version of the DSM is published in the middle of a plan year, plans and issuers will have at least one full year before they are required to use the updated version with respect to a plan year. For example, if a new version of the DSM is published on August 1, 2025, for a calendar year plan, that version of the DSM would be the most current version with respect to the plan year beginning on January 1, 2027.

It is important to provide specificity with regard to the relevant versions of the ICD and DSM instead of allowing the use of multiple versions, as suggested by commenters, to ensure that plans and issuers do not select a version that restricts access to mental health and substance use disorder benefits in a manner that is more restrictive than access to medical/surgical benefits. Because the Departments understand that the ICD and DSM are both broadly utilized by providers and facilities, as well as plans and issuers, and were referenced in the 2013 final regulations, these final rules continue to rely on such standards.

Finally, the preamble to the proposed rules noted that interested parties requested that the Departments confirm whether specific conditions are mental health conditions for purposes of MHPAEA. Consistent with the 2013 final regulations and section 13007 of the 21st Century Cures Act (Cures Act),⁵⁴ the Departments confirmed in the proposed rules that eating disorders, such as anorexia nervosa, bulimia nervosa, and binge-eating disorder, are mental health

⁵⁴ Pub. L. 114-255, 130 Stat. 1033 (Dec. 13, 2016). Section 13007 of the Cures Act states that, if a plan or an issuer offering group or individual health insurance coverage provides coverage for eating disorder benefits, including residential treatment, such group health plan or health insurance issuer shall provide such benefits consistent with the requirements of MHPAEA.

conditions under generally recognized independent standards of current medical practice.⁵⁵

Similarly, the proposed rules made clear that, for purposes of MHPAEA, ASD is a mental health condition under generally recognized independent standards of current medical practice.⁵⁶

Therefore, benefits for these disorders are considered mental health benefits, and subject to the protections of MHPAEA and its implementing regulations, including these final rules.

The Departments also solicited comments on other specific mental health conditions or substance use disorders that may warrant additional clarification for purposes of analyzing parity and ensuring compliance with MHPAEA. The Departments received only a few comments in response, including a request to clarify whether gender dysphoria is a mental health condition. Because the most current versions of both the ICD and DSM include gender dysphoria as a mental health condition as of the time of the issuance of these final rules, benefits for this condition are currently subject to the protections of MHPAEA and its implementing regulations, consistent with the framework described earlier in this preamble.⁵⁷

b. Processes, Strategies, Evidentiary Standards, and Factors

The proposed rules included proposed new definitions of terms used in paragraph (c)(4)(i) of the 2013 final regulations, which states that a plan or issuer may not impose an NQTL with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any “processes,” “strategies,” “evidentiary standards,” or other “factors” used in applying the NQTL to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, those used in applying the limitation with respect to medical/surgical benefits in the same classification. These terms and the corresponding standard

⁵⁵ See, e.g., DSM Disorders (5th ed.), Section II: Diagnostic Criteria and Codes, Feeding and Eating Disorders; ICD-10, Chapter V: Mental and behavioral disorders, Code F50: Eating disorders.

⁵⁶ DSM (5th ed.), Section II: Diagnostic Criteria and Codes, Autism Spectrum Disorder.

⁵⁷ DSM (5th ed.), Section II: Diagnostic Criteria and Codes, Gender Dysphoria; ICD-10, Chapter V: Mental and behavioural disorders, Code F64: Gender identity disorders.

were incorporated into MHPAEA’s statutory language in the amendments made by the CAA, 2021.⁵⁸ Because the Departments heard from interested parties prior to the issuance of the proposed rules that it can be difficult to determine what constitute relevant processes, strategies, evidentiary standards, and other factors, the Departments proposed definitions of these terms and included an illustration of the interaction of the definitions of these terms in the preamble to the proposed rules. The illustration described how a plan might rely on various combinations of processes, strategies, evidentiary standards, and other factors in designing and applying an NQTL, and gave examples of each term. The Departments also solicited comments on the proposed definitions, including any alternate definitions or additional clarifications that should be considered.

In general, many commenters supported the proposed definitions of these key terms, which they described as foundational to the development of sufficient comparative analyses and necessary to hold plans and issuers accountable for discriminatory NQTLs. Several commenters described widespread misinterpretation by plans and issuers of the meaning of these key terms. Other commenters wrote that the proposed definitions would help clarify the difference between “factors” and “evidentiary standards,” and draw a clear distinction between “strategies” and “processes,” which relate, respectively, to plans’ and issuers’ approaches to the design of an NQTL, and to their application of an NQTL. Other commenters stated that the definitions of these terms should clearly distinguish between each component of a plan’s or issuer’s required comparative analysis and assign each step of the analysis to a particular component of the comparative analysis. Additionally, a commenter requested more specific examples of processes and evidentiary standards, and the differences between factors and evidentiary standards. One commenter stated that the proposed definitions are not coherent as applied to network contracting activities, development of reimbursement methodologies, or most other network

⁵⁸ Code section 9812(a)(8)(A), ERISA section 712(a)(8)(A), and PHS Act section 2726(a)(8)(A).

composition NQTLs. This commenter claimed that there is no algorithmic approach to decision making that can be documented and requested the Departments to provide guidance on how the many activities involved in constructing provider networks and provider reimbursements across different plan types, service settings, and reimbursement methodologies should be categorized.

As stated in the preamble to the proposed rules, the proposed definitions for the terms “processes,” “strategies,” “evidentiary standards,” and “factors” are intended to further clarify how to properly apply and distinguish between these terms, and to help facilitate proper comparisons between the design and application of NQTLs to medical/surgical benefits and mental health and substance use disorder benefits in the same classification, compliance with the requirements related to NQTLs, and the development of sufficient comparative analyses, as required under the CAA, 2021 and these final rules. The definitions in these final rules improve clarity and add specificity to the terms used in MHPAEA, as amended by the CAA, 2021, to reduce misinterpretations, and are consistent with the requirements in these final rules that set forth the manner in which plans and issuers are required to perform and document comparative analyses, discussed later in this preamble. The Departments also provide additional guidance on how plans and issuers must comply with the provisions of these final rules with respect to NQTLs related to network composition,⁵⁹ later in this preamble.

The Departments note that nothing in these final rules requires an “algorithmic” decision making process; however, plans and issuers must perform and document their comparative analyses as required under 26 CFR 54.9812-2, 29 CFR 2590.712-1 and 45 CFR 146.137 to show that the processes, strategies, evidentiary standards, and other factors used in designing or applying an NQTL to mental health and substance use disorder benefits, as written and in

⁵⁹ The term “NQTLs related to network composition” generally refers to the NQTLs listed in 26 CFR 54.9812-1(c)(4)(ii)(D), 29 CFR 2590.712(c)(4)(ii)(D), and 45 CFR 146.136(c)(4)(ii)(D) of these final rules: standards related to network composition, including but not limited to standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan or coverage.

operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing or applying the NQTL to medical/surgical benefits in the relevant classification. Additionally, anything used by a plan or issuer to design or apply an NQTL should be considered a process, strategy, evidentiary standard, or factor (or information, evidence, sources, or standards on which a factor or evidentiary standard is based), consistent with the Departments' broad interpretation of these terms.

Under the proposed rules, the Departments proposed that evidentiary standards generally would not be considered factors, but instead would be considered or relied upon in designing or applying a factor. The Departments noted that, although the framework established in the 2013 final regulations treated the terms within the phrase “processes, strategies, evidentiary standards, and other factors” as having overlapping meanings (and the term “other factors” was utilized as a catch-all), the CAA, 2021 added to MHPAEA other references to factors and evidentiary standards that indicate Congress meant to distinguish between them.⁶⁰ The Departments requested comments on this approach to defining evidentiary standards separately from factors, including whether there are any circumstances under which an evidentiary standard should also be considered a factor under the framework outlined in the proposed rules, but did not receive any specific comments on this issue. Therefore, under these final rules, consistent with the proposed rules, evidentiary standards are not considered to be factors.

The proposed rules provided that the term “evidentiary standards” would mean any evidence, sources, or standards that a plan or issuer considered or relied upon in designing or applying a factor with respect to an NQTL, including specific benchmarks or thresholds. The

⁶⁰ The preamble to the proposed rules noted that, for example, Code section 9812(a)(8)(A)(iii), ERISA section 712(a)(8)(A)(iii), and PHS Act section 2726(a)(8)(A)(iii) refer to the evidentiary standards *that are used for* the factors to determine that an NQTL will apply to benefits, and those provisions go on to distinguish between factors and any other sources or evidence relied upon to design or apply an NQTL. *See* 88 FR 51552, 51567 (Aug. 3, 2023).

proposed definition further provides that evidentiary standards may be empirical, statistical, or clinical in nature, and include sources acquired or originating from an objective third party, such as recognized medical literature, professional standards and protocols (which may include comparative effectiveness studies and clinical trials), published research studies, payment rates for items and services (such as publicly available databases of the “usual, customary, and reasonable” rates paid for items and services), and clinical treatment guidelines. The proposed definition also provides that evidentiary standards would include internal plan or issuer data, such as claims or utilization data or criteria for assuring a sufficient mix and number of network providers, and benchmarks or thresholds, such as measures of excessive utilization, cost levels, time or distance standards, or network participation percentage thresholds.

One commenter recommended not including specific benchmarks or thresholds and professional standards and protocols in the definition of the term “evidentiary standards.” The commenter noted that many plans and issuers do not define their evidentiary standards numerically and that finalizing the definition as proposed could require plans and issuers to do so, thereby compelling plans and issuers not to use relevant, critical data in the development of their NQTLs. The commenter also remarked that including professional standards and protocols in the definition would require plans and issuers to incorporate potentially unproven medical guidance as a standard to dictate mental health or substance use disorder benefits, which could override common medical management practices. The commenter added that, if the reference to professional standards and protocols is retained, the Departments should clarify that the definition of “evidentiary standards” does not imply that all professional standards and protocols must be referenced or that benchmarks or thresholds are required to be applied to professional standards and protocols.

The Departments are finalizing the definition of “evidentiary standards” as proposed. The definition is consistent with the use of the term by Congress in the amendments made to

MHPAEA by the CAA, 2021. The definition of the term “evidentiary standards” does not require plans and issuers to define their evidentiary standards numerically, nor does it imply that all professional standards and protocols must be referenced or that benchmarks or thresholds are required to be applied to professional standards and protocols (for example, where the standards are qualitative in nature). However, to the extent these types of evidentiary standards are used to design or apply an NQTL, they must be analyzed for compliance with MHPAEA. The list of examples of evidentiary standards included in the definition is not intended to be exhaustive, nor are any of the evidentiary standards listed required to be considered or relied upon in designing or applying a factor with respect to an NQTL.

In the proposed rules, the Departments proposed that the definition of the term “factors” be read broadly, so that factors are all information, including processes and strategies (but not evidentiary standards), that a plan or issuer considered or relied upon to design an NQTL or to determine whether or how the NQTL applies to benefits under the plan or coverage. The Departments noted that by defining the term “factor” broadly, the Departments’ intention was to capture any information used to design or apply an NQTL (other than evidentiary standards), regardless of whether a plan or issuer believes that information could also be characterized as a “process” or a “strategy,” as those terms were proposed to be defined. The Departments proposed that the term “factors” includes information (but not evidentiary standards) that the plan or issuer considered but rejected, consistent with previous guidance on MHPAEA in the context of the documents or plan information the Departments consider relevant to a compliance determination.⁶¹ The proposed definition also provided examples of factors, which include, but

⁶¹ See FAQs About Affordable Care Act Implementation Part 31, Mental Health Parity Implementation, and Women’s Health and Cancer Rights Act Implementation, Q9 (Apr. 20, 2016), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-31.pdf> and <https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-set-31>, which states that a plan must provide documents and plan information to a participant or beneficiary, or their authorized representative, including the specific underlying processes, strategies, evidentiary standards, and other factors (including, but not limited to, all evidence) considered by the plan (including factors that were relied upon and were rejected) in

are not limited to, provider discretion in determining diagnosis or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; claim types with a high percentage of fraud; quality measures; treatment outcomes; severity or chronicity of condition; variability in the cost of an episode of treatment; high cost growth; variability in cost and quality; elasticity of demand; and geographic location.

With respect to the “broad” reading of the term “factor,” a commenter stated that the proposed definition subsumes “processes” and “strategies,” and suggested eliminating or clarifying this distinction with additional guidance. The commenter also remarked that the broad definition of “factor” would make the multiple steps in a comparative analysis less distinguishable, and the requirement that plans identify, define, and describe the use of every factor in the design or application of an NQTL unworkably expansive. A few commenters remarked that the breadth of the definition of “factor” makes it unclear how a plan or issuer would demonstrate that a factor is unbiased or not discriminatory for the purposes of the comparative analyses and recommended narrowing the definition of “factor” to distinguish it from evidentiary standards, processes, and strategies, and instead use the term to describe the basis for the plan’s or issuer’s application of an NQTL. Another commenter recommended not including information that the plan or issuer considered but rejected in the definition of factors, because it is not illustrative of the ultimate value of the mental health or substance use disorder benefit or the plan’s or issuer’s compliance with MHPAEA’s NQTL standards. The commenter stated that the actual design of the benefit and how it translates to payments, denials, and reimbursement should substantiate whether the benefit design complies with parity requirements, without examining extraneous information on considerations early in the benefit’s development process. A commenter suggested the Departments include an example of what the Departments

determining that the NQTL will apply to a particular mental health and substance use disorder benefit or any medical/surgical benefits within the benefit classification at issue.

would consider a complete definition of a factor and information about how to specify the weight assigned to factors.

The Departments are finalizing the definition of the term “factor” as proposed. The definition and list of examples of factors in the definition contained in these final rules are sufficiently detailed to provide context to plans and issuers in identifying factors, including by distinguishing evidentiary standards from factors and acknowledging that factors other than processes and strategies, which are types of factors, may exist. Under the 2013 final regulations, plans and issuers were permitted to utilize a wide array of factors in designing and applying their NQTLs to mental health and substance use disorder benefits provided they were comparable to, and applied no more stringently than, those utilized to design and apply NQTLs to medical/surgical benefits. Similarly, the CAA, 2021 did not limit what factors plans and issuers could use to design and apply their NQTLs, but instead required that these factors be identified and analyzed in the comparative analyses.

As noted in the preamble to the proposed rules, taking into account not only the factors that the plan or issuer relied upon, but also those that were considered but ultimately rejected in the definition of factors, is consistent with previous guidance on MHPAEA, namely because it is a factor that a plan or issuer uses in designing and applying an NQTL. The Departments recognize that the language used in the proposed rules, which included factors that were *considered* and rejected, rather than those that are *relied upon* and rejected, could be interpreted as including a broader set of information than prior guidance, which had interpreted “considered” to include “factors that were relied upon and were rejected.” The Departments did not intend to broaden the set of information included as a factor, and agree with the commenter who questioned the utility of providing information that was considered early in the design process but rejected. However, the Departments affirm that taking into account information that the plan

or issuer relied upon and rejected in the definition of factors is necessary to analyze compliance with MHPAEA.

In the proposed rules, the Departments proposed to define “processes” and “strategies” as types of factors, and to clarify the differences between the two terms as they relate to the design and application of an NQTL. Specifically, the Departments proposed defining “processes” as relating to the application of an NQTL, while “strategies” would relate to the design of an NQTL. After review of the comments, the Departments continue to be of the view that the best read of the statutory text (as well as the 2013 final regulations) is that processes and strategies are types of factors, rather than components of a factor to be separately evaluated.

The Departments proposed to define “processes” to mean actions, steps, or procedures that a plan or issuer uses to apply an NQTL, including actions, steps or procedures established by the plan or issuer as requirements in order for a participant or beneficiary to access benefits, including through actions by a participant’s or beneficiary’s authorized representative or a provider or facility. Under the proposed rules, processes include, but are not limited to: prior authorization procedures, provider referral requirements, and the development and approval of a treatment plan. The proposed definition also provided that processes include the specific procedures used by staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) to administer the application of NQTLs, such as how a panel of staff members applies the NQTL (including the qualifications of staff involved, number of staff members allocated, and time allocated), consultations with panels of experts in applying the NQTL, and reviewer discretion in adhering to criteria hierarchy when applying an NQTL.

A commenter expressed appreciation for the proposed rules’ intent and requested the Departments to include more specific examples of “processes.” Another commenter stated that the proposed definition for “processes” is too broad and focuses only on the end result of access to benefits, which the commenter stated is inconsistent with the Departments’ previous guidance

and regulations, and recommended narrowing the definition to focus on the operational application of any requirements.

After reviewing comments, the Departments are finalizing the definition of the term “processes,” with minor changes so that the examples of processes more clearly illustrate the way the action, step, or procedure is used to apply an NQTL.⁶² While the Departments decline to add examples to the definition, these modifications will add clarity to the definition in these final rules.⁶³ The Departments note that the final definition of the term does not focus only on the end result of access to benefits, but also includes the operational application of an NQTL, as evidenced by the framing of the definition in terms of actions, steps, or procedures used to apply an NQTL. For example, prior authorization processes include the procedures established by a plan or issuer for a review to determine how a specific request for prior authorization should be granted or denied. Concurrent review processes include the procedures established by a plan or issuer for a review to determine whether a specific request should be granted or denied, such as when peer-to-peer review is required.

The proposed rules proposed to define “strategies” as practices, methods, or internal metrics that a plan or issuer considers, reviews, or uses to design an NQTL, and included examples of strategies. The proposed definition of strategies included the following examples: the development of the clinical rationale used in approving or denying benefits; deviation from generally accepted standards of care; the selection of information (such as from medical or clinical guidelines) deemed reasonably necessary to make a medical necessity determination; reliance on treatment guidelines or guidelines provided by third-party organizations; and rationales used in selecting and adopting certain threshold amounts, professional protocols, and

⁶² The Departments are also finalizing a non-substantive modification so that the definition more closely parallels the definition of “strategies.”

⁶³ For example, these final rules clarify that provider referral requirements are processes if they are used to determine when and how a participant or beneficiary may access certain services. Similarly, the development and approval of a treatment plan are processes if they are used in a concurrent review process to determine whether a specific request should be granted or denied.

fee schedules. The proposed definition of strategies also specifically included: the creation and composition of the staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) that deliberates, or otherwise makes decisions, on the design of NQTLs, including the plan's or issuer's decisions related to qualifications of staff involved; number of staff members allocated, and time allocated; breadth of sources and evidence considered; consultations with panels of experts in designing the NQTL; and the composition of the panels used to design an NQTL.

One commenter supported the inclusion in the definition of "strategies" of practices that involve "deviations from generally accepted standards of care." Several commenters also recommended that the Departments include actions to detect or prevent and prove fraud, waste, and abuse in the definitions of either or both "processes" and "strategies," rather than including those actions as a stand-alone exception from the NQTL requirements in the final rules. Another commenter appreciated the clear distinction made in the proposed definitions of processes and strategies and stated that they would appreciate if these distinctions tracked with separate steps in the comparative analyses.⁶⁴

The Departments are generally finalizing the definition of the term "strategies" with some minor changes to the examples to add specificity. The definition of the term "strategies" in these final rules includes examples of strategies used to design an NQTL, such as the method of determining whether and how to deviate from generally accepted standards of care in concurrent reviews; rationales used in selecting and adopting certain threshold amounts to apply an NQTL; professional standards and protocols to determine utilization management standards; and fee schedules used to determine provider reimbursement rates, used as part of an NQTL. The Departments note that, once a plan or issuer uses a strategy to design an NQTL, that design also may result in the establishment or use of processes to apply the NQTL.

⁶⁴ The content elements of comparative analyses are addressed later in this preamble.

While the Departments acknowledge comments suggesting that actions to detect or prevent and prove fraud, waste, and abuse be defined as either “processes” or “strategies,” and acknowledge that such actions certainly could constitute either processes or strategies (depending on whether the action is undertaken to design or apply the NQTL), the Departments decline to add a specific reference to actions to detect or prevent and prove fraud, waste, and abuse to the relevant definitions, as the proposed exception for standards to detect or prevent and prove fraud, waste, and abuse is not being finalized, as discussed later in this preamble.⁶⁵ However, the Departments are providing additional language to explain what constitutes a standard to detect or prevent and prove fraud and abuse (also referred to as “fraud and abuse measures”) later in this preamble and how such standards must comply with MHPAEA under these final rules.

c. Treatment Limitations

The Departments proposed to amend the definition of “treatment limitations” to clarify that the illustrative list of NQTLs to which the definition refers is non-exhaustive and to amend the last sentence to state that a “complete” (rather than “permanent”) exclusion of all benefits for a particular condition or disorder is not a treatment limitation for purposes of the definition. In the preamble to the proposed rules, the Departments noted that, while NQTLs are generally defined as treatment limitations that are not expressed numerically, the application of an NQTL in a numerical way does not modify its nonquantitative character simply because the NQTL sometimes involves numerical standards, and such NQTLs would still be evaluated in accordance with the rules for NQTLs under the statute and implementing regulations.

⁶⁵ The proposed rules referred to fraud, waste, and abuse. However, as explained later in this preamble, the Departments agree with commenters that the term “waste” can be construed in a manner that is overly broad. Thus, in these final rules, when discussing the exception in the proposed rules for NQTLs that are narrowly and reasonably designed to detect or prevent and prove fraud, waste, and abuse, while minimizing the impact on access to appropriate mental health and substance use disorder benefits, this preamble refers to “fraud, waste, and abuse measures.” When discussing provisions of this final rule related to carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse, this preamble refers to “fraud and abuse measures.”

Several commenters supported the Departments' amendment to the definition of "treatment limitation" to specify that "a complete exclusion of all benefits for a particular condition or disorder is not a treatment limitation for purposes of this definition," rather than retaining the reference in the 2013 final regulations to a "permanent" exclusion. These commenters stated that the proposed definition more clearly specifies that a plan or issuer can exclude a particular condition or service without creating an NQTL, but that in doing so, the exclusion must be total. The commenters suggested the Departments include specific examples of permissible exclusions and impermissible exclusionary language. Other commenters expressed concern that the proposed definition of "treatment limitation" is too broad and argued that the proposed definition would lead to increased uncertainty in determining which common plan practices could constitute an NQTL. One commenter stated that if there is no comparable medical or surgical treatment limitation, there is nothing to compare a treatment limitation on a mental health or substance use disorder benefit to, and that therefore such a limitation on the mental health or substance use disorder benefit is not subject to parity requirements. Several commenters recommended adopting a consistent and exhaustive definition for determining whether a medical management technique is a treatment limitation.

The Departments are finalizing the definition of "treatment limitation" as proposed, with minor modifications to add an example of an NQTL. As reflected in the definition, medical management techniques are NQTLs if they limit the scope or duration of treatment. While the definition as amended is broad, plans and issuers have great latitude in the types of limitations that they may impose, and the Departments understand that plans and issuers do in fact impose a broad range of limitations on the scope or duration of treatment. In enacting MHPAEA and the amendments to MHPAEA contained in the CAA, 2021, Congress did not prohibit the use of these limitations for mental health and substance use disorder benefits, but required that plans and issuers ensure that NQTLs satisfy the statutory requirements that (1) any treatment

limitations imposed on mental health and substance use disorder benefits are no more restrictive than the predominant treatment limitations imposed on substantially all medical/surgical benefits; (2) that no treatment limitations be imposed only with respect to mental health and substance use disorder benefits; and (3) that plans and issuers perform and document comparative analyses of the design and application of NQTLs. Because of the broad range of treatment limitations that plans and issuers may impose, combined with the freedom that plans and issuers have to design their own unique limitations, the Departments cannot provide a comprehensive and exhaustive list of all limitations, as further explained later in this preamble.

The Departments note that if a plan or issuer applies a treatment limitation to mental health and substance use disorder benefits where medical/surgical benefits are not subject to a comparable treatment limitation in the same classification, the plan or issuer would violate MHPAEA because it must not apply separate treatment limitations only to mental health and substance use disorder benefits. Further, the Departments have stated that, if a plan or issuer provides any benefits for a mental health condition or substance use disorder but excludes benefits for items or services for that condition or disorder in a classification in which it provides medical/surgical benefits, such an exclusion of a benefit for a condition or disorder that is otherwise covered is a treatment limitation because it is a limit on the scope or duration of treatment offered.⁶⁶ While the Departments decline to provide additional examples of permissible exclusions and impermissible exclusionary language in these final rules, examples of such exclusions and language have been provided in guidance and in the Departments' reports to Congress.

3. Nonquantitative Treatment Limitations - 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4)

⁶⁶ See 75 FR 5410, 5413 (Feb. 2, 2010).

In the proposed rules, the Departments proposed changes designed to better ensure that plans and issuers do not design and implement NQTLs that impose greater restrictions on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. The Departments proposed to add requirements that apply to NQTLs with respect to mental health and substance use disorder benefits, to ensure that plans and issuers do not impose a greater burden on participants and beneficiaries accessing those benefits than the burden imposed on participants and beneficiaries accessing medical/surgical benefits, while preserving the ability of plans and issuers to impose NQTLs to the extent they are consistent with generally recognized independent professional medical or clinical standards or legitimate and narrowly designed standards related to fraud, waste, and abuse. Subject to those two narrow exceptions for those types of NQTLs, the proposed rules provided that plans and issuers would not be permitted to impose an NQTL on mental health or substance use disorder benefits unless they satisfied all of the following three requirements: (1) the NQTL is no more restrictive as applied to mental health and substance use disorder benefits than to medical/surgical benefits (also referred to as the no more restrictive requirement); (2) the plan or issuer satisfies requirements related to the design and application of the NQTL (also referred to as the design and application requirements); and (3) the plan or issuer collects, evaluates, and considers the impact of relevant data on access to mental health and substance use disorder benefits relative to access to medical/surgical benefits; and subsequently takes reasonable action, as necessary, to address any material differences in access shown in the data to ensure compliance with MHPAEA (also referred to as the relevant data evaluation requirements).

Specifically, under the no more restrictive requirement, the proposed rules specified that a plan or issuer may not apply any NQTL to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all medical/surgical benefits in the same

classification. This requirement was intended to ensure that the implementing regulations more closely mirrored the statutory language in Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A).

The proposed rules outlined a four-prong test for a plan or issuer to determine compliance with the no more restrictive requirement. Specifically, this provision would have required plans and issuers to determine: (1) the portion of plan payments for medical/surgical benefits subject to an NQTL in a classification; (2) whether the NQTL applies to substantially all medical/surgical benefits in the classification; (3) if the NQTL applies to substantially all medical/surgical benefits in the classification, the predominant variation of the NQTL that applies to substantially all medical/surgical benefits in the classification; and (4) whether the NQTL, as applied to mental health and substance use disorder benefits in the classification, is more restrictive than the predominant variation of the NQTL as applied to substantially all medical/surgical benefits.

The second proposed requirement for NQTLs, the design and application requirements, retained the requirements for NQTLs from the 2013 final regulations focused on the processes, strategies, evidentiary standards, and other factors used to apply an NQTL, with a proposed modification to better align the rules with the statute's focus on the design of an NQTL in addition to its application. In addition, the Departments proposed to prohibit plans and issuers from relying upon any factor or evidentiary standard if the information, evidence, sources, or standards on which the factor or evidentiary standard was based discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits.

The third requirement for NQTLs under the proposed rules, the relevant data evaluation requirements, proposed to require plans and issuers to collect and evaluate relevant outcomes data and take reasonable action to address material differences in access

between mental health and substance use disorder benefits and medical/surgical benefits as necessary to ensure compliance, in operation, with MHPAEA. This requirement also included a proposed special rule for NQTLs related to network composition.

The proposed rules stated that, if a plan or issuer fails to meet any of the three requirements under the proposed rules with respect to an NQTL in a classification, the NQTL would violate MHPAEA and, as a result, could not be imposed on mental health or substance use disorder benefits in the classification without changes to the terms of the plan or coverage, or the way the NQTL is designed or applied, to ensure compliance with MHPAEA.

The Departments proposed two limited exceptions to some of the requirements for NQTLs, consistent with the Departments' intention to avoid interference with a plan's or issuer's attempts to ensure that NQTLs imposed with respect to benefits for treatment of mental health conditions or substance use disorders are consistent with generally accepted independent professional medical or clinical standards of care (also referred to as independent professional medical or clinical standards) or are narrowly and reasonably designed to detect or prevent and prove fraud, waste, and abuse, while minimizing the impact on access to appropriate mental health and substance use disorder benefits (also referred to as fraud, waste, and abuse measures). The Departments proposed to exempt NQTLs qualifying for the exception for independent professional medical or clinical standards from compliance with the no more restrictive requirement, the prohibition on discriminatory factors and evidentiary standards, and the relevant data evaluation requirements. The Departments proposed to exempt NQTLs qualifying for the exception for fraud, waste, and abuse measures from compliance with the no more restrictive requirement and the prohibition on discriminatory factors and evidentiary standards, but not the relevant data evaluation requirements.

Finally, the Departments proposed to make clear that a plan or issuer that has received a final determination of noncompliance under the comparative analysis review process established by the CAA, 2021, including a final determination of noncompliance based on failure to provide a sufficient comparative analysis, would also be in violation of the substantive requirements that apply to NQTLs under MHPAEA, as determined by the Departments. Upon such a determination, the proposed rules would permit the Departments to direct the plan or issuer to not impose the NQTL that is the subject of the comparative analysis, unless and until the plan or issuer can demonstrate compliance or take appropriate action to remedy the violation.

The Departments requested comments on all aspects of these proposed amendments, including the exceptions to the proposed rules regarding NQTLs. Many commenters expressed support for these provisions of the proposed rules as a whole, as a means of achieving increased access to mental health and substance use disorder benefits by targeting NQTLs that otherwise impede access. Other commenters expressed support for the proposed rules' enhanced specificity with respect to the requirements for imposing NQTLs, with one commenter also indicating that the proposals would help State insurance regulators better enforce MHPAEA and clarify plans' and issuers' compliance obligations.

However, other commenters expressed the view that these provisions of the proposed rules were complex, ambiguous, confusing, subject to interpretation, or difficult to operationalize, which they argued could lead to substantial uncertainty for plans and issuers attempting to comply. Commenters also stated that it may be impossible for plans or issuers to meet the proposed mathematical substantially all and predominant tests as applied to NQTLs, leading them to eliminate necessary utilization management tools. Some commenters also indicated that these provisions of the proposed rules could lead to inconsistent application of NQTLs across plans administered by the same TPA or issuer,

which could result in administrative complexity and cause confusion for consumers and providers. Other commenters highlighted that the proposed requirements would significantly increase the cost of administering plans and health insurance coverage. One commenter indicated that some plans might consider excluding all treatments or services for a particular mental health condition or substance use disorder as a result of the additional burdens imposed by the substantially all and predominant tests, if finalized as proposed. Some commenters also stated that the additional proposed requirements for NQTLs do not add value beyond distinctions already captured by the design and application requirements included in the 2013 final regulations, with some commenters stating those additional requirements go beyond MHPAEA's statutory requirements. Comments specific to each of the three requirements and two exceptions proposed at 26 CFR 54.9812-1(c)(4)(i), (ii), and (iv); 29 CFR 2590.712(c)(4)(i), (ii), and (iv); and 45 CFR 146.136(c)(4)(i), (ii), and (iv) are discussed in greater detail later in this preamble.

The Departments acknowledge the concerns expressed by commenters and, in response to comments, the Departments are finalizing a modified framework that is still intended to prevent plans and issuers from designing and applying NQTLs that impose greater burdens on access to mental health and substance use disorder benefits as compared to medical/surgical benefits, while limiting uncertainty, increases in cost, operational difficulty, and unintended consequences. These final rules streamline the proposed rules' general requirements to eliminate redundancies and add clarity for plans and issuers in a manner that remains consistent with the statutory text of MHPAEA, while also ensuring participants and beneficiaries will not face greater restrictions on access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

These final rules do not finalize the language of the proposed "no more restrictive" requirement, as discussed in more detail later in this preamble, and instead incorporate the

statutory requirements of Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A) as the overall general rule for NQTLs in 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4). Specifically, these final rules state that, consistent with the fundamental purpose of MHPAEA, a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) may not impose any NQTL with respect to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification. However, as discussed later in this preamble, the Departments are declining to finalize the proposed four-prong test for the no more restrictive requirement, which was proposed to determine compliance with statutory requirements as they apply to NQTLs.⁶⁷ Rather, to demonstrate compliance with the no more restrictive requirement, which is now the general rule for NQTLs, a plan or issuer is required under these final rules to satisfy (1) the design and application requirements and (2) the relevant data evaluation requirements, each of which the Departments are finalizing with modifications, as discussed in more detail later in this preamble. Additionally, the Departments are not finalizing the exceptions set forth in the proposed rules, but have added language to these final rules to explain how plans and issuers should analyze and account for independent professional medical or clinical standards and fraud and abuse measures in designing and applying their NQTLs. Finally, the Departments are finalizing a provision providing that, depending on the relevant facts and circumstances, the Departments or an applicable State authority may direct a plan or issuer that has received a final determination of noncompliance under the comparative analysis review process established by the CAA, 2021 to not apply an impermissible NQTL.

⁶⁷ Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A).

a. Requirement That NQTLs Be No More Restrictive for Mental Health Benefits and Substance Use Disorder Benefits - 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4)

Through the proposed mathematical substantially all and predominant tests for NQTLs as part of the no more restrictive requirement, the Departments proposed to require plans and issuers to follow similar steps to those that apply when analyzing parity with respect to financial requirements or quantitative treatment limitations under the 2013 final regulations (referred to in this preamble as the proposed mathematical substantially all and predominant tests). As noted in the proposed rules, the steps in the proposed mathematical substantially all and predominant tests would have involved determining the portion of plan payments for medical/surgical benefits subject to an NQTL in a classification; whether the NQTL applies to substantially all medical/surgical benefits in the classification; if the NQTL applies to substantially all medical/surgical benefits in the classification, the predominant variation of the NQTL that applies to substantially all medical/surgical benefits in the classification; and whether the NQTL, as applied to mental health and substance use disorder benefits in the classification, is more restrictive than the predominant variation of the NQTL, as applied to substantially all medical/surgical benefits.

Many commenters generally supported application of the proposed mathematical substantially all and predominant tests to NQTLs, with some indicating that the tests would provide additional clarity, eliminate subjectivity, assist regulators, and result in compliance improvements. Many of these commenters also stated that the statute clearly supports the tests, as it requires treatment limitations to be “no more restrictive” than the predominant treatment limitations that apply to substantially all medical/surgical benefits. Other commenters generally opposed the inclusion of the substantially all and predominant tests for NQTLs as part of the no more restrictive requirement. Some of these commenters stated

that the proposed mathematical substantially all and predominant tests are a reversal of policy from the 2013 final regulations and are inconsistent with congressional intent, because Congress codified the design and application requirements from the 2013 final regulations in the CAA, 2021. These commenters highlighted that the Departments had stated previously that they understood NQTLs could not be easily quantified and that the Departments had not sufficiently explained their change in interpretation under the proposed rules.

Some commenters expressed general concerns that NQTLs are inherently unquantifiable, arguing that the proposal would result in unworkable standards or arbitrary outcomes that could prohibit plans and issuers from using evidence-based medical guidelines or other relevant factors specific to the item or service under consideration. Commenters also raised concerns that imposition of the proposed mathematical substantially all and predominant tests on certain types of NQTLs that are not commonly utilized for medical/surgical benefits may lead to some types of legitimate NQTLs no longer being permitted with respect to mental health and substance use disorder benefits. Specifically, several of these commenters contended that the proposed mathematical substantially all and predominant tests, as proposed, would result in the elimination of plans' and issuers' ability to impose certain NQTLs with respect to mental health and substance use disorder benefits, such as step therapy, prior authorization, and concurrent review, which they posited would negatively impact the quality and cost of care. Some commenters also cited potential negative, unintended consequences of the application of the proposed mathematical substantially all and predominant tests, as proposed, including patient safety concerns; impacts on health outcomes, quality, and affordability; and a chilling effect on access improvements and innovation. Further, some commenters expressed concern with the increased costs associated with complying with the proposed mathematical substantially all

and predominant tests, with some stating that this increased burden would not be offset by any resulting increase in access to mental health and substance use disorder benefits for participants and beneficiaries.

Several commenters expressed confusion as to how these tests, as proposed, would be applied in practice and highlighted the need for more detail. Specifically, some commenters stated that these proposed provisions lack clarity in how the tests apply to certain types of NQTLs (including those related to network composition), and the potential consequences of enforcement of these requirements. Many commenters provided specific comments and feedback on aspects of each part of the substantially all and predominant tests included in the proposed rules, as discussed later in this preamble, and highlighted ambiguities and challenges operationalizing the proposed quantitative testing requirements with respect to NQTLs.

Under the first prong of the proposed mathematical substantially all and predominant tests, plans and issuers would have been required to determine the portion of plan payments for medical/surgical benefits in the classification expected to be subject to the NQTL based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan or coverage for the plan year (or the portion of the plan year after a change in benefits that affects the applicability of the NQTL). The proposed rules stated that, for purposes of this determination, any reasonable method could be used to determine the dollar amount expected to be paid under a plan for medical/surgical benefits.

The Departments received many comments on the proposed requirement that the plan or issuer determine the portion of plan payments for medical/surgical benefits expected to be subject to an NQTL in the benefit classification. Several commenters indicated that the determination of the dollar amount of all plan payments for medical/surgical benefits expected to be paid may be an inappropriate measure altogether because NQTLs like medical

management, assessments related to medical necessity, experimental/investigational treatment exclusions, prior authorization requests, and provider network admission standards are not generally attached to claims. Some commenters highlighted that self-insured plan sponsors may face challenges in obtaining a complete and reliable set of plan-level claims data, and accordingly, would have limited data to use to assess individual NQTLs, or would incur additional costs.

After determining the portion of plan payments for medical/surgical benefits in the classification expected to be subject to the NQTL, the Departments proposed that, under the second prong, plans and issuers would be required to determine whether the NQTL applies to substantially all medical/surgical benefits in the classification, based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year. Under the proposed rules, an NQTL would be considered to apply to substantially all medical/surgical benefits in a classification if it applies to at least two-thirds of all medical/surgical benefits in that classification. Under the proposed rules, whether the NQTL applies to at least two-thirds of all medical/surgical benefits would be determined without regard to whether the NQTL was triggered based on a particular factor or evidentiary standard.⁶⁸ The proposed rules further provided that if an NQTL does not apply to at least two-thirds of all medical/surgical benefits in a classification, that NQTL would not be permitted to be applied to mental health or substance use disorder benefits in that classification.

⁶⁸ For example, if a plan or issuer applies a general exclusion for all benefits in a classification that are for experimental or investigative treatment, and defines experimental or investigative treatment to be treatments with less than a certain number of peer-reviewed studies demonstrating efficacy, under the proposed rules, the exclusion would be treated as applying to all of the benefits in the classification—not just those that may be subject to the general exclusion for experimental or investigative treatment because they lack the requisite number of peer-reviewed studies (that is, those that actually triggered the NQTL based on the evidentiary standard). 88 FR 51552, 51570 (Aug. 3, 2023).

The Departments received many comments regarding this prong of the proposed mathematical substantially all and predominant tests. As mentioned earlier in this preamble, many commenters stated that, in practice, a numerical “substantially all” determination would be difficult to apply and assess for NQTLs for many reasons, including because they are often not quantifiable, and there are more medical/surgical items and services (and associated benefits) than there are mental health and substance use disorder items and services. Additionally, commenters highlighted that plans and issuers already experience difficulty in obtaining data from service providers and would have difficulty in determining which NQTLs apply to at least two-thirds of medical/surgical benefits in a classification. Some commenters predicted that, if the Departments finalize the substantially all and predominant tests as proposed, plans and issuers might increase the application of NQTLs to medical/surgical benefits to meet the two-thirds threshold.

Further, some commenters requested that the Departments specify and provide examples showing how to apply the substantially all test to NQTLs that are not associated with plan payments, such as prescription drug formularies and network composition standards. One commenter highlighted that it is difficult to calculate the amount of plan payments expected to be paid for prescription drugs subject to an NQTL. Another commenter urged the Departments to clarify the determination of whether an NQTL applies regardless of whether the NQTL was triggered. For example, this commenter highlighted that insurers might state that prior authorization “applies” to all benefits in a classification where a benefit is considered or evaluated under the various factors for determining whether to apply prior authorization, even if the benefit ultimately is determined to not be subject to prior authorization based on the application of factors and evidentiary standards.

In addition, in the proposed rules, the Departments solicited comments on whether plans and issuers maintain systems capable of determining, under the proposed mathematical

substantially all and predominant tests, whether an NQTL applies to substantially all medical/surgical benefits in a classification, and the administrative burden that would be associated with such determinations. Several commenters highlighted that it would be difficult to comply with the substantially all and predominant tests as proposed, including because the requisite data may be housed in different parts of a plan's or issuer's organization. One commenter emphasized that current administrative systems would need to be adapted, and plans and issuers would need to hire additional staff or service providers to be able to perform the analysis that would be required under the proposed mathematical substantially all and predominant tests.

Under the proposed rules, if a plan or issuer determined that an NQTL applies to substantially all medical/surgical benefits in a classification, the third prong of the test would require a plan or issuer to determine the predominant variation of the NQTL that is applied to substantially all medical/surgical benefits subject to the NQTL in the classification. The Departments proposed that the term "predominant" would, for this purpose, mean the most common or most frequent variation of an NQTL within a benefit classification.

The Departments received many comments regarding this part of the proposed tests. Numerous commenters stated that this aspect of the substantially all and predominant tests is unworkable. Some commenters noted that, with a lack of guidance on how to identify all the variations of a particular NQTL (especially those that are complex and nuanced), the proposed rules may not be feasible for plans, issuers, and regulators to apply in real-life situations. Several commenters stated that, while financial requirements and quantitative treatment limitations will have only a few different variations, NQTLs are multifactorial and each difference could be considered a different variation, or even a separate NQTL. For example, some of these commenters highlighted that prior authorization or concurrent review may take varied forms: an admission that requires advance prior authorization; an admission

that requires notification but no clinical review; a nonclinical review based on predetermined standards; a first-level or nurse clinical review; a second-level or physician clinical review; and a peer-to-peer clinical review. These commenters noted that some processes may be automated or manual, some may be handled by vendors or directly by the plan or issuer, and some may have multiple utilization management systems within all of the aforementioned categories. Another commenter highlighted that a plan or regulator could conceivably determine that “variations” include a wide range of aspects, such as the credentials of the reviewer, the type or source of clinical criteria applied, the timing of the review (for example, urgent vs. nonurgent), the modality of authorization submission (for example, via electronic health record vs. fax or pdf form), among others. As a result, these commenters stated that determining how to identify the predominant variation of an NQTL may not be feasible without additional clarifications. Many commenters requested that the Departments provide a definition of the term “variation” and an explanation of how to determine whether a variation exists, as well as additional guidance and examples illustrating when an NQTL has no variation and when an NQTL has multiple variations (beyond variations based on numerical distinctions). These commenters also noted that, under the proposed rules, the predominant variation may only apply to a small percentage of medical/surgical services or items in the applicable benefit classification.

Lastly, under the fourth prong, the proposed rules provided that an NQTL applied to mental health or substance use disorder benefits cannot be *more restrictive* than the predominant variation of the NQTL applied to substantially all medical/surgical benefits in the same classification. Under the proposed rules, for this purpose, an NQTL would be considered restrictive if it imposes conditions, terms, or requirements that limit access to benefits under the terms of the plan or coverage. For this purpose, conditions, terms, or requirements would include, but not be limited to, those that compel an action by or on behalf of a participant or

beneficiary to access benefits or limit access to the full range of treatment options available for a condition or disorder under the plan. As discussed later in this preamble, the Departments also proposed that an NQTL applied to mental health or substance use disorder benefits in any classification would not be considered to violate the no more restrictive requirement if the NQTL impartially applies independent professional medical or clinical standards or fraud, waste, and abuse measures, that meet specific requirements.

Some commenters supported this approach to the “more restrictive” part of the test in the proposed rules because, according to these commenters, it provided a more concrete and less subjective standard. Other commenters emphasized, as discussed earlier in this preamble, that the proposed mathematical substantially all and predominant tests, which provide a quantitative basis for comparison, are unworkable for NQTLs and administratively burdensome. Many of these commenters requested that, if the proposed mathematical substantially all and predominant tests are finalized, the Departments provide extensive and detailed implementation guidance to assist plans and issuers in complying with what the commenters characterized as this challenging framework. Another commenter suggested that the Departments establish a safe harbor for plans and issuers from the substantially all and predominant tests for any variation in NQTL outcomes data driven by State law or regulation.

The Departments appreciate the detailed comments received on all aspects of the proposed mathematical substantially all and predominant tests, including comments particular to each aspect of the proposed four-prong test. The Departments acknowledge that many commenters expressed concerns that applying to NQTLs the same proposed mathematical substantially all and predominant tests that are applicable to financial requirements or quantitative treatment limitations may be difficult to operationalize and could be unworkable. The Departments acknowledge that this framework was first developed for financial

requirements and quantitative treatment limitations, where there are relatively clear and limited numbers of variations, and that the framework might be impractical or impossible for NQTLs, which differ in how they are designed and applied to various benefits.

At the same time, the Departments agree with commenters who stated that applying the statutory no more restrictive requirement to NQTLs under the proposed rules would assist regulators tasked with enforcing MHPAEA's requirements and result in overall compliance improvements by formalizing and providing greater clarity on what plans and issuers must do to comply with MHPAEA. The Departments also agree with commenters who emphasized the importance of the statutory requirement that plans and issuers shall ensure that the treatment limitations they impose on mental health and substance use disorder benefits generally are no more restrictive than those they impose on medical/surgical benefits. The proposed rules made clear that the incorporation of this statutory language into regulations is key to ensuring that people seeking mental health and substance use disorder treatment do not face a greater burden on access to benefits for such treatment than on access to benefits for medical treatment and surgical procedures, a premise that is central to MHPAEA.

After reviewing all the comments on the proposed four prongs of the no more restrictive requirement, the Departments have sought to address many of the workability concerns expressed by commenters, while honoring statutory requirements. Specifically, due to concerns raised by the commenters, the Departments are declining to finalize the proposed mathematical substantially all and predominant tests for NQTLs, which would have based these determinations on the dollar amount of all plan payments for medical/surgical benefits expected to be paid, similar to the steps that apply when analyzing parity with respect to financial requirements or quantitative treatment limitations under the 2013 final regulations. These final rules address commenters' operability and feasibility concerns with respect to the proposed mathematical substantially all and predominant tests, while continuing to set forth a standard for parity

compliance that is grounded in MHPAEA's statutory text and is also sufficiently flexible to account for the unique and nonquantifiable nature of NQTLs. As noted later in this preamble, these final rules retain the focus on the design and application of NQTLs, including with respect to relevant outcomes measures, to ensure that NQTLs are no more restrictive in the context of mental health and substance use disorder benefits than in the context of medical/surgical benefits.

Therefore, these final rules do not finalize the provisions proposed under 26 CFR 54.9812-1(c)(4)(i)(A) through (E), 29 CFR 2590.712(c)(4)(i)(A) through (E), and 45 CFR 146.136(c)(4)(i)(A) through (E). Instead, consistent with MHPAEA's express statutory requirement,⁶⁹ the Departments are finalizing under 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) the general rule that, consistent with the fundamental purpose of MHPAEA, a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) may not impose any NQTL with respect to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification. Through this requirement, the Departments reiterate the importance of promoting the goals of the statute and ensuring that individuals have access to the mental health and substance use disorder benefits under their plan or coverage in a way that is not more restrictive than their access to the medical/surgical benefits under their health coverage. For this purpose, consistent with the fundamental purpose of MHPAEA, an NQTL is more restrictive than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification if the plan or issuer fails to satisfy the design and application requirements at 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i) or the relevant data evaluation requirements at 26 CFR 54.9812-1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45

⁶⁹ Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A).

CFR 146.136(c)(4)(iii). Accordingly, plans and issuers must ensure that the processes, strategies, evidentiary standards, and other factors used to design and apply an NQTL to mental health or substance use disorder benefits are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to design and apply the NQTL for medical/surgical benefits, including by ensuring that the information, evidence, sources, or standards on which factors and evidentiary standards are based are not biased and are objective. Additionally, plans and issuers must comply with the relevant data evaluation requirements, including by collecting and evaluating relevant data, determining whether the data suggest an NQTL contributes to material differences in relevant outcomes related to access to mental health and substance use disorder benefits as compared to medical/surgical benefits, and if material differences in relevant outcomes related to access exist, taking reasonable action, as necessary, to address the material differences to ensure compliance, in operation, with 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4). Absent compliance with both the design and application requirements and the relevant data evaluation requirements with respect to an NQTL, which are addressed in more detail later in this preamble, a plan or issuer fails to comply with Code section 9812(a)(3)(A)(ii), ERISA section 712(a)(3)(A)(ii), and PHS Act section 2726(a)(3)(A)(ii), as applicable, and may not impose the NQTL with respect to mental health or substance use disorder benefits. These requirements, taken together, require a plan to consider and evaluate an NQTL’s design, application, and resulting outcomes to ensure that an NQTL is not more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification.

These final rules also include a few technical changes to this language, including relocation of the reference to 26 CFR 54.9812-1(a)(1), 29 CFR 2590.712(a)(1), and 45 CFR 146.136(a)(1) from the beginning of the general rule of the design and application requirements to the beginning of the regulatory requirements for NQTLs at 26 CFR 54.9812-1(c)(4), 29 CFR

2590.712(c)(4), and 45 CFR 146.136(c)(4), to make clear that plans and issuers should consider the fundamental purpose of MHPAEA in complying with all parts of the requirements for NQTLs. Additionally, the Departments are incorporating the phrase “may not impose” from the beginning of the proposed regulatory requirements for NQTLs, to make clear that this standard applies both to the design and application of NQTLs. The Departments are also replacing the word “applied” with “applies” in the clause describing “the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification.” This adjustment from past to present tense is intended to clarify that plans and issuers should evaluate compliance with MHPAEA with respect to NQTLs that are currently imposed under the plan or coverage, rather than just those that might have been imposed at some point in the past.

b. Requirements Related to Design and Application of the NQTL – 26

CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i)

The Departments proposed to redesignate the requirement at 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i) in the 2013 final regulations as paragraph (c)(4)(ii)(A) and amend it to align with the Departments’ interpretation that a plan or issuer may not impose an NQTL with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage) as written and in operation, any processes, strategies, evidentiary standards, or other factors used in *designing and applying* (as compared to only applying, as under the 2013 final regulations) the NQTL to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than those used in designing and applying the limitation with respect to medical/surgical benefits in the classification. To codify this interpretation, and for consistency with the statutory language added by the CAA, 2021, the Departments proposed to revise the regulatory text to make this requirement with respect to designing the NQTL explicit.

Some commenters generally supported the proposed design and application requirements as part of an overall framework for evaluating compliance with MHPAEA’s requirements with respect to NQTLs. Some commenters indicated that they have encountered barriers in identifying whether plans and issuers comply with MHPAEA’s requirements, and this proposal would help them identify whether the plan or issuer is compliant with respect to the design and application of NQTLs. Other commenters generally opposed the proposed changes to the design and application requirements. One commenter also stated that the design and application requirements would not improve benefit quality and would also constitute an impermissible retroactive application of the regulation in the case of regulated entities that were not required to comply with MHPAEA when they designed their benefit plans.

With respect to commenters’ concern that the design and application requirements would not improve benefit quality, the Departments anticipate that greater clarity with respect to these requirements, including the definitions of the terms “processes,” “strategies,” “evidentiary standards,” and “factors” under these final rules, as discussed earlier in this preamble, will help plans and issuers assess their compliance and remedy any parity violations, which will result in improved benefit quality overall. The Departments also disagree with the concern expressed by commenters that the design and application requirements impermissibly apply to plans and issuers that were not required to comply with MHPAEA when they designed their benefit plans. As stated earlier in this preamble, this provision codifies the Departments’ longstanding interpretation of the design and application requirements and the CAA, 2021 amendments to the MHPAEA statute. The CAA, 2021 amendments apply generally to plans and issuers that offer both medical/surgical benefits and mental health or substance use disorder benefits and impose NQTLs on mental health or substance use disorder benefits. Congress did not exempt plans or issuers whose plans or benefit designs predated these requirements, and the Departments

similarly did not take such an approach in implementing the 2010 interim final regulations or the 2013 final regulations. In fact, as described in more detail later in this preamble, Congress included a provision in the CAA, 2023 that sunsets the option for self-funded non-Federal governmental plans to elect to opt out of compliance with respect to MHPAEA, so that plans that previously were exempt from the requirements as a result of an opt-out election will no longer be able to make such an election.

The Departments are finalizing as proposed the general rule with respect to the design and application requirements for NQTLs, with a few minor amendments. Accordingly, this provision clarifies that to satisfy these requirements, a plan or issuer must consider, as part of its assessment of an NQTL's compliance with the no more restrictive requirement, whether any processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than those used in designing and applying the limitation with respect to medical/surgical benefits in the classification. By requiring processes, strategies, evidentiary standards, or other factors used to be comparable to and applied no more stringently than, the design and application requirements of these final rules give meaning to the statutory terms "substantially all" and "predominant." By making explicit in these final rules the Departments' interpretation of the design and application requirements, and codifying the requirements of the CAA, 2021, this provision will help plans and issuers better understand their MHPAEA compliance obligations with respect to NQTLs, by emphasizing that, as written and in operation, the design of an NQTL is equally relevant as how it is applied. The design and application requirements of these final rules will also ensure that plans and issuers do not place greater burdens on access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

The Departments note that a plan or issuer must comply with the relevant requirements under these final rules with respect to NQTLs applicable to mental health or substance use disorder benefits once the final rules become applicable to the plan or coverage, including with respect to any NQTLs that were developed and imposed when a plan or issuer was not subject to MHPAEA and that continue to be imposed after the applicability date. However, these final rules are not applicable to an NQTL imposed with respect to mental health or substance use disorder benefits for any such prior period of time (including a period when MHPAEA was not applicable).

In these final rules, the Departments are codifying the design and application requirements at 26 CFR 54.9812-1(c)(4)(i)(A), 29 CFR 2590.712(c)(4)(i)(A), and 45 CFR 146.136(c)(4)(i)(A), rather than as proposed at 26 CFR 54.9812-1(c)(4)(ii)(A), 29 CFR 2590.712(c)(4)(ii)(A), and 45 CFR 146.136(c)(4)(ii)(A) because, as discussed earlier in this preamble, these final rules structure the design and application requirements as part of the statutory no more restrictive requirement, rather than as a unique prong of the three requirements for NQTLs included in the proposed rules. In addition, the Departments are making a technical correction by amending the regulatory text to refer to health insurance coverage, rather than an issuer, to generally use consistent terminology throughout the regulations. Finally, as noted earlier in this preamble, these final rules move the reference to 26 CFR 54.9812-1(a)(1), 29 CFR 2590.712(a)(1), and 45 CFR 146.136(a)(1) from the beginning of the general rule of the design and application requirements to the beginning of the regulatory requirements for NQTLs at 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4).

Prohibition on Discriminatory Factors and Evidentiary Standards

The proposed rules would add a new provision that, for purposes of determining comparability and stringency under the design and application requirements of proposed 26 CFR 54.9812-1(c)(4)(ii)(A), 29 CFR 2590.712(c)(4)(ii)(A), and 45 CFR 146.136(c)(4)(ii)(A), plans

and issuers would be prohibited from relying upon any factor or evidentiary standard if the information, evidence, sources, or standards on which the factor or evidentiary standard is based discriminate against mental health or substance use disorder benefits as compared to medical/surgical benefits. The proposed rules stated that information would be considered to discriminate against mental health or substance use disorder benefits if it is biased or not objective, in a manner that results in less favorable treatment of mental health or substance use disorder benefits, based on all the relevant facts and circumstances. Such relevant facts and circumstances would include, but not be limited to, the source of the information, the purpose or context of the information, and the content of the information. Therefore, under the proposed rules, plans and issuers would not be permitted to rely on information that reflects bias, as those factors or evidentiary standards would be discriminatory.

For this purpose, the Departments stated in the proposed rules that information resulting in the less favorable treatment of mental health and substance use disorder benefits without legitimate justification or that is otherwise not objective would be considered to be biased and to discriminate against mental health and substance use disorder benefits. When determining which information, evidence, sources, or standards should inform the factors or evidentiary standards used to design or apply an NQTL, plans and issuers would not be permitted under the proposed rules to use information, evidence, sources, or standards if they are biased in favor of imposing greater restrictions on access to covered mental health and substance use disorder benefits or not objective, based on all the relevant facts and circumstances. The Departments also proposed that impartially applied independent professional medical or clinical standards and fraud, waste, and abuse measures that meet specific requirements would qualify for an exception and would not be considered to discriminate against mental health or substance use disorder benefits.

Additionally, in the preamble to the proposed rules the Departments noted that the proposed prohibition on discriminatory factors and evidentiary standards would prohibit

plans and issuers from relying on historical plan data or other historical information from a time when the plan or coverage was not subject to MHPAEA or was in violation of MHPAEA's requirements, where the use of such data results in less favorable treatment of mental health and substance use disorder benefits. The Departments provided an example illustrating that a plan or issuer would not be permitted to calculate reimbursement rates based on historical data on total plan spending for each specialty that is divided between mental health and substance use disorder providers and medical/surgical providers, when the total spending by the plan was based on a time period when the plan or coverage was not subject to MHPAEA or was in violation of MHPAEA, if the data result in less favorable treatment of mental health and substance use disorder benefits. Consequently, under the framework in the proposed rules, plans and issuers could not use such data to develop a factor or evidentiary standard for the design or application of an NQTL to mental health or substance use disorder benefits. The proposed rules stated, to the extent a plan or issuer relies on any factor or evidentiary standard that discriminates against mental health or substance use disorder benefits, or any information, evidence, sources, or standards that inform such factors or evidentiary standards to design and apply NQTLs, the plan or issuer would violate the prohibition on discriminatory factors and evidentiary standards set forth in proposed 26 CFR 54.9812-1(c)(4)(ii)(B), 29 CFR 2590.712(c)(4)(ii)(B), and 45 CFR 146.136(c)(4)(ii)(B).

Many commenters expressed general support for this provision of the proposed rules. For example, one commenter noted that the prohibition on discriminatory factors and evidentiary standards would more effectively protect against the inappropriate application of NQTLs that, although appearing to be compliant with MHPAEA as written, have a disproportionately negative effect on access to mental health and substance use disorder benefits. Some commenters also indicated that the proposed provision is consistent with the text and purpose of MHPAEA, as well as the ACA, and favored a broad interpretation of the

requirement to address particular examples of discrimination by plans and issuers, to which some of them expressly cited. Other commenters expressed opposition to the proposed prohibition on discriminatory factors and evidentiary standards. Some of these commenters stated that the proposal would be administratively burdensome, and it would be difficult for plans and issuers to operationalize due to ambiguity and inherent subjectivity. Some commenters opposed to the proposed prohibition stated that it is duplicative of the proposed relevant data evaluation requirements. These commenters thought the prohibition on discriminatory factors and evidentiary standards should be eliminated as superfluous, because the required evaluation of outcomes data under the proposed rules is intended to ensure that factors are applied no more stringently to mental health and substance use disorder benefits than medical/surgical benefits and do not result in a material difference in access.

Some commenters expressed concern that the proposed requirement that information must not be biased and must be objective (which is based on facts and circumstances) is too subjective, can only be determined retroactively (yet must be applied prospectively), and is too difficult to apply for plans or issuers to be certain of compliance. One commenter requested clarification on the documentation and evidence required to demonstrate the absence of bias. Another commenter expressed concern that plans may not have the ability to prove that information is unbiased and objective.

One commenter stated that it is unclear whether the Departments intend to focus on the factors and evidentiary standards themselves or on the effects of using those factors and standards. Some commenters assumed that whether a factor or evidentiary standard is discriminatory would be based on an evaluation of outcomes, and that therefore any disparity in outcomes data could be viewed as use of a discriminatory factor or evidentiary standard. These commenters requested examples of outcomes that would demonstrate compliance. In addition,

many commenters requested examples of discriminatory factors and evidentiary standards and of nondiscriminatory information and data sources. Several commenters requested the Departments to make clear that plans and issuers may not establish compliance by relying on a fee schedule used by Medicare, although another commenter requested that plans and issuers be able to access a safe harbor if they paid above-Medicare rates.

After considering commenters' feedback, the Departments are finalizing the prohibition on discriminatory factors and evidentiary standards with modifications. As the Departments stated in the preamble to the proposed rules this provision will help address the concern that various factors and evidentiary standards that plans and issuers have relied on to design NQTLs with respect to mental health or substance use disorder benefits might themselves discriminate against mental health and substance use disorder benefits by treating them in a less favorable manner. At the same time, the Departments acknowledge commenters' concerns about potential ambiguities in the proposed prohibition on discriminatory factors and evidentiary standards, questions about whether this provision is duplicative of other parts of the proposed rules, and confusion about how to operationalize the prohibition.

In response to these concerns, and to assist plans and issuers in complying with the prohibition on discriminatory factors and evidentiary standards in these final rules, the Departments have modified the prohibition by providing additional clarity regarding what it means for information, evidence, sources, or standards to be "biased or not objective." The final rules both clarify the prohibition in a manner to ensure that it can be applied prospectively and revise it to expressly provide that potentially biased or not objective information, evidence, sources, or standards can be corrected, cured, or supplemented, and then relied upon by a plan or issuer to inform a factor or evidentiary standard that is not

discriminatory. The Departments also provide additional examples of discriminatory factors and evidentiary standards later in this preamble.

First, with respect to the general prohibition on discriminatory factors and evidentiary standards, these final rules at 26 CFR 54.9812-1(c)(4)(i)(B), 29 CFR 2590.712(c)(4)(i)(B), and 45 CFR 146.136(c)(4)(i)(B)⁷⁰ provide that, for purposes of determining comparability and stringency under 26 CFR 54.9812-1(c)(4)(i)(A), 29 CFR 2590.712(c)(4)(i)(A), and 45 CFR 146.136(c)(4)(i)(A), a plan (or health insurance coverage) may not rely upon discriminatory factors and evidentiary standards to design an NQTL to be imposed on mental health or substance use disorder benefits. The Departments intend that the focus of this prohibition be specifically on the design of NQTLs, to further distinguish the prohibition on discriminatory factors and evidentiary standards from the relevant data evaluation requirements. These final rules provide the necessary clarity for plans and issuers to determine whether information, evidence, sources, or standards are biased or not objective, and if so, cannot be used as the basis for a factor or evidentiary standard used to design an NQTL applicable to mental health or substance use disorder benefits.

Specifically, these final rules state that a factor or evidentiary standard is discriminatory if the information, evidence, sources, or standards on which the factor or evidentiary standard are based are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. This language is similar to that included under proposed 26 CFR 54.9812-1(c)(4)(ii)(B), 29 CFR 2590.712(c)(4)(ii)(B), and 45 CFR 146.136(c)(4)(ii)(B) but adds the phrase “is biased or not objective in a manner that,” preceding the word “discriminates.” This

⁷⁰ As noted earlier in this preamble, the Departments are codifying the design and application requirements (including the prohibition on discriminatory factors and evidentiary standards) at 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i), rather than as proposed at 26 CFR 54.9812-1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), and 45 CFR 146.136(c)(4)(ii), because these final rules structure the design and application requirements as part of the no more restrictive requirement, rather than as a unique prong of the 3-part test proposed in the proposed rules.

phrase, in conjunction with the other changes to the prohibition on discriminatory factors and evidentiary standards discussed later in this preamble, was modified in response to comments and is intended to help clarify that a plan or issuer is expected to assess whether the information, evidence, sources, or standards on which each factor or evidentiary standard are based are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. This analysis is distinct from the final rules' requirement to compare the comparability and stringency of factors and evidentiary standards used to design and apply an NQTL.

Second, the Departments are finalizing a modified version of the provision originally proposed under 26 CFR 54.9812-1(c)(4)(ii)(B)(3), 29 CFR 2590.712(c)(4)(ii)(B)(3), and 45 CFR 146.136(c)(4)(ii)(B)(3) as 26 CFR 54.9812-1(c)(4)(i)(B)(1), 29 CFR 2590.712(c)(4)(i)(B)(1), and 45 CFR 146.136(c)(4)(i)(B)(1) of these final rules. This provision of the proposed rules provided that information is considered to discriminate against mental health or substance use disorder benefits if it is biased or not objective, in a manner that results in less favorable treatment of mental health or substance use disorder benefits, based on all the relevant facts and circumstances. As mentioned earlier in this preamble, the Departments received many comments opposing this provision as proposed, including comments expressing confusion as to how it is different from the relevant data evaluation requirements, questions regarding the kind of documentation and evidence needed to show compliance, and concern that it is subjective and difficult to operationalize.

The prohibition on discriminatory factors and evidentiary standards is intended to work together with the other provisions of these final rules, including the relevant data evaluation requirements. Like all the provisions of these final rules, the provision further implements the statutory requirement that NQTLs be no more restrictive with respect to mental health or substance use disorder benefits than the predominant limitations applicable

to substantially all medical/surgical benefits. The test specifically focuses on the importance of ensuring that the factors and evidentiary standards relied upon by plans and issuers in designing NQTLs do not have built-in biases (at the time NQTLs are designed) against mental health or substance use disorder benefits as compared to medical/surgical benefits. To the extent plans and issuers rely upon factors and evidentiary standards to design NQTLs that systematically disfavor access or are specifically designed to disfavor access to mental health and substance use disorder benefits, the resultant NQTLs are more restrictive with respect to mental health or substance use disorder benefits than for medical/surgical benefits.

The Departments note that a factor or evidentiary standard may be based on or include information that solely relates to medical/surgical benefits (and is silent or without corollary with respect to mental health or substance use disorder benefits). Such a factor or evidentiary standard is not considered discriminatory for this purpose. For example, a plan can reasonably rely on a source of information on the clinical efficacy of a treatment or service to inform a factor used to design a medical management NQTL, even though that source does not address the clinical efficacy of any treatment of any mental health conditions or substance use disorders, without violating the prohibition on discriminatory factors and evidentiary standards. However, the use of such factor or evidentiary standard must comply with the design and application requirements, as described earlier in this preamble.

In response to comments to provide additional clarity, the final rules elaborate on the meaning of the phrase “biased and not objective in a manner that discriminates against mental health or substance use disorder benefits.” Specifically, these final rules provide that information, evidence, sources, or standards are considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all the relevant facts and circumstances,

they systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits.

For purposes of determining whether information, evidence, sources, or standards are considered to be biased or not objective under these final rules, relevant facts and circumstances may include, but are not limited to, the reliability of information, evidence, sources, or standards, including any underlying data and the independence of the information, evidence, sources, and standards relied upon. The Departments note that internal data or information, such as claims data, would generally not be considered independent, but would not necessarily be considered discriminatory on that basis alone. In the Departments' view, independence is a relevant fact and circumstance for determining whether information, evidence, sources, or standards are considered to be biased or not objective. For example, a standard that is created or funded by the plan or issuer, or its service provider, would likely lack independence compared to a standard created by an impartial third party or governmental entity, and might require strong indicators of reliability in order to demonstrate that it is objective and unbiased. Additionally, relevant facts and circumstances include the analyses and methodologies employed to select the information, evidence, sources, or standards, and the consistency of their application; and any known safeguards deployed to prevent reliance on skewed data or metrics when determining whether they are biased or not objective. The Departments note that these final rules only provide examples, and not a comprehensive list, of relevant facts and circumstances that indicate information, evidence, sources, or standards are biased or not objective. Because plans and issuers rely on myriad factors and evidentiary standards to design NQTLs for their own unique benefit designs, this evaluation necessarily will be specific to the particular plan or coverage.

Under these final rules, information, evidence, sources, and standards are not considered biased or not objective for purposes of the prohibition on discriminatory factors

and evidentiary standards, if a plan or issuer has taken steps necessary to address the bias or lack of objectivity by correcting, curing, or supplementing the information, evidence, sources, or standards that would have been biased or not objective in the absence of such steps. If information, evidence, sources, or standards are corrected, cured, or supplemented, they may be used by plans and issuers as the basis for factors and evidentiary standards used to design an NQTL.

Several commenters asked about the use of a fee schedule used by Medicare and CMS-set standards, such as network time and distance standards, by a plan or issuer to inform plan design. For example, some plans use the Medicare Physician Fee Schedule⁷¹ to establish base rates for in-network physician services. The Departments do not consider fee schedules used by Medicare and standards set by CMS to be biased or not objective, as defined under these rules, when used as the basis for a factor or evidentiary standard to design an NQTL such as reimbursement rate methodology.

The Departments note, however, that the mere use of the Medicare Physician Fee Schedule, for example, as one type of information, evidence, source, or standard that informs a factor used to design an NQTL does not automatically render the NQTL permissible. For example, in most cases, a plan would be unable to justify a reimbursement rate methodology that paid physicians in medical/surgical specialties 125 percent of the Medicare Physician Fee Schedule rate and that paid physicians in mental health and substance use disorder specialties 75 percent of the Medicare Physician Fee Schedule rate.

⁷¹ The Medicare Physician Fee Schedule is developed by CMS. To develop the Medicare Physician Fee Schedule, CMS utilizes recommendations from an independent assessment by a multi-specialty body and other market-based information sources, as well as independent assessment by CMS medical officers, to develop proposed relative value units for each physician service. CMS then engages in notice and comment rulemaking, including consideration of public comments, before establishing payment rates for specific services. Furthermore, CMS has made, and continues to make, numerous adjustments to the underlying methodology to increasingly ensure appropriate reimbursement for services paid under the Medicare Physician Fee Schedule, including behavioral health services. *See, e.g.*, Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program, 88 FR 78818 (Nov. 16, 2023).

The Departments received several comments in support of the example included in the preamble to the proposed rules that illustrated the prohibition on plans' and issuers' reliance on historical plan data or other historical information from a time when the plan or coverage was not subject to MHPAEA, or not compliant with MHPAEA. Some commenters recognized that many plans and issuers have used their own historical data from a time when their plan or coverage was not subject to MHPAEA and have benefited from historic inequities in benefit structures that MHPAEA sought to prohibit. One commenter requested that this example be codified in the regulatory text of the final rules. The Departments agree that the example illustrating how the prohibition on discriminatory factors and evidentiary standards applies to the use of historical data and information to design an NQTL should be clearly set forth in the regulation text at 26 CFR 54.9812-1(c)(4)(ii)(B)(2), 29 CFR 2590.712(c)(4)(ii)(B)(2), and 45 CFR 146.136(c)(4)(ii)(B)(2). To ensure compliance with this standard, plans and issuers that utilize historical data or information from a time when their plan or coverage was not subject to, or not compliant with, MHPAEA should ensure that the use of such data and information (for example, in cost calculations and controls) for mental health and substance use disorder benefits does not include, as a baseline, years when financial requirements and treatment limitations that would have been impermissible under MHPAEA were imposed on such benefits (unless they take steps to correct, cure, or supplement the data or information, as discussed earlier in this preamble).

Some commenters provided other examples that they recommended including as illustrations of discriminatory factors and evidentiary standards in these final rules, including prior authorization for a prescription of buprenorphine to treat opioid use disorder (OUD) requiring additional licensure or certification for mental health and substance use disorder providers that is not required of similar medical/surgical providers; subjecting mental health and substance use disorder claims to different fraud, waste, and abuse

processes, or requiring more documentation, than for medical/surgical claims; not covering nutrition counseling for the treatment of eating disorders while covering it for medical conditions; and requiring that mental health and substance use disorder claims and appeals be filed with a TPA, but not making this clear to enrollees, nor properly coordinating operations between the plan/issuer and TPA.

However, many of these examples focus on the use of a factor to apply an NQTL to mental health and substance use disorder benefits in a manner that is not comparable or is more stringent than the use of the factor to apply an NQTL to medical/surgical benefits, or focus on the NQTL itself (rather than the discriminatory factor or evidentiary standard). The prohibition on discriminatory factors and evidentiary standards in these final rules, however, focuses on the information, evidence, sources, and standards that inform the factors and evidentiary standards used to design an NQTL. Factors and evidentiary standards that incorporate or otherwise rely on underlying data or information that systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits place a greater burden on access to such benefits. Therefore, these final rules prohibit the use of any factor or evidentiary standard to design an NQTL if the underlying information, evidence, sources, and standards are themselves biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, unless the plan or issuer takes steps to correct, cure, or supplement the information, evidence, sources and standards to address the bias or lack of objectivity.

These final rules set forth a general rule to determine which specific factors and evidentiary standards (and the information, evidence, sources, and standards on which they are based) might or might not be biased and not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. The

Departments have provided new examples in these final rules illustrating the prohibition on discriminatory factors and evidentiary standards, which are discussed later in this preamble. The Departments acknowledge that these examples are not exhaustive and may provide additional examples in future guidance.

Finally, as discussed in greater detail later in this preamble, the Departments are not finalizing the exceptions to the prohibition on discriminatory factors and evidentiary standards for independent professional medical or clinical standards and fraud, waste, and abuse measures. However, these final rules expressly clarify at 26 CFR 54.9812-1(c)(4)(i)(B)(3), 29 CFR 2590.712(c)(4)(i)(B)(3), and 45 CFR 146.136(c)(4)(i)(B)(3) that generally recognized independent professional medical or clinical standards and fraud and abuse measures that minimize the negative impact on access to appropriate mental health and substance use disorder benefits are not information, evidence, sources, or standards that are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits.

The Departments recognize that commenters requested specificity as to what qualifies as independent professional medical or clinical standards. To ensure that they are not biased and are objective, independent professional medical or clinical standards should reflect the standards of care and clinical practice that are generally recognized in relevant clinical specialties across a range of settings of care and should be transparent. For example, sources that include such standards could be peer-reviewed scientific studies and medical literature, formal published recommendations of Federal Government agencies, drug labeling approved by the United States Food and Drug Administration (FDA), and recommendations of relevant nonprofit health care provider professional associations and specialty societies, including, but not limited to, patient placement criteria and clinical practice guidelines. Additionally, fraud and abuse measures should be reliably established through unbiased and objective data and narrowly tailored in a

manner that minimizes the negative impact on access to appropriate mental health and substance use disorder benefits.

These final rules also clarify that plans and issuers that rely on independent professional medical or clinical standards or fraud and abuse measures must comply with the general rule of the design and application requirements at 26 CFR 54.9812-1(c)(4)(i)(A), 29 CFR 2590.712(c)(4)(i)(A), and 45 CFR 146.136(c)(4)(i)(A). If such a standard or measure is used as an NQTL, the plan or issuer also must comply with the relevant data evaluation requirements at 26 CFR 54.9812-1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii) in these final rules.

c. Illustrative, Non-Exhaustive List of NQTLs – 26 CFR 54.9812-1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), and 45 CFR 146.136(c)(4)(ii)

The proposed rules proposed to move the illustrative, non-exhaustive list of NQTLs from 26 CFR 54.9812-1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), and 45 CFR 146.136(c)(4)(ii) to 26 CFR 54.9812-1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii) and make several minor changes to this list. First, the Departments proposed amendments to make clear that this illustrative list of NQTLs is non-exhaustive and that there are additional NQTLs not captured in the list. The Departments also proposed to amend the illustrative, non-exhaustive list of NQTLs to replace “[s]tandards for provider admission to participate in a network, including reimbursement rates” with “standards related to network composition, including, but not limited to, standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide covered services under the plan or coverage.” Additionally, the Departments proposed to amend the description of the illustrative NQTL “plan methods for determining usual, customary, and

reasonable charges” to encompass a broader range of methods for determining out-of-network rates, such as allowed amounts; usual, customary, and reasonable charges; or application of other external benchmarks for out-of-network rates. Finally, the Departments proposed to add a specific reference to prior authorization requirements as an example of a medical management standard limiting or excluding benefits based on medical necessity or medical appropriateness, consistent with Example 1 in 26 CFR 54.9812-1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii) of the 2013 final regulations.

Some commenters supported the clarification in the proposed rules that the illustrative list is non-exhaustive and that there are additional NQTLs not included in the list. In general, many commenters found the list to be helpful for plans and issuers to identify NQTLs. Some of these commenters pointed out that the non-exhaustive nature of the list would allow new NQTLs developed by plans and issuers to fall under the scope of the requirements in these final rules. One commenter also noted that the definition of an NQTL is sufficiently clear such that an exhaustive list would not be needed to put plans or issuers on notice of their compliance obligations.

Other commenters requested that the Departments instead provide an exhaustive list of NQTLs to eliminate uncertainty, promote consistency, and clarify plans’ and issuers’ compliance obligations. Several of these commenters suggested that the Departments update such an exhaustive list as new NQTLs are identified and allow adequate time for plans and issuers to come into compliance with respect to such NQTLs. Other commenters advocated for an approach where an exhaustive list of NQTLs would also represent the scope of NQTLs for which the relevant Secretary could request a comparative analysis. Some of these commenters requested that to the extent the relevant Secretary requested a comparative analysis for an NQTL not on the list, plans and issuers be provided with additional time to respond.

The Departments agree with the commenter generally stating that the definition of an NQTL under 26 CFR 54.9812-1(a), 29 CFR 2590.712(a), and 45 CFR 146.136(a), in addition to the non-exhaustive, illustrative list of NQTLs, is sufficient to put plans and issuers on notice that a given plan provision would fall under the definition of an NQTL. Therefore, the Departments are finalizing as proposed the clarification that this illustrative list of NQTLs is non-exhaustive.

The Departments decline to provide an exhaustive list of NQTLs, as requested by commenters, in these final rules; however, as described further below, the Departments may consider issuing separate guidance to add additional examples if needed. Plans and issuers, rather than the Departments, are best positioned to initially identify NQTLs, including any NQTLs that plans and issuers newly implement as their plan or coverage designs evolve over time. MHPAEA does not limit the scope of NQTLs that plans and issuers may impose on mental health and substance use disorder benefits. However, for any NQTLs applicable to such benefits, a plan or issuer must comply with MHPAEA and its implementing regulations. Any exhaustive list of NQTLs published by the Departments would likely lag behind those actually utilized by plans and issuers due to this information gap, along with the wide variability in NQTLs that exist now and could exist in the future. Furthermore, while some commonalities exist, plans and issuers generally do not use uniform nomenclature to refer to their medical management techniques or other NQTLs, making the task of identifying an exhaustive list difficult, if not impossible.

An exhaustive list of NQTLs that does not include the full scope of NQTLs utilized by plans and issuers at any given time would undermine the fundamental purpose of MHPAEA and these final rules. While the Departments acknowledge and have considered plans' and issuers' requests for a finite list of NQTLs for which the Departments may request comparative analyses, the exhaustive nature of such a list would leave open a compliance

loophole by incentivizing plans and issuers to wait to evaluate, document, and address compliance for an NQTL that is newly developed or has not come to the attention of the Departments. The approach some commenters suggested to expressly limit the comparative analysis requirement under 26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137 to only those NQTLs identified in an exhaustive list is similarly untenable due to a foreseeable mismatch between the NQTLs included on such an exhaustive list, and those utilized by plans and issuers over time, particularly where the Departments may receive a complaint or have reason to believe there may be a potential violation. The Departments recognize the desire of plans and issuers to have a list of NQTLs on which the Departments will focus their enforcement efforts. The Departments highlight that the most recent reports to Congress on MHPAEA contain lists of the NQTLs on which the Departments have focused their enforcement efforts, and the NQTLs the Departments have mostly commonly found to be noncompliant.⁷² Additionally, the 2020 MHPAEA Self-Compliance Tool includes an illustrative, non-exhaustive list of NQTLs.⁷³ The statute, however, requires the Departments to request comparative analyses from a plan or issuer for any NQTL that involves potential violations of MHPAEA or complaints regarding noncompliance with MHPAEA that concern NQTLs. To limit the Departments to requesting comparative analyses for only certain NQTLs identified in a list would not only be inconsistent with the statute but would also limit the ability of the Departments to dynamically respond to new NQTLs that plans and issuers

⁷² See, e.g., 2022 MHPAEA Report to Congress (Jan. 2022), pg. 13, 19-20, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf> ; 2023 MHPAEA Comparative Analysis Report to Congress (July 2023), pg. 47-48, 55-56, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf> and <https://www.cms.gov/ccio/resources/forms-reports-and-other-resources#mental-health-parity>.

⁷³ See Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA) (2020), <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf>.

design and apply that may restrict participant and beneficiary access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

Additionally, allowing plans and issuers to categorically have additional time to assemble a comparative analysis for NQTLs that are not on a finite list of NQTLs, as requested by commenters, would also be inconsistent with the statutory requirement that, without exception, plans and issuers perform and document such comparative analyses of NQTLs applicable to mental health or substance use disorder benefits, beginning 45 days after the enactment of the CAA, 2021, and would result in the post-hoc justifications addressed with the CAA, 2021's enactment.⁷⁴ The Departments nonetheless acknowledge commenters' requests for additional guidance about plan provisions that would be considered to be NQTLs and intend to provide additional examples of NQTLs through future reports to Congress, updates to the 2020 MHPAEA Self-Compliance Tool, and other guidance.

The Departments received a handful of comments on the proposed expansion of the illustrative list's description of standards for provider admission to participate in a network, including reimbursement rates, to also refer to standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide covered services under the plan or coverage. Some commenters supported these proposed amendments to ensure that patients have an adequate provider network. Others suggested that parity requirements for provider networks should address the administrative burden and credentialing requirements on providers when joining networks, which may limit network adequacy. The Departments are finalizing this amendment as proposed. The Departments agree with commenters who stated that MHPAEA applies to credentialing standards, as well

⁷⁴ Code section 9812(a)(8)(A), ERISA section 712(a)(8)(A), and PHS Act section 2726(a)(8)(A).

as the procedures to join a network, and note that methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan or coverage are intended to be interpreted broadly, consistent with the fundamental purpose of MHPAEA. Because these final rules do not retain the proposed mathematical substantially all and predominant tests, the illustrative list appears in these final rules at 26 CFR 54.9812-1(c)(4)(ii), 29 CFR 2590.712(c)(4)(ii), and 45 CFR 146.136(c)(4)(ii) instead of 26 CFR 54.9812-1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii) as in the proposed rules.

d. Required Use of Outcomes Data and Special Rule for NQTLs Related to Network Composition – 26 CFR 54.9812-1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii)

In the proposed rules, the Departments proposed to amend the 2013 final regulations to add a requirement that, when designing and applying an NQTL, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on access to mental health and substance use disorder benefits and medical/surgical benefits, and consider the impact as part of the plan's or issuer's analysis of whether the NQTL, in operation, complies with the proposed no more restrictive requirement and the design and application requirements. The proposed rules included the general types of data that plans and issuers would have to collect and evaluate with regard to all NQTLs and additional data sets that would have to be collected and evaluated for NQTLs related to network composition standards. To the extent the relevant data collected and evaluated by the plan or issuer show material differences in access to mental health benefits and substance use disorder benefits as compared to medical/surgical benefits, under the proposed rules, the differences would be considered a strong indicator that the plan or issuer violated the proposed rules. In these instances, a plan or issuer

would be required to take reasonable action to address any material differences in access as necessary to ensure compliance, in operation, with proposed 26 CFR 54.9812-1(c)(4)(i) and (ii), 29 CFR 2590.712(c)(4)(i) and (ii), and 45 CFR 146.136(c)(4)(i) and (ii), and would also be required to document the action that has been or is being taken by the plan or issuer to mitigate any material differences in access in the plan's or issuer's comparative analysis for the NQTL in that classification.

Additionally, the Departments noted in the preamble to the proposed rules their concerns about standards related to network composition and other related NQTLs. Specifically, the Departments noted that network composition is the result of the design and application of myriad NQTLs and is informed by various processes, strategies, evidentiary standards, and other factors, many of which interact in complex ways. The Departments also expressed concern that NQTLs related to network composition inherently impact a participant's or beneficiary's access to mental health and substance use disorder benefits. Accordingly, the proposed rules included a special rule applicable to NQTLs related to network composition. Specifically, under the proposed rules, when designing and applying one or more NQTLs related to network composition standards, a plan or issuer would fail to meet the requirements of proposed 26 CFR 54.9812-1(c)(4)(i) and (ii), 29 CFR 2590.712(c)(4)(i) and (ii), and 45 CFR 146.136(c)(4)(i) and (ii), in operation, if the relevant data show material differences in access to in-network mental health benefits and substance use disorder benefits as compared to in-network medical/surgical benefits in a classification.

The Departments also proposed that plans and issuers would not be required to comply with the relevant data evaluation requirements for NQTLs that impartially apply independent professional medical or clinical standards. However, proposed 26 CFR 54.9812-1(c)(4)(iv)(D), 29 CFR 2590.712(c)(4)(iv)(D), and 45 CFR 146.136(c)(4)(iv)(D) did not provide a comparable exception for fraud, waste, and abuse measures, as the Departments stated these tools, while

important, are more likely to result in NQTLs that improperly restrict access to mental health or substance use disorder benefits and therefore the impact of those NQTLs should be assessed.

In General

The Departments received many comments expressing general support for the proposal to require plans and issuers to collect and evaluate relevant data to assess an NQTL's impact on access to mental health and substance use disorder benefits and medical/surgical benefits, including the proposed requirement related to data for network composition NQTLs. These commenters noted that the data collection and evaluation requirements would promote transparency and compliance with MHPAEA, stating that collecting and evaluating outcomes data is essential to assessing in-operation compliance and that plans and issuers had failed to conduct and share such analyses. Other commenters noted that collection and evaluation of data is critical to assessing an NQTL's impact on access to mental health and substance use disorder benefits as compared to medical/surgical benefits, and by requiring plans and issuers to collect and assess outcomes data and to address material differences in access, the Departments are better aligning the focus of NQTL compliance with the fundamental purpose of MHPAEA. These commenters stated that, under the 2013 final regulations, plans and issuers rarely appropriately measure and analyze an NQTL's impact on access in the manner outlined in the proposed rules, and instead rely on process-related rationales to justify disparate access to treatment for mental health conditions and substance use disorders as compared to access to treatment for medical conditions and surgical procedures.

Other commenters stated that requiring plan sponsors to evaluate outcomes data to determine whether access to mental health and substance use disorder benefits is in parity with access to medical/surgical benefit is not supported by the statute and stated this provision of the proposed rules would be a significant departure from previous guidance under MHPAEA, under which the Departments stated that outcomes are not determinative of compliance. These

commenters also stated that, because not all NQTLs are quantifiable, data metrics should not be required to determine parity, and disagreed with the Departments' interpretation of the term "in operation" as the basis for the requirement that plans and issuers measure outcomes. The Departments also received many comments on the various components and specific comment solicitations related to the relevant data evaluation requirements in the proposed rules.

The determination of whether an NQTL is "more restrictive," within the meaning of the statute, as applied to mental health and substance use disorder benefits, cannot be divorced from the impact the NQTL has on access to these benefits. Accordingly, the Departments are finalizing the relevant data evaluation requirements, with some modifications based on the comments. These final rules require that plans and issuers be attentive to the impact of their NQTLs, in operation, by collecting and evaluating relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access, and carefully considering the impact as part of the plan's or issuer's evaluation.

For this purpose, the term "relevant data" under these final rules is meant to be interpreted broadly but does not require a plan or issuer to collect and evaluate duplicative or overlapping data that reflect the same analysis. The obligation is to collect and evaluate relevant data in a manner reasonably designed to assess the impact of NQTLs. It is not a requirement to exhaustively survey all available data, nor a requirement that plans and issuers evaluate additional data that is duplicative or unlikely to change the determination of whether there is a material difference in access to mental health and substance use disorder benefits as compared to medical/surgical benefits. However, as discussed later in this preamble, a plan or issuer may be required to collect and evaluate more than one form of data to assess the aggregate impact of the NQTL (or NQTLs as related to network composition). For example, under these final rules, to assess the aggregate impact of NQTLs related to network composition, a plan or issuer could evaluate, as appropriate, in-network and out-of-network utilization rates (including data related

to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (for comparable services and as benchmarked to a reference standard).

Further, a plan's or issuer's data collection and evaluation approach will not be considered to be conducted in a manner reasonably designed to assess the impact of an NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits if the plan or issuer does not consider data that it knows or reasonably should know suggest that the NQTL is associated with a material difference in access. The Departments expect that, in designing their data collection and evaluation approach, plans and issuers will consider outcomes data as necessary to assess the impact of the NQTL on access to mental health and substance use disorder benefits and medical/surgical benefits in the same classification. As explained later in this preamble, the plan's or issuer's evaluation of this data must be included as part of the comparative analysis of the NQTL. The Departments may require a plan or issuer to submit additional information to ensure that plans and issuers do not only collect and evaluate the impact of some relevant data, while disregarding other relevant data that is reasonably available and suggests the NQTL contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits.

The statutory language requires that a plan or issuer ensure that the treatment limitations (quantitative or nonquantitative) themselves that are applicable to mental health or substance use disorder benefits “are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered” by the plan (or coverage).⁷⁵ The relevant data evaluation requirements at 26 CFR 54.9812-1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii) are intended to give particular meaning to the statutory language with respect to an NQTL itself, which, in these final rules, also requires compliance, in operation,

⁷⁵ Code section 9812(a)(3)(A)(ii), ERISA section 712(a)(3)(A)(ii), and PHS Act section 2726(a)(3)(A)(ii).

with the design and application requirements under 26 CFR 54.9812-1(c)(4)(i), 29 CFR 2590.712(c)(4)(i), and 45 CFR 146.136(c)(4)(i). The Departments agree with commenters who noted that these requirements will promote transparency and compliance with MHPAEA, that such information is critical to assessing an NQTL's compliance with the statute, and that requiring plans and issuers to collect and assess outcomes data and address material differences in access appropriately aligns the focus of NQTL compliance more closely with the fundamental purpose of MHPAEA.

As stated in the preamble to the proposed rules, it is necessary to review and consider quantitative outcomes data to ascertain how the NQTL functions in the context of the plan's or issuer's administration and provision of benefits.⁷⁶ Because the relevant data evaluation requirements in these final rules are meant to ensure and determine compliance, in operation, with the statutory language in Code section 9812(a)(3)(A)(ii), ERISA section 712(a)(3)(A)(ii), and PHS Act section 2726(a)(3)(A)(ii), as noted earlier in this preamble, plans and issuers must comply with both the design and application requirements and the relevant data evaluation requirements in these final rules to demonstrate compliance with MHPAEA. That is, if, with respect to an NQTL, a plan or issuer fails to comply with either set of requirements in 26 CFR 54.9812-1(c)(4)(i) or (iii), 29 CFR 2590.712(c)(4)(i) or (iii), and 45 CFR 146.136(c)(4)(i) or (iii), as applicable, the plan or issuer will be considered to violate MHPAEA and the relevant NQTL may not be imposed with respect to mental health or substance use disorder benefits in the classification unless and until the plan or issuer takes appropriate action to remedy the violation.

Relevant Data

The proposed rules identified types of relevant data that plans and issuers would be required to collect and evaluate for all NQTLs in each individual comparative analysis. Under the proposed rules, relevant data for all NQTLs would include, but would not be limited to, the

⁷⁶ 88 FR 51552, 51575. (Aug. 3, 2023).

number and percentage of claims denials and any other data relevant to the NQTL as required by State law or private accreditation standards. Additionally, relevant data for network composition NQTLs would include, but would not be limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (including as compared to billed charges). The proposed rules further provided that the Departments may specify the type, form, and manner for the relevant data evaluation requirements in future guidance.⁷⁷

Many commenters supported the required use of data outcomes as proposed. Several commenters noted that many plans and issuers do not have access to the data they would need to comply with the relevant data evaluation requirements. Specifically, the Departments received several comments regarding limited access to data held by service providers, highlighting inconsistencies in service providers' willingness or ability to provide data and the extensive systems changes and expenses necessary to allow data to be provided. Some commenters suggested that, because plan sponsors do not have access to complete and reliable sets of claims data, the final rules should specify that a plan or issuer can meet its obligations related to the relevant data evaluation requirements by requesting access to data, documenting such requests, and advising service providers that their refusal to provide data will be relayed to the Departments.

⁷⁷ Contemporaneously with the proposed rules, DOL, in collaboration with HHS and the Treasury, issued Technical Release 2023-01P, which set out principles and asked for public comment to inform future guidance with respect to data submissions for NQTLs related to network composition and a potential enforcement safe harbor. The comment period for the Technical Release closed on October 2, 2023. Comments on the Technical Release are available on DOL's website at <https://www.dol.gov/agencies/ebsa/laws-and-regulations/rules-and-regulations/public-comments/tr-23-01>. Those comments were solicited separately and are not addressed in these final rules. Plans and issuers would be allowed adequate time to conform to any future guidance on the type, form, and manner of collection and evaluation for the relevant data required under the final rules.

Some commenters suggested the Departments issue the “type, form, and manner of collection and evaluation” for the relevant data evaluation requirements in guidance that can be periodically updated. Other commenters suggested that the final rules provide an exception from the relevant data evaluation requirements for NQTLs for which no such data are reasonably available, and that data evaluation be required only for outcomes that can be reasonably measured. One of these commenters highlighted that many NQTLs, including certain types of medical management techniques, assessments related to medical necessity, and exclusions for experimental/investigational treatments, are not generally associated with claims. Some commenters requested that the Departments provide an exhaustive list of a uniform set of outcomes data that plans and issuers are required to collect and assess as part of their comparative analysis with respect to an NQTL.

Commenters suggested additional or different types of data that should be considered relevant data and that could be provided by plans and issuers, as well as their service providers, including the percentage of in-network claims covered vs. those submitted; time and distance data that includes virtual or telehealth visits; median in-network payments as compared to Medicare rates for inpatient benefits, office visits, and outpatient benefits; member satisfaction, as reported by standardized surveys such as the Consumer Assessment of Healthcare Providers and Systems program; and allowed amounts for certain specific Current Procedural Terminology (CPT) codes for various types of mental health and substance use disorder and medical/surgical providers. Many commenters suggested that relevant data include the number of authorizations issued for participants and beneficiaries for each of the levels (and sub-levels) of care described in the American Society for Addiction Medicine (ASAM) criteria and the age-specific Level of Care Utilization Services family of criteria. Some of these commenters also suggested outcomes data be reported separately for both mental health and substance use disorder services. Another commenter also suggested that relevant data include the number and percentage of drugs subject

to prior authorization and step therapy (as an alternative to claims denials for the prescription drug classification), turnaround time for prior authorization, and inter-rater reliability. One commenter suggested using, as a parity indicator, a ratio of mental health utilization to primary care (for both initial and follow-up services) using data from the Medical Expenditure Panel Survey. Some commenters requested that, for fully insured coverage, the relevant data evaluation requirements apply at the issuer or “product” level instead of the “plan” level (as those terms are defined in 45 CFR 144.103),⁷⁸ while others sought clarification regarding whether the data to be analyzed should be group-specific or aggregate-level, as well as any differences in the level of data needed for fully insured and self-funded plans.

Some commenters objected to the proposal to require the collection and evaluation of out-of-network utilization data for NQTLs related to network composition, stating that high out-of-network utilization of mental health and substance use disorder services alone does not necessarily indicate a network access deficiency and could instead be the product of other factors, such as a patient’s preference to use a particular provider. One commenter suggested requiring the collection and evaluation of provider-to-enrollee ratio data, and another commenter expressed support for requiring the collection and evaluation of data on whether in-network providers are accepting new patients. Some commenters expressed support for the collection and evaluation of data on appointment wait times, time and distance data, types and numbers of mental health and substance use disorder providers that are available in a network, and telehealth. Some commenters suggested collection and evaluation of provider reimbursement rates, stating that those rates have an impact on whether providers are able to join a network, how many patients they treat, and whether they can provide wages to attract and retain staff.

⁷⁸ 45 CFR 144.103 states “[p]roduct” means “a discrete package of health insurance coverage benefits that are offered using a particular product network type (such as health maintenance organization, preferred provider organization, exclusive provider organization, point of service, or indemnity) within a service area” and “[p]lan” means, “with respect to a product, the pairing of the health insurance coverage benefits under the product with a particular cost-sharing structure, provider network, and service area.”

Other commenters objected to the requirement to collect and evaluate provider reimbursement data, arguing that reimbursement rates are not equivalent data when comparing between medical/surgical and mental health and substance use disorder benefits because of the nature of mental health and substance use disorder treatment and the associated time and cost. Other commenters objected to the inclusion of billed charges, arguing that these are arbitrary amounts not necessarily tied to any independent standard or benchmark of what is a reasonable charge and that Medicare rates should be used instead.

After review of the comments, the Departments decline to provide a list of all relevant outcomes data required to be collected and evaluated by plans and issuers at this time; however, the Departments intend to issue in future guidance the type, form, and manner of collection and evaluation for the data required and the lists of examples of data that are relevant across the majority of NQTLs,⁷⁹ as well as additional relevant data for NQTLs related to network composition. As part of this guidance, the Departments intend to update the MHPAEA Self-Compliance Tool to provide a robust framework and roadmap for plans and issuers to determine which data to collect and evaluate.

While, as discussed earlier in this preamble, commenters provided various suggestions for relevant outcomes data to be collected and evaluated, many comments also suggested that what data are considered relevant depends on the nature of an NQTL. The Departments agree and intend to issue future guidance to help ensure that the data required to be collected and evaluated under the relevant data evaluation requirements of these final rules provide a meaningful representation of whether a plan or issuer is improperly applying an NQTL under

⁷⁹ As explained later in this preamble, these final rules provide additional provisions on how to comply with the relevant data evaluation requirements for an NQTL newly imposed by a plan or issuer or an NQTL where no data exist that can reasonably assess any relevant impact of the NQTL on access. The provisions of these final rules with respect to these types of NQTLs shall only apply in very limited circumstances.

MHPAEA. In developing this guidance, the Departments intend to take into consideration the feedback received regarding relevant data elements.

Until additional guidance is provided, the Departments expect a plan or issuer with a typical plan or coverage design will collect and evaluate certain data that are likely to be relevant for the majority of NQTLs under the relevant data evaluation requirements. As the relevant data for any given NQTL will depend on the facts and circumstances of the NQTL at issue and the circumstances under which the NQTL was designed and applied, these final rules provide some flexibility for plans and issuers to determine what relevant data should be collected and evaluated, as appropriate.

Under these final rules, relevant data for the majority of NQTLs could include, as appropriate, but are not limited to, the number and percentage of claims denials in a classification of benefits and any other data relevant to the NQTL required by State law or private accreditation standards. However, the Departments note that these final rules do not mandate that plans or issuers use private accreditation standards or evaluate data under State laws to which they are not subject. In addition, relevant data for a typical plan or coverage might include utilization data for mental health and substance use disorder services and medical/surgical services. For NQTLs such as prior authorization, relevant data could include rates of approvals and denials of prior authorization requests, rates of denials of post-service claims, application of penalties for a failure to obtain prior authorization, and turnaround times for prior authorization requests. Such information could be provided for benefits subject to prior authorization in each benefit classification in which the NQTL is imposed on mental health and substance use disorder benefits and medical/surgical benefits. All such examples of relevant data are non-exhaustive and whether any particular type of data is relevant for a plan or coverage is based on each plan's or coverage's unique design.

Relevant data for NQTLs related to network composition standards could include, as appropriate, but are not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions); network adequacy metrics (including time and distance data, and data on providers accepting new patients); and provider reimbursement rates (for comparable services and as benchmarked to a reference standard). The Departments modified this illustrative list of relevant data for NQTLs related to network composition by specifying that provider reimbursement rates should be analyzed for comparable services and as benchmarked to a reference standard, to better ensure that comparisons between access to mental health and substance use disorder benefits and medical/surgical benefits will be informative. Thus, for example, the Departments expect a plan or issuer with a typical plan or coverage design could look at the ratio of inpatient, in-network and outpatient, in-network mental health and substance use disorder and medical/surgical claims, as compared to inpatient, out-of-network and outpatient, out-of-network mental health and substance use disorder and medical/surgical claims. Plans and issuers could also look at the number of providers (or facilities) within specified mental health and substance use disorder and medical/surgical provider categories (or categories of facilities) per 1,000 participants and beneficiaries who have actively submitted claims within the past 6 months, which would reflect the experience of a plan's or issuer's participants and beneficiaries within a recent period of time, controlled for plan or issuer size. Additionally, a plan or issuer could look at the turnaround time for applications to be approved for a provider to join the plan's or issuer's network and the approval and denial rates for applications submitted by mental health and substance use disorder providers as compared to medical/surgical providers. The Departments recognize that providers may differ in education, training, and specialization, and the categories of mental health and substance use disorder and medical/surgical providers for which data is compared should take this into account. Additionally, relevant data could include the percentage of participants and beneficiaries who

can access, within a specified time and distance by county-type designation, one (or more) in-network providers who are available to accept new patients for mental health and substance use disorder and medical/surgical provider categories. Relevant data for NQTLs related to network composition could also include median in-network reimbursement rates for services with the same CPT codes, as well as median in-network reimbursement rates for inpatient mental health and substance use disorder benefits and medical/surgical benefits, as compared to Medicare rates; and median in-network reimbursement rates for outpatient mental health and substance use disorder benefits, and medical/surgical benefits, as compared to Medicare rates.

The Departments have the authority to request data – in addition to what a plan or issuer determines to be relevant data for any particular NQTL and includes in its comparative analyses – to sufficiently analyze the plan’s or issuer’s assertions, pursuant to the applicable enforcement statutes and as permitted by the amendments made by the CAA, 2021 to the Code, ERISA, and the PHS Act.⁸⁰ Similarly, nothing in these final rules would prohibit an applicable State authority from requesting additional data with regard to an issuer’s comparative analysis. Accordingly, plans and issuers may be required to take reasonable action if the additional data requested by the Departments or an applicable State authority reveal material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

The Departments understand that many plans and issuers rely on TPAs and other service providers to administer a group health plan or health insurance coverage and acknowledge that several commenters highlighted the difficulty plans and issuers sometimes face obtaining the necessary information from their service providers to perform and document their comparative analyses. However, other commenters highlighted categories of data that TPAs and other service providers are able to provide for purposes of the relevant data evaluation requirements. Plans and

⁸⁰ See Code section 9812(a)(8)(B)(ii), ERISA sections 504 and 712(a)(8)(B)(ii), and PHS Act sections 2723 and 2726(a)(8)(B)(ii).

issuers remain responsible for compliance with MHPAEA, and for ERISA-covered group health plans, fiduciaries, including TPAs or other service providers who are acting as fiduciaries, must work with plan sponsors and issuers to ensure that the plans and coverage they help establish and administer comply with the law. In the preamble to the proposed rules, the Departments highlighted that, under ERISA, TPAs may be fiduciaries with respect to private sector, employment-based group health plans. To the extent these TPAs are fiduciaries for those plans, they are subject to the provisions governing fiduciary conduct and liability, including the provisions for co-fiduciary liability under ERISA section 405. The Departments also noted their commitment to using all available authority to ensure compliance by plans and issuers with MHPAEA and requested specific comments on how best to ensure all the entities involved in the design and administration of a group health plan's benefits provide the necessary information to plans and issuers to support their efforts to comply with MHPAEA.

Some commenters requested that the Departments require that plan sponsors include MHPAEA compliance provisions in their contracts with TPAs, likening such a requirement to actions taken by HHS to require that covered entities include provisions in their contracts with outside entities related to obligations under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. Others suggested focusing on compliance at the service provider level and working with Congress to obtain the ability to issue civil monetary penalties for violations of MHPAEA.

The Departments decline to make any changes in these final rules to specifically address these issues after consideration of the suggestions contained in the comments. These proposals, including requiring the inclusion of contracting provisions similar to HIPAA "business associate agreements," would go beyond the scope of this rulemaking. However, these types of contract provisions are a best practice that could be helpful to many plans and issuers in complying with

their obligations to perform and document comparative analyses of NQTLs applied to mental health or substance use disorder benefits and medical/surgical benefits.

Additionally, DOL also underscores its commitment to holding fiduciaries of ERISA-covered group health plans liable through existing means and working with all relevant entities, including service providers, to effectuate MHPAEA compliance. DOL remains committed to its current enforcement approach, which prioritizes potential violations that affect not just one plan or coverage, but hundreds or thousands of plans that provide coverage for thousands or millions of individuals. Where NQTL violations are identified in a plan or coverage, DOL generally examines the role that each of the plan's or issuer's service providers have in the design and administration of each NQTL to ascertain whether any of the service providers play a similar role serving other plans or issuers that might have the same violations, and seeks to bring them into compliance. Where necessary, DOL determines who is a fiduciary under ERISA and what additional enforcement actions are necessary. DOL notes that determinations of fiduciary liability are often based on the facts and circumstances specific to individual cases, but to the extent a TPA exercises discretionary authority or discretionary responsibility in the administration of an ERISA-covered health plan, DOL generally considers them to be fiduciaries.⁸¹

The Departments acknowledge both the challenges, cost, and complexity of collecting and evaluating data and the importance of data to measure the impact of an NQTL on access. The Departments also understand the importance of performing and documenting comparative analyses consistent with the statute. Therefore, these final rules provide additional provisions on how to comply with the relevant data evaluation requirements for an NQTL newly imposed by a

⁸¹ ERISA section 3(21)(A). *See, e.g., Mertens v. Hewitt Assocs.*, 508 U.S. 248, 262 (1993) (stating that a fiduciary is defined “not in terms of formal trusteeship, but in functional terms of control and authority over the plan”); *Hamilton v. Allen-Bradley Co., Inc.* 244 F.3d 819, 824 (11th Cir. 2001) (stating a person is a fiduciary “to the extent” that “he has any discretionary authority or discretionary responsibility in the administration of such plan”).

plan or issuer or an NQTL where no data exist that can reasonably assess any relevant impact of the NQTL on access. A rule of construction at 26 CFR 54.9812-1(c)(4)(iii)(A)(3)(iii), 29 CFR 2590.712(c)(4)(iii)(A)(3)(iii), and 45 CFR 146.136(c)(4)(iii)(A)(3)(iii) in these final rules explains that the provisions of these final rules with respect to these types of NQTLs shall only apply in very limited circumstances and, where applicable, shall be construed narrowly, consistent with the fundamental purpose of MHPAEA. The Departments are of the view that relevant data can be collected and evaluated for nearly all NQTLs, and note that, when designing a new NQTL, or making changes to an existing NQTL, plans and issuers must consider what data is relevant and how it will be collected and evaluated.

The Departments recognize that there may be a lag between when an NQTL is newly designed and applied and when relevant data are available if there are no data available initially to assess the NQTL's impact on access to mental health and substance use disorder benefits and medical/surgical benefits. Under these final rules, if a plan or issuer newly imposes an NQTL (including because the plan or coverage itself is newly offered) for which data are initially and temporarily unavailable, and the plan or issuer therefore cannot comply with the relevant data evaluation requirements for the NQTL, a plan or issuer must include in its comparative analysis a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed. Additionally, the plan or issuer must comply with the relevant data evaluation requirements as soon as practicable once relevant data becomes available. These additional provisions are intended to be applicable only in very limited circumstances where a plan or issuer newly imposes an NQTL for which no relevant data is available for a limited time after it is first imposed, and will not be available for a new NQTL where data is available but not evaluated due to lack of collection. The Departments note that a change in an NQTL's design or application is generally not considered a new NQTL for which there is no data initially available.

In the very limited situations where a data lag exists for a new NQTL, the Departments expect a plan or issuer to comply with the relevant data evaluation requirements and include data in its comparative analyses within a limited amount of time (as soon as practicable, but no later than the end of the second plan year that follows the imposition of a new NQTL).

These final rules also acknowledge that some limited circumstances may exist in which no data exists that can reasonably assess any relevant impact of an NQTL on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Such NQTLs might include, in certain circumstances, for example, some exclusions based on whether a treatment is experimental or investigative. As commenters have highlighted, these NQTLs are not generally attached to claims, so plans and issuers may not have reliable data on the impact of these excluded services with respect to participants and beneficiaries. In the limited circumstances where no relevant data exist relating to an NQTL, these final rules require the plan or issuer to include in its comparative analysis a reasoned justification as to the basis for its conclusion that there are no data that can reasonably assess the NQTL's impact, why the nature of the NQTL prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure that the NQTL complies with MHPAEA. A plan or issuer also must comply with the relevant data evaluation requirements as soon as practicable if the plan or issuer becomes aware (or reasonably should become aware) of data that can reasonably assess any relevant impact of the NQTL.

The Departments also note that the unavailability of data for purposes of the relevant data evaluation requirements of these final rules does not affect the plan's or issuer's obligation to comply with the design and application requirements.

Material Differences in Access

Under the proposed rules, to the extent the relevant data evaluated show material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, the differences would be considered a strong indicator that the plan or issuer has violated the proposed no more restrictive requirements or the design and application requirements. In such instances, the proposed rules would require plans and issuers to take reasonable action to address the material differences in access as necessary to ensure compliance, in operation, with the proposed no more restrictive requirement and design and application requirements, and document the action that has been or is being taken by the plan or issuer to address any material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits. The Departments stated in the preamble to the proposed rules that material differences alone would not automatically result in a finding of noncompliance, except where related to network composition, as discussed in more detail later in this preamble.

Some commenters supported the proposal that material differences in access would constitute a strong indicator of noncompliance, stating that such approach is a reasonable method to identify potential instances of noncompliance while allowing for instances where disparities in access are due to factors beyond the plan's or issuer's control. Several commenters opposed the proposal that material differences would constitute a strong indicator of noncompliance, stating that this would be inconsistent with the Departments' previous statements in the 2020 MHPAEA Self-Compliance Tool that negative outcomes data is a red flag, but not determinative of compliance. One commenter stressed that it was important to provide clarity on how the Departments would impose this standard.

Several commenters requested that the Departments define the term "material differences," and many commenters provided suggested meanings for the term. A number of

commenters requested that the term be defined as a serious or significant variation, or one that would have a major effect on access to care. One commenter suggested that the definition of material differences should set a high standard to identify clear outliers and major differences in access rather than moderate variations. Some commenters stated that any definition of material differences in access should be based only on statistical significance. One commenter suggested a 10-percent difference as the definition of a material difference. Other commenters requested that the Departments adopt a “de minimis” standard, rather than a material differences in access standard. Additionally, some commenters suggested that material differences in access should mean that a substantial number of members could not access mental health and substance use disorder benefits. Several other commenters suggested that material differences be defined to allow an acceptable level of difference in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, accounting for participant behavior as a driver of accessibility, with consideration of data credibility and the amount of available data. Another commenter highlighted that relevant factors should include the size of the data pool, variability over time, availability of complementary measures, and the degree of control.

Some commenters suggested that differences in data outcomes might result from a wide variety of reasons that do not indicate noncompliance, including random variability, provider or member behavior, changes to unrelated Federal or State laws, or other factors that are outside of the plan’s or issuer’s control. One commenter requested that plans and issuers be permitted to take into account relevant context (for example, there are many more drugs that are considered medical/surgical benefits than mental health and substance use disorder benefits, so the percentage of mental health and substance use disorder drugs to which NQTLs apply may be higher).

The Departments are finalizing language specifying that, to the extent the relevant data evaluated suggest that the NQTL contributes to material differences in access to mental health

and substance use disorder benefits as compared to medical/surgical benefits in a classification, such differences will be considered a strong indicator that the plan or issuer is in violation of MHPAEA. The material differences standard reflects an interpretation of the statutory terms “substantially all” and “predominant” in a manner that takes into account the multifaceted nature of NQTLs, as well as the complexity of analyzing such NQTLs. The material differences standard is intended to set forth a principle-based approach to determining whether relevant data suggest that an NQTL applied to mental health or substance use disorder benefits is more restrictive than the predominant NQTL applied to substantially all medical/surgical benefits in a classification. The standard also allows plans and issuers, when applying an outcomes-based analysis, the flexibility to assess comparability in a way that can be tailored to a variety of different types of NQTLs, and to account for outliers or claims experience that may not be reflective of a difference in access resulting from the NQTL itself.

The Departments emphasize that the material differences standard works together with the other requirements contained in these final rules. A plan or issuer cannot determine whether an NQTL applied to mental health or substance use disorder benefits is more restrictive than the predominant NQTL applied to substantially all medical/surgical benefits without evaluating the effect of imposing the NQTL on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Additionally, when the plan or issuer knows or should know that one or more of its NQTLs is contributing to material differences in access, it cannot simply disregard or avoid ascertaining that information, and continue its current practices, but instead must act consistent with its obligation to ensure that NQTLs applied to mental health and substance use disorder benefits generally are no more restrictive than those applied to medical/surgical benefits.

While the preamble to the 2013 final regulations stated that “[d]isparate results alone do not mean that the NQTLs in use do not comply with these requirements,”⁸² the Departments have consistently stressed in subregulatory guidance that disparate results are a red flag or a warning sign of noncompliance, including in the 2020 MHPAEA Self-Compliance Tool, which states that “. . . while outcomes are not determinative of a MHPAEA violation, they can often serve as red flags or warning signs to alert the plan or issuer that a particular provision may warrant further review.”⁸³ The experience of the Departments in enforcing MHPAEA, moreover, has shown that plans and issuers are commonly unprepared to explain material differences in outcomes data, and in some cases, have mistakenly considered the 2013 final regulations as granting freedom to ignore potentially problematic or significant differences, even where such differences appear to have a direct causal link to the plan’s practices and limitations.

These final rules, as discussed later in this preamble, make clear that plans and issuers must consider whether such material differences exist, and whether the differences are attributable to the NQTL. In instances where the relevant data suggest that the NQTL contributes to material differences, these final rules require plans and issuers to take reasonable action, as necessary, to address the material differences and to document that such action has or will be taken to ensure compliance, in operation, with the requirements for NQTLs under these final rules.

This increased emphasis on outcomes data and the material differences standard will help ensure that more restrictive NQTLs are not imposed on mental health and substance use disorder benefits as compared to the predominant NQTLs applied to substantially all medical/surgical

⁸² 78 FR 68240, 68245 (Nov. 13, 2013).

⁸³ Final FAQs About Mental Health and Substance Use Disorder Parity Implementation and the 21st Century Cures Act Part 39, Q 7 (Sept. 5, 2019), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-39-final.pdf> and <https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-final-set-39> (FAQs Part 39); EBSA, Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA) (2020), pg. 27, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf>.

benefits in the same classification by identifying when an NQTL results in differences in access that are likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits. This standard generally would not include a de minimis difference in access or a difference driven by an outlier, such as a single plan participant's claims experience or a single claim. The Departments also note that the existence of material differences in access do not automatically result in a finding of noncompliance, and that plans and issuers will continue to have the opportunity provide additional information as part of the NQTL comparative analysis process, as well as to respond to the Departments in any enforcement actions, by submitting additional data, the sources of the data, explanatory material, related documents, evidence of reasonable actions that have been or are being taken by the plan or issuer to address such differences, and other material and information to demonstrate compliance with MHPAEA.

The Departments acknowledge comments from plans and issuers asking for guidance on how to determine whether a difference is material for purposes of the relevant data evaluation requirements, as well as those asking for a principle-based approach rather than specific thresholds for each outcome measure, because what is material will likely vary by NQTL, market, plan, and benefit classification for each item or service, as well as the number of participants and beneficiaries affected. In these final rules, the Departments set forth a standard that takes into account the range of commenters' suggestions and incorporates them into a single standard, while helping to ensure that participants' and beneficiaries' access to mental health and substance use disorder benefits is in parity with their access to medical/surgical benefits.

Specifically, under these final rules, relevant data are considered to suggest that the NQTL contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all relevant facts and

circumstances, and taking into account specific considerations,⁸⁴ the difference in the data suggests that the NQTL is likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits. For this purpose, these final rules specify that relevant facts and circumstances may include, but are not limited to, the terms of the NQTL at issue, the quality or limitations of the data, causal explanations and analyses, evidence as to the recurring or non-recurring nature of the results, and the magnitude of any disparities. The Departments note that plans and issuers may consider other relevant facts and circumstances that are not specifically listed in these final rules, as appropriate, and that differences in access to mental health or substance use disorder benefits attributable to independent professional medical or clinical standards or fraud and abuse measures are not considered to be material, as discussed later in this preamble.

The Departments are of the view that the quality or limitations of the relevant data are a key consideration in determining whether a difference in the data suggests that an NQTL contributes to a material difference in access to mental health and substance use disorder benefits as compared to medical/surgical benefits. As discussed earlier in this preamble, the Departments acknowledge the difficulty some plans and issuers may face in obtaining the necessary information, including data, from their service providers to perform and document their comparative analyses. The Departments are also aware that plans and issuers might not have direct control over the quality of the data they receive from a service provider. Despite this, the Departments do not intend for this consideration to create a loophole that allows plans and issuers to avoid determining materiality when evaluating differences in relevant data. Rather, the

⁸⁴ The considerations outlined in these final rules refer to differences in access to mental health or substance use disorder benefits attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits. See 26 CFR 54.9812-1(c)(4)(iii)(B)(2)(ii), 29 CFR 2590.712(c)(4)(iii)(B)(2)(ii), and 45 CFR 146.136(c)(4)(iii)(B)(2)(ii). Differences solely attributable to such standards or measures are not treated as material differences for purposes of these final rules.

Departments expect plans and issuers to consider the quality and limitations of any available relevant data as just one of multiple potential facts and circumstances when assessing the impact of an NQTL on access to mental health and substance use disorder benefits and medical/surgical benefits.

When considering causal explanations and analyses in determining whether a difference in the data suggests that an NQTL contributes to a material difference in access, plans and issuers should consider whether they are attributable to the NQTL, instead of being attributable to other factors or considerations. As discussed in more detail later in this preamble, a plan's or issuer's comparative analysis for an NQTL applicable to mental health and substance use disorder benefits and medical/surgical benefits must include a discussion of the actions that have been or are being taken by the plan or issuer to address any material differences in access. This discussion must include, as applicable, a reasoned explanation of any considerations beyond a plan's or issuer's control that contribute to the existence of material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, including those that result in the persistence of such material differences despite reasonable actions that have been or are being taken to address such differences by the plan or issuer.

For example, if a plan or issuer identifies, based on reliably established indicia of fraud and abuse, that a particular provider or facility has submitted fraudulent claims for mental health or substance use disorder benefits, resulting in a higher percentage of denials of claims for mental health or substance use disorder benefits than for medical/surgical benefits in the same classification, the evidence of fraud and abuse could be considered part of the relevant facts and circumstances for purposes of determining whether a material difference in access exists. Further, if a material difference in access exists, the evidence of fraud and abuse could also be considered part of the relevant facts and circumstances for purposes of determining whether the difference is attributable to the NQTL. In such a case, the plan or issuer might reasonably

conclude that the difference in outcomes is attributable to higher underlying levels of fraud for mental health and substance use disorder benefits than for medical/surgical benefits in the same classification (with the commission of the fraud being a circumstance that is beyond the plan's or issuer's control), rather than the application of a more restrictive NQTL to mental health or substance use disorder benefits. As explained later in this preamble, under these final rules, the plan or issuer must include in its comparative analysis a reasoned explanation of the reliably established indicia of fraud and abuse beyond the plan's or issuer's control that contribute to the existence of material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits.

The Departments note that a difference in access to mental health or substance use disorder benefits as compared to medical/surgical benefits that is driven by an outlier, such as a single plan participant's claims experience or a single claim, will generally not be considered material for this purpose because the nature of the results of the evaluation of relevant data would not be considered recurring. Therefore, such a difference would not trigger the requirement to take reasonable action, as necessary, under these final rules.

In the preamble to the proposed rules, the Departments solicited comments on whether materiality should be defined in terms of the results of statistical testing and requested feedback from interested parties on the optimal method for assembling data and statistical analysis. As highlighted earlier in this preamble, commenters requested that the definition of material differences account for statistically significant differences, and take into account the amount of available data, while also excluding differences related to random variability. The Departments are of the view that plans and issuers can explain in their comparative analyses whether differences are or are not statistically significant and why, based on the relevant facts and circumstances, such differences are determined to be or not to be material. However, the Departments also recognize that statistical significance might not always be appropriate to

consider, and that there would be challenges with requiring plans and issuers to use a statistical analysis in determining whether material differences in access exist for all NQTLs, as well as whether and how those differences are attributable to the NQTL or NQTLs in question.⁸⁵

Plans and issuers should carefully consider the magnitude of any negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits and whether the relevant data therefore suggest an NQTL contributes to a material difference in access that might require the plan or issuer to take reasonable action, as necessary, to ensure compliance, in operation, with the requirements for NQTLs under these final rules. As noted earlier in this preamble, a difference in access to mental health or substance use disorder benefits as compared to medical/surgical benefits that is de minimis will not be considered material for purposes of the relevant data evaluation requirements. The size of any negative impact on access, even if small, is part of the relevant facts and circumstances that could determine whether a disparity in access is material. These final rules do not require a plan or issuer to obtain a statistical, actuarial, or other equivalent opinion to support a conclusion as to whether a difference in access demonstrated by relevant data is material, based on the relevant facts and circumstances. However, a plan or issuer may obtain such an opinion, and if relying on it as part of performing its comparative analysis, the plan or issuer should document the relevance of that opinion to the conclusion that a difference in data suggests or does not suggest material difference in access, as part of the comparative analysis. For plans and issuers that do use such an opinion to support a conclusion as to the materiality of differences in access, the Departments would expect these opinions or determinations to be made by a qualified and, if applicable, licensed or otherwise accredited individual or organization. Additionally, the

⁸⁵ The Departments also recognize that smaller plans may have limited relevant data to evaluate, which could result in the plan not having sufficient data to identify statistically significant differences in the data. The Departments note that, because these final rules do not require that a difference be statistically significant to constitute a material difference, small sample size does not amount to circumstances under which the provisions in 26 CFR 54.9812-1(c)(4)(iii)(A)(3), 29 CFR 2590.712(c)(4)(iii)(A)(3), and 45 CFR 146.136(c)(4)(iii)(A)(3) would apply.

individual's or organization's qualifications must be documented as part of the comparative analysis, along with a description of the extent to which the plan or issuer ultimately relied upon the individual's or organization's evaluation in performing and documenting the comparative analysis of the design and application of the NQTL, as discussed in more detail later in this preamble. The Departments note that a statistical, actuarial, or other equivalent opinion obtained by a plan or issuer to support a conclusion as to whether a difference in access based on relevant data is or is not material is not dispositive simply because it is made by a qualified, licensed or otherwise accredited individual or organization. In the course of enforcement, the Departments and applicable State authorities may review and assess the validity of the assertions, and the factors upon which such assertions are based, contained in such an opinion, as well as a plan's or issuer's determination as to whether any particular difference in access to mental health or substance use disorder benefits as compared to medical/surgical benefits is or is not material.

In these final rules, the Departments decline to finalize the proposed exception to the relevant data evaluation requirements for independent professional medical or clinical standards, as discussed later in this preamble. The Departments are of the view that plans and issuers that impose NQTLs that utilize such standards as the basis for, or as, factors or evidentiary standards, should collect and evaluate relevant data, to determine the impact of NQTLs developed or applied using these standards on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. However, reliance on such standards can improve care and health outcomes for participants and beneficiaries. The Departments also recognize that clinical differences between mental health conditions, substance use disorders, medical conditions, and surgical procedures may sometimes drive apparent differences in data outcomes, even where plans and issuers rely on independent professional medical or clinical standards. Therefore, under these final rules, differences in access to mental health or substance use disorder benefits attributable to generally recognized independent professional medical or

clinical standards that are used as the basis for a factor or evidentiary standard used to design or apply an NQTL are not considered to be material. To the extent a plan or issuer attributes any differences in access to the application of such standards, the plan or issuer must explain its bases for that conclusion in the plan's or issuer's comparative analysis, as discussed later in this preamble.

The Departments did not propose that NQTLs related to fraud, waste, and abuse measures would be excepted from the relevant data evaluation requirements. However, as discussed earlier in this preamble, reliably established indicia of fraud and abuse could, if appropriate, be considered relevant facts and circumstances taken into account by a plan or issuer when determining whether a difference in access is material. Indicia of fraud and abuse could also be relevant in determining whether a material difference in access is attributable to an NQTL or, instead, is attributable to the use of fraud and abuse measures. Therefore, under these final rules, a difference in access to mental health or substance use disorder benefits attributable to carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits are not considered to be material. As discussed later in this preamble, in such a case, a plan's or issuer's comparative analysis must provide a thorough and reasoned explanation that indicia for fraud and abuse have been reliably established through objective and unbiased data, and that such measures are narrowly designed to minimize the negative impact on access to appropriate mental health and substance use disorder benefits as compared to medical/surgical benefits in the same classification.

Reasonable Action, As Necessary, to Address Material Differences in Access

The proposed rules provided that a plan or issuer would be required to take reasonable action to address any material differences in access as necessary to ensure compliance, in operation, with the proposed no more restrictive requirement and design and application

requirements. The preamble to the proposed rules noted that whether any particular action would be considered reasonable in response to any material differences in access resulting from an evaluation of outcomes data would be determined based on the relevant facts and circumstances, including the NQTL itself, the relevant data, the extent of the material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, and the impact of the material differences in access on participants and beneficiaries. The Departments proposed that, in addition to taking reasonable action to address material differences, a plan or issuer would also be required to document in its comparative analyses any such action that has been or is being taken by the plan or issuer to mitigate any material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits. The Departments noted in the preamble to the proposed rules that plans and issuers could use this documentation to explain why material differences demonstrated by the relevant outcomes data should not be considered a violation of the rules for NQTLs (other than NQTLs related to network composition) and solicited comments on what additional information is necessary to clarify what would constitute reasonable action in response to relevant data that reveal material differences in access.

Several commenters supported the requirement to take reasonable action in response to relevant data that reveals material differences in access. Some commenters suggested that “reasonable action” should be defined and should mean actions, including, but not limited to, internal reforms and modifications or elimination of the NQTL to resolve the material differences. One commenter stated that requiring reasonable action where there is no violation of the law and without an opportunity to explain why material differences in access may not in fact be a violation of MHPAEA is arbitrary and capricious and goes beyond the authority of the Departments. Therefore, the commenter noted reasonable action should be required only after an opportunity to rebut a presumption of noncompliance.

Under these final rules, when a plan or issuer knows or reasonably should know that NQTLs may be contributing to material differences in access, it must take reasonable action, as necessary, to ensure compliance, in operation, with the requirements for NQTLs under these final rules. The standard is not focused on inconsequential differences, but rather only on those that are material, meaning those that are likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits. If a plan or issuer is aware of information that suggests a potential violation of MHPAEA, the statute requires the plan or issuer to address such potential violations as necessary to satisfy its obligation to ensure that the NQTLs comply with the substantive requirements of the statute,⁸⁶ and to be able to continue to impose the NQTL. The requirement to take reasonable action, as necessary, where material differences in access exist is consistent with the statutory requirement that plans and issuers ensure that treatment limitations (including NQTLs) applicable to mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical/surgical benefits. If the relevant data suggest that an NQTL contributes to material differences in access, a plan or issuer generally is not able to ensure compliance with MHPAEA, in operation, unless the plan or issuer takes action that is reasonably designed to try to close the gap and address those differences.

The proposed rules would have required plans and issuers to take reasonable action to address material differences in access as necessary to ensure compliance, in operation, with the proposed no more restrictive requirement and design and application requirements. However, as discussed earlier in this preamble, these final rules do not retain the proposed mathematical substantially all and predominant tests and instead retain language that incorporates the statutory requirements of Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A), as the general rule for NQTLs. Therefore, these final rules make technical

⁸⁶ Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A).

changes to replace the cross-references in the material differences standard to the proposed no more restrictive requirement and design and application requirements, and replace them with a cross-reference to the general rule for NQTLs.

The Departments acknowledge commenters' requests for guidance on what constitutes reasonable action for this purpose. The Departments anticipate that, in many cases, the reasonable actions that plans and issuers might take, as necessary, to address material differences in access will be similar to actions they might have taken independent of the requirements contained in these final rules. For example, some plans and issuers may already take certain action in response to changes in demand for services, needs of patients, or requests from plan sponsors, which could be considered reasonable action for this purpose, depending on the relevant facts and circumstances. Commenters highlighted that, since the enactment of MHPAEA, plans and issuers have increased spending and raised reimbursement rates for mental health and substance use disorder services, and invested in programs to help members identify mental health and substance use disorder care needs and to connect them to the appropriate services as early as possible. Commenters also highlighted that plans and issuers have also developed mental health assessment screening tools for youth populations to detect those at risk. Depending on the facts and circumstances, all of these actions could be examples of reasonable actions that plans and issuers can take, as necessary, where the relevant data suggest that an NQTL contributes to material differences, as required under these final rules. However, plans and issuers will ultimately be responsible for assessing the nature of a material difference in access to determine what reasonable action should be taken, as necessary, to address those differences.

In addition, a plan or issuer must document the actions that have been or are being taken in the plan's or issuer's comparative analysis and include a reasoned explanation of any material differences in access that persist despite reasonable actions that have been or are being taken. For

a plan or issuer designing and applying one or more NQTLs related to network composition standards, the comparative analysis must include a discussion of the actions that have been or are being taken to address material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits.

Special Rule for NQTLs Related to Network Composition

In the preamble to the proposed rules, the Departments noted a growing disparity between in-network reimbursement rates for mental health and substance use disorder providers and medical/surgical providers, as well a significant disparity between how often participants and beneficiaries have little or no choice under their plan or coverage but to utilize out-of-network mental health and substance use disorder providers and facilities, as compared to medical/surgical providers and facilities. The Departments also expressed their specific concerns about standards related to network composition and other related NQTLs, because these standards are critical to ensuring parity in access to mental health and substance use disorder benefits for participants and beneficiaries. Therefore, the Departments included in the proposed rules a requirement that, in addition to the relevant data required for all NQTLs, plans and issuers would also be required to collect and evaluate relevant data for NQTLs related to network composition. For this purpose, the proposed rules stated that network composition NQTLs include, but are not limited to, standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates; credentialing standards; and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan or coverage. Under the proposed special rule, when designing and applying one or more NQTLs related to network composition standards, a plan or issuer would fail to meet the requirements of the proposed no more restrictive requirement and design and application requirements, in operation, if the relevant data show material differences in access to in-network mental health or

substance use disorder benefits as compared to in-network medical/surgical benefits in a classification. This standard proposed to set a higher bar for NQTLs related to network composition than for other NQTLs by treating material differences in access to in-network mental health or substance use disorder benefits as compared to in-network medical/surgical benefits as a failure to meet the requirements of MHPAEA, instead of as a strong indicator of a violation of MHPAEA.

The Departments proposed that plans and issuers be required to take action to address material differences in access for NQTLs related to network composition or no longer impose the relevant NQTLs to avoid a violation of MHPAEA. Examples of such actions listed by the Departments in the preamble to the proposed rules for NQTLs related to network composition include ensuring that plans and issuers or their service providers (as applicable) make special efforts to contract with a broad range of mental health and substance use disorder providers who are available, including authorizing greater compensation or other inducements to the extent necessary; expanding telehealth arrangements as appropriate to manage regional shortages; notifying participants and beneficiaries in clear and prominent language on the plan's or issuer's website, employee brochures, and the summary plan description of a toll-free number for help finding in-network providers; ensuring that the plan's or issuer's service providers (as applicable) reach out to the treating professionals and facilities to see if they will enroll in the network; and ensuring the network directories are accurate and reliable. The Departments also recognized that shortages of mental health and substance use disorder providers could pose challenges to issuers, plans, and their service providers. The preamble to the proposed rules noted that, if, despite taking appropriate action, relevant data collected and evaluated for NQTLs related to network composition continue to reveal material differences due to, for example, provider shortages that the plan or issuer cannot effectively address through no fault of its own, the Departments would not cite such a plan or issuer for failure to comply with the proposed

relevant data evaluation requirements with respect to NQTLs related to network composition if the plan or issuer otherwise complied with other applicable MHPAEA requirements. However, the Departments noted that plans and issuers should be prepared to document the actions they have taken and to demonstrate why any disparities are attributable to provider shortages in the geographic area, rather than their NQTLs related to network composition.

Several commenters supported the special rule for NQTLs related to network composition, stating that it would address significant barriers to accessing mental health and substance use disorder services, and requested that the heightened requirement for such NQTLs be maintained in the final rules. Some commenters questioned the justification for treating standards for network composition differently than all other NQTLs. Several commenters stated that the Departments misrepresented several of the key studies they relied on to support the proposed special rule. Some commenters highlighted that analyzing outcomes data related to network composition is a long-recognized and widely accepted tool in population health management but stated that the proposed rules would turn this tool into a compliance standard that would be virtually impossible to satisfy. One commenter highlighted that MHPAEA requires equity in treatment, not equity in outcomes, and that the special rule would go beyond what is required by statute, as well as the Departments' own admission that parity across mental health and substance use disorder and medical/surgical networks does not necessarily mean an equal number of providers in a classification. Another commenter stressed that the special rule was inappropriate without clarity about what the definition of a material difference would be. This commenter stated that the Departments should finalize, following additional public comment, an NQTL definition, a specific set of measures with technical specifications, and a benchmark for what they will consider to be "material difference" for each NQTL type. Other commenters suggested that the Departments not finalize this proposed provision.

Some commenters noted that there can be many reasons why outcomes might be different for mental health and substance use disorder benefits than medical/surgical benefits when evaluating relevant data, particularly with respect to network composition. Some of these commenters highlighted reasons that are outside the control of plans and issuers, such as shortages of mental health and substance use disorder providers or specialists. Some commenters requested that the final rules address situations where material differences in access are due to a lack of mental health and substance use disorder providers, while other commenters stated that general citations to provider shortages as the only cause of material differences in access should be rejected as inadequate, especially without evidence that those shortages drove disparities, rather than plan or issuer choices. One commenter argued that plans and issuers should have the opportunity to address any apparent gaps in network access and explain long-term initiatives to address those gaps.

Several commenters expressed concern that the special rule as proposed would have adverse consequences for patient outcomes and safety because it would encourage plans and issuers to accept lower quality providers into their networks. One commenter noted that behavioral health care is commonly provided by primary care providers, and without including those providers in relevant data, a significant percentage of mental health treatment would not be captured when determining whether material differences in access exist. Other commenters expressed the importance of taking into account telehealth providers when analyzing relevant data for purposes of NQTLs related to network composition.

The Departments acknowledge the concerns raised by commenters on this aspect of the proposed rules; namely, the fact that a variety of metrics could be consulted as a plan or issuer evaluates its parity compliance regarding NQTLs related to network composition, and that parity for mental health and substance use disorder benefits as compared to medical/surgical benefits does not necessarily mean an equal number of mental health or substance use disorder and

medical/surgical network providers. The Departments also understand the value of a consistent approach with regard to all NQTLs, while recognizing the impact of NQTLs related to network composition on access to care. Additionally, the Departments acknowledge the questions some commenters raised requesting more specific details on how to account for material differences in access for network composition NQTLs, including those due to provider shortages, which plans and issuers may not be able to effectively address through no fault of their own despite taking reasonable action. The Departments also note that certain outcomes measures, such as high out-of-network utilization for mental health or substance use disorder benefits as compared to medical/surgical benefits, may not necessarily represent a per se violation of MHPAEA.

The Departments agree with commenters that it is important to allow plans and issuers to address apparent gaps in relevant data, and that it is also important that the regulatory standard for NQTLs related to network composition is one that plans and issuers are able to satisfy. However, as stated in the preamble to the proposed rules, the Departments also recognize that network composition and access to mental health and substance use disorder benefits are the product of myriad NQTLs; processes, strategies, evidentiary standards, and other factors used to design and apply NQTLs; and information, evidence, sources, and standards on which factors and evidentiary standards are based. As a result, the Departments remain concerned that plans and issuers could too readily evade their obligations under MHPAEA, if they were not obligated to diligently collect and evaluate relevant data, perform a careful analysis to determine whether material differences in access to mental health and substance use disorder benefits exist as a result of the cumulative impact of NQTLs related to network composition, and take reasonable actions that meaningfully address such differences in access.

After consideration of the comments, the Departments are not finalizing the proposed special rule for NQTLs related to network composition, and are instead including language in these final rules to explain how plans and issuers are expected to comply with the relevant data

evaluation requirements with respect to those NQTLs. Specifically, these final rules require that a plan or issuer must collect and evaluate data in a manner reasonably designed to assess the aggregate impact of all such NQTLs on access to mental health and substance use disorder benefits and medical/surgical benefits, instead of evaluating relevant data for each NQTL separately (which is generally required under these final rules for NQTLs other than those related to network composition), to determine if there is a material difference in access. Furthermore, the final rules provide examples of possible actions that a plan or issuer could take to comply with the requirement to take reasonable action, as necessary, to address any material differences in access with respect to network composition NQTLs. While under these final rules, material differences in access related to network composition NQTLs are not automatically treated as a violation of MHPAEA (and instead are treated as a strong indicator of a violation, the same as all other NQTLs), the Departments emphasize that plans and issuers must engage in, and document in their comparative analyses, all reasonable actions, as necessary, to address any material differences in access.

While the approach to material differences for NQTLs related to network composition is different than that set forth in the proposed rules, these final rules will achieve the same goal of ensuring access to mental health and substance use disorder benefits in parity with access to medical/surgical benefits, by requiring plans and issuers to take reasonable action, as necessary, to address material differences in access for in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits. Furthermore, the approach for NQTLs related to network composition in these final rules will ensure that participants and beneficiaries are not subject to NQTLs with respect to mental health and substance use disorder benefits that are more restrictive than the predominant NQTLs applied to substantially all medical/surgical benefits under the plan or coverage.

The Departments stress the importance of the requirement under these final rules that plans and issuers take reasonable action, as necessary, where relevant data suggest that NQTLs related to network composition contribute to a material difference in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits in a classification, to ensure compliance with MHPAEA. These final rules provide an illustrative list of possible actions the Departments expect plans and issuers, working with their service providers, to take, as necessary, to address any material differences in access with respect to NQTLs related to network composition under the relevant data evaluation requirements. This includes plans and issuers working with their service providers, as applicable, to strengthen efforts to recruit and encourage a broad range of available mental health and substance use disorder providers and facilities to join the plan's or issuer's network of providers, including taking actions to increase compensation or other inducements, streamline credentialing processes, or contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network, and expand the availability of telehealth arrangements to mitigate overall mental health and substance use disorder provider shortages in a geographic area. Additionally, plans and issuers should provide additional outreach and assistance to participants and beneficiaries enrolled in the plan or coverage to assist them in finding available in-network mental health and substance use disorder providers and facilities, and ensure that provider directories are accurate and reliable (including in accordance with Code section 9820(a), ERISA section 720(a), PHS Act section 2799A-5(a), and future implementing regulations and guidance). The Departments also expect plans and issuers to take other reasonable actions, as necessary, that are intended to mitigate any material differences (even if not enumerated in these final rules).

As with other types of NQTLs, these final rules require plans and issuers to explain in their comparative analyses for NQTLs related to network composition the circumstances of any

material differences in access and the actions that have been or are being taken to address these differences. If such actions do not fully resolve the material differences, a plan or issuer must provide a reasoned explanation in its comparative analysis of any material differences that persist despite reasonable actions that have been or are being taken. The Departments stress that a comparative analysis making only a cursory reference to provider shortages with little or no explanation of reasonable actions taken to address material differences in access will likely result in a finding by the relevant Secretary that the comparative analysis is insufficient and, without additional comparative analyses in response to an insufficiency notice or initial determination of noncompliance from the Secretary, may result in a final determination of noncompliance. As noted elsewhere in this preamble, the Departments expect that, if a plan or issuer intends to rely on an explanation of existing circumstances that cannot effectively be addressed through reasonable action, the explanation should include significant detail as to the circumstances resulting in material differences in access that are outside the plan's or issuer's control, and a robust discussion of the reasonable actions the plan or issuer has taken or is taking in an attempt to address such material differences.

Exception for Independent Professional Medical or Clinical Standards

The proposed rules specified a narrow exception under which plans and issuers would not be required to comply with the relevant data evaluation requirements for NQTLs that impartially apply independent professional medical or clinical standards.⁸⁷ As discussed in the following section of the preamble to these final rules, the Departments are not finalizing this proposed exception.

⁸⁷ The proposed rules did not include a similar exception from the relevant data evaluation requirements for standards related to fraud, waste, and abuse.

e. Independent Professional Medical or Clinical Standards and Fraud and Abuse Measures

In the preamble to the proposed rules, the Departments acknowledged that the application of independent professional medical or clinical standards and fraud, waste, and abuse measures generally improve and help to ensure appropriate care for participants and beneficiaries, rather than restrict access to needed benefits. The Departments stated that NQTLs that reflect independent professional medical or clinical standards or guard against fraud, waste, and abuse (while minimizing the negative impact on access to appropriate benefits) are premised on standards that generally provide an independent and less suspect basis for determining access to mental health and substance use disorder treatment. Accordingly, the Departments proposed two narrow exceptions; one for NQTLs that impartially apply independent professional medical or clinical standards, and one for NQTLs reasonably designed to detect or prevent and prove fraud, waste, and abuse. Under those proposed exceptions, an NQTL that, with respect to mental health or substance use disorder benefits in any classification, impartially applies independent professional medical or clinical standards (consistent with generally accepted standards of care) would not be considered under the proposed rules to violate the proposed no more restrictive requirements, the prohibition on discriminatory factors and evidentiary standards, and the relevant data evaluation requirements. An NQTL that applies fraud, waste, and abuse measures would not be considered under the proposed rules to violate the proposed no more restrictive requirements or the prohibition on discriminatory factors and evidentiary standards.

The Departments noted in the preamble to the proposed rules that they do not intend to interfere with a plan's or issuer's ability to ensure that coverage for benefits for the treatment of mental health conditions and substance use disorders is consistent with independent professional medical or clinical standards or fraud, waste, and abuse measures. The Departments also recognized that there are instances in which the application of independent professional medical

or clinical standards or fraud, waste, and abuse measures might result in differences in the design or application of NQTLs to mental health or substance use disorder benefits as compared to medical/surgical benefits due to clinical differences between mental health conditions and substance use disorders and medical/surgical conditions, as well as differences in the model of care, in a manner that could otherwise violate certain aspects of the requirements for NQTLs in the proposed rules.

Several commenters opposed the proposed exceptions because they stated that plans and issuers would exploit them to improperly limit access to mental health and substance use disorder services. Some of these commenters stated that the Departments lack authority or a legal basis to implement the proposed exceptions because, in their view, the statute does not provide authority to establish exceptions to MHPAEA's requirements. Commenters also stated that the proposed exceptions could significantly undermine the other provisions of the proposed rules that would otherwise strengthen MHPAEA protections by creating opportunities for misuse or exploitation. Conversely, some commenters generally supported the proposed exceptions, but highlighted ambiguities related to how the exceptions would operate under the proposed rules to allow NQTLs to be applied with respect to mental health and substance use disorder benefits. These commenters also stated that the exceptions may be too narrow as proposed and that it is unclear how and what a plan or issuer must demonstrate to confidently rely on the proposed exceptions.

The Departments acknowledge these comments, as well as the comments received on each of the two proposed exceptions, which are addressed in more detail in this section of the preamble. After considering the comments, and for the reasons discussed later in this preamble, the Departments are not finalizing the proposed exceptions for independent professional medical or clinical standards or fraud, waste, and abuse measures, but explain how plans and issuers can

account for such standards and fraud and abuse measures in implementing the provisions of these final rules.

Exception for Independent Professional Medical or Clinical Standards

To qualify for the exception for independent professional medical or clinical standards under the proposed rules, an NQTL would have to impartially apply those standards (consistent with generally accepted standards of care) to medical/surgical benefits and mental health or substance use disorder benefits. The NQTL could not deviate from those standards in any way, such as by modifying or otherwise imposing additional or different requirements. Under the proposed rules, an NQTL qualifying for this exception would not be required to satisfy the proposed no more restrictive requirement or the proposed relevant data evaluation requirements. In addition, the independent professional medical or clinical standards would not be considered a discriminatory factor or evidentiary standard. The Departments noted that, under the proposed rules, the plan or issuer would still be required to ensure that such an NQTL complies with the rest of the design and application requirements. Additionally, the plan or issuer would be required to perform and document comparative analyses for NQTLs that impartially apply independent professional medical or clinical standards.

Some commenters stated that the exception for NQTLs that impartially apply independent professional medical or clinical standards should not be finalized, because the Departments rejected a similar exception in previous rulemaking. Specifically, these commenters highlighted that the Departments included an exception to the NQTL requirements for “recognized clinically appropriate standards of care” in the 2010 MHPAEA interim final regulations, which was later deleted in the 2013 final regulations. The preamble to the 2013 final regulations supported the decision to eliminate the exception by pointing to commenters’ concern about abuse and the use of this exception by plans and issuers to try to justify stricter

application of NQTLs.⁸⁸ These commenters highlighted that MHPAEA’s statutory standard, as amended by the CAA, 2021 does not contain such exceptions to the NQTL requirements.

Some commenters urged the Departments to not finalize the proposed exception for NQTLs that impartially apply independent professional medical or clinical standards and instead require those standards to be considered as a factor in the NQTL comparative analysis, subject to all applicable requirements for NQTLs under the proposed rules. Alternatively, commenters requested that plans and issuers be required to document in their comparative analyses the ways in which the clinical standards and practices used to design and apply NQTLs deviate from independent professional medical or clinical standards, which should be tied to criteria or guidelines from relevant nonprofit clinical specialty associations. These commenters also stated that they support analogous State definitions of “generally accepted standards of care” instead of the proposed “generally recognized independent professional medical or clinical standards.”⁸⁹ Additionally, they suggested support for tying the definition to the criteria or guidelines from the relevant nonprofit clinical specialty associations.

Some commenters highlighted that the proposed exception appears to presume that there is a single set or “gold standard” of independent professional medical or clinical standards, when in practice, these standards can vary greatly, and consensus may not always exist for a particular condition. The commenters noted that medical and clinical standards are generally designed to guide health care providers and facilities in determining appropriate care for a given diagnosis or stage of treatment, not to determine how the standards should best be utilized for other purposes, so plans and issuers may need to adapt clinical standards to apply them in the context of health coverage. Therefore, they stated, it is unclear that the exception for independent professional

⁸⁸ 78 FR 68240, 68245 (Nov. 13, 2013).

⁸⁹ 215 Ill. Comp. Stat. 5/370c, <https://www.ilga.gov/legislation/ilcs/fulltext.asp?DocName=021500050K370c>; Cal. Health & Saf. Code section 1374.72, https://leginfo.ca.gov/faces/billTextClient.xhtml?bill_id=201920200SB855; Ga. Code section 33-1-27 <https://www.legis.ga.gov/api/legislation/document/20212022/211212>; and N.M. Stat. section 59A-23-22, <https://www.nmlegis.gov/Sessions/23%20Regular/final/SB0273.pdf>.

medical or clinical standards as proposed could be relied on by plans and issuers as they design and apply NQTLs as it is unclear if this necessary adaptation would cause a plan or issuer to fail to impartially apply such standards.

Other commenters, who generally supported this proposed exception, stated that they found it to be generally vague and undefined. These commenters urged the Departments to define more clearly what constitutes independent professional medical or clinical standards for purposes of the proposed exception, and many commenters suggested language for the Departments to consider providing as additional clarifications. Some commenters noted that to “apply” such standards should be understood to mean to primarily rely on these resources when developing NQTLs and claimed that these standards lack the precision and detail necessary for the exception to be useful. Additionally, commenters requested that the Departments provide examples of standards that would qualify for the proposed exception and descriptions of their application.

After considering the comments, the Departments are not finalizing the exception for independent professional medical or clinical standards as proposed. In light of the modifications to the requirements made in the final rules, the Departments agree with commenters that it is more appropriate for plans and issuers to include independent professional medical or clinical standards under the framework of the existing NQTL parity analysis than to provide an exception from the requirements of the final rules. Therefore, instead of finalizing the exception, the Departments are instead providing clarifications for how independent professional medical and clinical standards will be treated under these final rules. Specifically, NQTLs that are designed or applied, are based on, or are related to independent professional medical or clinical standards are subject to the design and application requirements and the relevant data evaluation requirements. As noted earlier in this preamble, such medical or clinical standards are not information, evidence, sources, or standards that are biased or not objective in a manner that discriminates

against mental health or substance use disorder benefits as compared to medical/surgical benefits. Additionally, for purposes of the relevant data evaluation requirements, differences in access to mental health or substance use disorder benefits that are attributable to the use of independent professional medical or clinical standards as the basis for a factor or evidentiary standard used to design or apply an NQTL are not considered to be material. To the extent the plan or issuer attributes any differences in access to the application of such standards, the plan or issuer must explain the bases for that conclusion in their comparative analysis.

Exception for Measures to Detect or Prevent and Prove Fraud and Abuse

The Departments also proposed an exception for NQTLs reasonably designed to detect or prevent and prove fraud, waste, and abuse. To qualify for the exception under the proposed rules, fraud, waste, and abuse measures would have to be reasonably designed to detect or prevent and prove fraud, waste, and abuse, based on indicia that have been reliably established through objective and unbiased data. The proposed rules also required that such standards be narrowly designed to minimize the negative impact on access to appropriate mental health and substance use disorder benefits. Under the proposed rules, an NQTL qualifying for this exception would not be required to satisfy the proposed no more restrictive requirement. In addition, fraud, waste, and abuse measures would not be considered a discriminatory factor or evidentiary standard. The Departments noted that, under the proposed rules, the plan or issuer would still be required to ensure that such an NQTL complies with the rest of the design and application requirements. The proposed rules would also apply the relevant data evaluation requirements to these NQTLs, as the Departments stated that these tools, while important, are more likely than independent professional medical or clinical standards to result in NQTLs that may improperly restrict access to mental health and substance use disorder benefits because these NQTLs are largely both designed by, and applied within the control of, the plan or issuer. Additionally, the plan or issuer

would be required to perform and document comparative analyses for NQTLs that are fraud, waste, and abuse measures.

Many commenters opposed the exception for NQTLs that are fraud, waste, and abuse measures. Similar to the objections to the exception for independent professional medical or clinical standards, these commenters highlighted that MHPAEA's statutory language, as amended by the CAA, 2021 does not contain exceptions for any NQTLs. These commenters voiced concern that the two proposed exceptions, together, could allow plans and issuers to avoid compliance with the strengthened requirements of MHPAEA set forth in the proposed rules. Commenters opposing the fraud, waste, and abuse exception generally recommended that the Departments remove it altogether; however, some commenters recommended that, if retained, the exception should include stronger language limiting plans' and issuers' ability to invoke the exception. These commenters also recommended that the Departments eliminate references to "waste," as this is arguably targeted by all forms of utilization management. Commenters requested that, alternatively, plans and issuers be required to document in their comparative analyses how their efforts to combat fraud, waste, and abuse comply with MHPAEA (including as a factor used to design or apply an NQTL).

Other commenters were generally supportive of the exception but expressed concerns that the Departments would interpret it too narrowly. They generally recommended that the Departments add definitional clarity to allow for flexibility and account for the use of a range of NQTLs that are fraud, waste, and abuse measures and provide examples. Some commenters also sought clarification about the documentation or evidence required for a plan or issuer to prove its qualification for the exception.

The Departments acknowledge that many NQTLs consider the potential for fraud, waste, and abuse as a factor in their design and application and have concluded that it is appropriate for plans and issuers to be required to treat these types of factors and NQTLs following the same

framework as other NQTLs, subject to all applicable requirements. The Departments also agree that the term “waste” is too broad and could arguably include all forms of utilization management. Therefore, instead of finalizing the exception as proposed, the Departments are providing clarifications on how fraud and abuse measures will be treated under these final rules. Specifically, NQTLs that are designed or applied, are based on, or are related to fraud and abuse measures are subject to the design and application requirements and the relevant data evaluation requirements. However, for purposes of the prohibition on discriminatory factors and evidentiary standards, the final rules provide that fraud and abuse measures are not information, evidence, sources, or standards that are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. Additionally, for purposes of the relevant data evaluation requirements, a difference in access to mental health and substance use disorder benefits attributable to the use of fraud and abuse measures as the basis for a factor or evidentiary standard used to design or apply an NQTL is not considered to be material. To the extent that a plan or issuer attributes any differences in access to the application of such measures, the plan or issuer must explain the bases for that conclusion in their comparative analyses.

Requests for Additional Exceptions

Some commenters suggested additional exceptions to the requirements for NQTLs that the Departments should consider adding to the final rules. Specifically, some commenters requested an exception for NQTLs related to the quality and safety of mental health and substance use disorder services. Similarly, another commenter recommended the Departments include an exception for practices to ensure high-quality care, based on the view that the two exceptions (for independent professional medical or clinical standards and fraud, waste, and abuse measures) in the proposed rules are not sufficient to curb substandard and ineffective treatment that does not reach the level of fraud, waste, and abuse. Other commenters suggested

exceptions for compliance with Federal and State law, an exception to ensure the quality and safety of mental health and substance use disorder benefits, an exception to the quantitative testing and discriminatory factor analysis for Network NQTLs, and an exception for when no outcomes data are reasonably available.

The Departments have considered whether additional exceptions beyond those included in the proposed rules should be included in these final rules. As discussed earlier in this preamble, there are a very limited number of NQTLs where no data exist that can reasonably assess the NQTL's impact on access. Such NQTLs might include, for example, exclusions based on whether the treatment is experimental or investigative. Therefore, the Departments have provided guidance in these final rules on how plans and issuers must comply with the relevant data evaluation requirements for such NQTLs. However, as noted earlier in this preamble, such plans and issuers must still consider whether data can be used to reasonably assess the impact of the NQTL on relevant outcomes related to mental health and substance use disorder benefits and medical/surgical benefits. Consistent with the reasons described earlier in this preamble as to why the Departments declined to finalize the exceptions contained in the proposed rules, these final rules do not contain any additional exceptions.

f. Effect of Final Determination of Noncompliance - 26 CFR 54.9812-1(c)(4)(v), 29 CFR 2590.712(c)(4)(v), and 45 CFR 146.136(c)(4)(v)

The proposed rules provided that if a plan or issuer receives a final determination from the relevant Secretary that it is not in compliance with the comparative analysis requirements with respect to an NQTL, the NQTL would violate the substantive requirements for NQTLs,⁹⁰ and the relevant Secretary may direct the plan or issuer not to impose the NQTL unless and until the plan or issuer demonstrates to the relevant Secretary compliance with the requirements of MHPAEA or takes appropriate action to remedy the violation. Whereas the requirement in the

⁹⁰ See 88 FR 51552, 51579 (Aug. 3, 2023).

introductory paragraph of proposed 26 CFR 54.9812–1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) states that a plan or issuer may not impose an NQTL in the first instance unless it meets all of the applicable substantive requirements for NQTLs under the proposed rules, this proposed provision addresses the effect of a final determination of noncompliance with the NQTL comparative analysis documentation requirements under proposed 26 CFR 54.9812–2, 29 CFR 2590.712–1, and 45 CFR 146.137.

The Departments noted in the proposed rules that MHPAEA requires that “such plan or coverage shall ensure that” the treatment limitations comply with the substantive requirements of the statute.⁹¹ The Departments also noted that the statute further requires that the plan or issuer perform and document adequate comparative analyses for NQTLs to ensure compliance.⁹² Therefore, to comply with MHPAEA, plans and issuers must comply with both the substantive MHPAEA requirements and the documentation requirements. Under the proposed rules, plans and issuers would be required to ensure both that they are complying with MHPAEA’s substantive requirements at all times an NQTL is imposed with respect to mental health or substance use disorder benefits, and that they have properly performed and documented comparative analyses for the NQTLs imposed on mental health or substance use disorder benefits (regardless of the timing of any request for such documentation).

Under the proposed rules, when a plan or issuer receives a final determination from the Departments with respect to an NQTL that it has failed to demonstrate compliance with the NQTL comparative analysis documentation requirements under proposed 26 CFR 54.9812-2, 29 CFR 2590.712-1, or 45 CFR 146.137, including because the plan or issuer has not submitted a sufficient comparative analysis to demonstrate compliance, the failure would be treated not only as a violation of the NQTL comparative analysis documentation requirements but also as a

⁹¹ Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A).

⁹² Code section 9812(a)(8), ERISA section 712(a)(8), and PHS Act section 2726(a)(8).

violation of the substantive NQTL rules under proposed 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4). The Departments acknowledged that immediate cessation of the application of an NQTL may not be feasible for all NQTLs. Therefore, under the proposed rules, a determination by the Departments of whether to require immediate cessation would be based on the evaluation of facts and circumstances involved in the specific violation and nature of the underlying NQTL. The Departments provided examples of such facts and circumstances, including the level of disruption in the provision of benefits under the plan or coverage if the NQTL immediately ceased to apply, the practicality and complexities involved in the cessation of the NQTL, the effect on participants and beneficiaries, and the likely time needed to cease or modify the NQTL. Additionally, the Departments noted that this kind of determination would take into account feedback from the plan or issuer. The Departments provided that these facts and circumstances would also be relevant to the Departments' assessment of the plan's or issuer's overall efforts to come into compliance with MHPAEA. The Departments solicited comments on this proposed provision, including whether there are specific challenges or considerations the Departments should be aware of regarding ceasing application of particular NQTLs.

Several commenters supported a provision that would give the Secretaries the ability to direct a plan or issuer to not impose an NQTL after a final determination of noncompliance and stated that meaningful consequences are important to incentivize plans and issuers to comply with MHPAEA. Some commenters urged the Departments to change the proposed language stating that "the relevant Secretary *may* direct the plan or issuer not to impose the NQTL" to "the relevant Secretary *shall* direct the plan or issuer not to impose the NQTL" to indicate that a plan or issuer will not be permitted to apply a noncompliant NQTL. Several commenters recommended extending this provision to States with primary enforcement authority for MHPAEA with respect to issuers. Some commenters opposed the proposed provision, stating

that in their view there is no legal authority under MHPAEA or the CAA, 2021 to demand immediate cessation of an NQTL without intervention of a court of law. Some commenters raised concerns about the ability of plans and issuers to immediately stop imposing an NQTL, particularly mid-year, and with regard to NQTLs related to network composition. Several commenters suggested that, in light of the significant potential consequences of a final determination of noncompliance, the Departments should provide some type of appeals process modeled on the process for appeals of civil money penalties for Medicare Advantage Organizations or require review by EBSA’s national office or the director of the Center for Consumer Information and Insurance Oversight (CCIIO) within CMS before taking such action when there is a final determination of noncompliance.

The Departments are finalizing the provision governing the effect of a final determination of noncompliance, with modifications. The language contained in proposed 26 CFR 54.9812-1(c)(4)(vii), 29 CFR 2590.712(c)(4)(vii), and 45 CFR 146.136(c)(4)(vii) is being finalized at 26 CFR 54.9812-1(c)(4)(v)(A), 29 CFR 2590.712(c)(4)(v)(A), and 45 CFR 146.136(c)(4)(v)(A). These final rules add references to the relevant statutory citation,⁹³ to make clear that the effect of the final determination of noncompliance provision of these final rules, including the evaluation of the relevant facts and circumstances used to determine whether cessation of an NQTL is appropriate, is only applicable with respect to a plan’s or issuer’s violation of the comparative analysis requirements, as set forth in Code section 9812(a)(8), ERISA section 712(a)(8), and PHS Act section 2726(a)(8). If, however, the plan or issuer violates MHPAEA’s substantive requirements, as set forth in Code section 9812(a)(3), ERISA section 712(a)(3), and PHS Act section 2726(a)(3), and 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4), by imposing an NQTL that violates the “no more restrictive” standard, the statute

⁹³ Code section 9812(a)(8), ERISA section 712(a)(8), and PHS Act section 2726(a)(8).

clearly contemplates that the plan or issuer not apply the NQTL, and the Departments have full authority to prohibit the plan or issuer from continuing to impose the unlawful NQTL.⁹⁴

The HHS final rules at 45 CFR 146.136(c)(4)(v)(A) also add references to an applicable State authority, as requested by commenters, so that the regulations are clear that, like the Departments, States with enforcement authority with respect to MHPAEA⁹⁵ are also permitted to direct issuers not to impose an NQTL when there is a final determination of noncompliance, unless and until the issuer demonstrates compliance or takes appropriate action to remedy the violation. These final rules also provide additional specificity by clarifying that this provision allows the Departments (and an applicable State authority) to direct a plan or issuer not to impose an NQTL with respect to mental health or substance use disorder benefits in the relevant classification.

Additionally, these final rules add new paragraph (c)(4)(v)(B) to make clear that a determination of whether the Departments will require cessation of the application of an NQTL will be based on an evaluation of the relevant facts and circumstances involved in the specific final determination and the nature of the underlying NQTL. For this purpose, the Departments expect that such facts and circumstances may include, but are not limited to, the level of disruption in the provision of benefits under the plan or coverage if the NQTL immediately ceased to apply, the practicality and complexities involved in the cessation of the NQTL, the effect on participants and beneficiaries of continuing or ceasing to apply the NQTL, and the likely time needed to cease or modify the NQTL. Under these final rules, such a determination

⁹⁴ Specifically, Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A) state that a plan or coverage “shall ensure that... the treatment limitations applicable to such mental health or substance use disorder benefits are no more restrictive than the predominant treatment limitations applied to substantially all medical and surgical benefits covered” by the plan (or coverage). If a plan or coverage does not ensure compliance with these statutory requirements, the Departments may require the plan or issuer to no longer impose the NQTL or to otherwise come into compliance. Similarly, 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) of these final rules state that a plan (or coverage) may not impose any NQTL unless it complies with the statutory requirement in Code section 9812(a)(3)(A), ERISA section 712(a)(3)(A), and PHS Act section 2726(a)(3)(A).

⁹⁵ PHS Act section 2723(a)(1).

will also take into account the interest of plan participants and beneficiaries and feedback from the plan or issuer. States that are the primary enforcers of MHPAEA may take into account these or other facts and circumstances when determining whether the State will require cessation of application of an NQTL.

The Departments decline to modify the proposed language to provide that the Secretary “shall” direct the plan or issuer not to impose the NQTL after a final determination of noncompliance with the comparative analysis requirements. In the preamble to the proposed rules and in these final rules, the Departments acknowledged that immediate cessation of the application of an NQTL may not be feasible for all NQTLs and that feedback from the plan or issuer would be taken into account. The Departments understand that not requiring immediate cessation of a noncompliant NQTL in every situation that involves a final determination of noncompliance with the comparative analysis requirements may allow participants and beneficiaries to be subject to noncompliant NQTLs. As these commenters noted, meaningful consequences are important to incentivize plans and issuers to comply with MHPAEA. However, the Departments are of the view that the potential negative impacts for participants and beneficiaries of continuing to apply the NQTL should be balanced with the operational feasibility of immediately modifying business practices, particularly for NQTLs that are inherent to the plan design and may require time to reform. Such potential negative impacts for participants and beneficiaries may be better evaluated after the Departments review the specific facts and circumstances of the relevant determination of noncompliance with the comparative analysis requirements. Therefore, these final rules specify that, when determining the effect of a final determination of noncompliance with the comparative analysis requirements, each specific violation will have its own analysis of the applicable facts and circumstances that will be taken into account.

The Departments stress that MHPAEA requires plans and issuers to ensure that the treatment limitations, including NQTLs imposed on mental health or substance use disorder benefits in a classification, are not more restrictive than those applied to medical/surgical benefits in the same classification. In many cases, a failure to submit a sufficient or compliant comparative analysis is evidence that a plan or issuer cannot substantiate an NQTL's compliance with these applicable requirements, and therefore is violating MHPAEA's substantive parity requirements. Therefore, where the Departments have come to a final conclusion that a comparative analysis is not compliant and are issuing a final determination of noncompliance, including because the plan or issuer has not submitted a sufficient comparative analysis to demonstrate compliance, the required corrective action may include the removal of such NQTL. The CAA, 2021 also requires the Departments to specify the actions a plan or issuer must take to address the violation, and include the required actions in the annual report to Congress.⁹⁶ This provision makes clear the Departments have broad authority to determine the appropriate remedy where a plan's or issuer's comparative analysis is not compliant, and this authority allows the Departments, depending on the relevant facts and circumstances, to specify removal of the NQTL as the appropriate remedy to address a determination of noncompliance. Nothing, however, prevents the Departments or applicable State authorities from specifying other or additional corrective actions or from taking enforcement action within their respective authorities.

As stressed in the Departments' reports to Congress, the Departments generally engage plans and issuers in repeated exchanges – asking follow-up questions, seeking additional documentation, performing further assessments, and affording opportunities for explanation –

⁹⁶ Code section 9812(a)(8)(B)(iv)(V), ERISA section 712(a)(8)(B)(iv)(V), and PHS Act section 2726(a)(8)(B)(iv)(V).

before making a final determination of noncompliance.⁹⁷ The Departments note that plans and issuers are given multiple opportunities to engage with the Departments after an initial request for comparative analysis and before a final determination of noncompliance. As described later in this preamble, after an initial request for a comparative analysis, if the Department concludes that a plan or issuer has not submitted sufficient information to review the requested comparative analyses, the plan or issuer will be provided with another opportunity to respond to the Department's initial request. If the Department reviews the comparative analyses (and any additional information submitted upon request) and makes an initial determination that the plan or issuer is not in compliance, the plan or issuer is provided another opportunity to respond to the Department. Because of the multiple opportunities to engage with the Departments prior to a final determination of noncompliance, the Departments decline to add any additional formal appeal or review requirements beyond that required under the statute. Any direction not to impose an NQTL provided to a plan or issuer by the relevant Department will take into account all correspondence and discussions with the plan or issuer.

g. NQTL Examples - 26 CFR 54.9812-1(c)(4)(vi), 29 CFR 2590.712

(c)(4)(vi), and 45 CFR 146.136(c)(4)(vi)

The proposed rules contained thirteen examples illustrating the NQTL requirements, including revised versions of some examples included in the 2013 final regulations and several new examples. Additionally, the proposed rules proposed to eliminate some examples that were included in the 2013 final regulations, in light of the additional proposed requirements.

The Departments received comments on each of the proposed examples and comments recommending additional examples be added. Some commenters suggested the Departments use

⁹⁷ See, e.g., 2023 MHPAEA Comparative Analysis Report to Congress (July 2023), pg. 52, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf> and <https://www.cms.gov/cciiio/resources/forms-reports-and-other-resources#mental-health-parity>.

different data elements in the examples related to the relevant data evaluation requirements that in their view would better evaluate compliance with MHPAEA. Other commenters expressed concerns regarding how the proposed exceptions to the NQTL requirements discussed earlier in this preamble would apply and requested that the examples address what a plan or issuer would be required to document to rely on these exceptions. One of these commenters also requested an example showing analysis of an NQTL that is developed based on multiple standards, some of which qualify for the proposed exception for independent professional medical or clinical standards and some of which do not. Some commenters expressed concern regarding whether the proposed mathematical substantially all and predominant tests could be performed on all NQTLs and requested more detailed examples of how to apply such tests.

As noted earlier in this preamble, the Departments are declining to finalize the proposed mathematical substantially all and predominant tests, as well as the proposed exceptions for NQTLs that impartially apply independent professional medical or clinical standards or fraud, waste, and abuse measures. Therefore, rather than providing examples to address these provisions, the examples address the substantive provisions the Departments are finalizing in these final rules, including the general requirement that NQTLs for mental health and substance use disorder benefits not be more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification, the design and application requirements, and the relevant data evaluation requirements (including potential data elements that plans and issuers may consider to be relevant data with respect to an NQTL).

The Departments are adapting some of the fact patterns used in the examples in the proposed rules related to provisions that are not being finalized to instead illustrate concepts applicable in these final rules, but these final rules do not include all of the examples included in the proposed rules (or all of the examples included in the 2013 final regulations). The

Departments note that the exclusion in these final rules of any particular fact pattern that was previously addressed in examples in the proposed rules or the 2013 final regulations is not intended to indicate that any particular set of facts is permissible or prohibited under these final rules. Rather, the examples in these final rules are included to illustrate the application of the various provisions included in these final rules. Thus, plans and issuers are expected to apply the requirements in paragraph (c)(4) of these final rules to the specific facts and circumstances of the benefit design of their respective plans and coverage options with respect to all NQTLs applicable to mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to design or apply them, and any information, evidence, sources, or standards on which a factor or evidentiary standard is based. Additionally, as in the proposed rules, any example that concludes that the plan violates or complies with a requirement of these final rules for NQTLs should not be read to imply compliance with any other requirements of these final rules for NQTLs.

Example 1 – Not comparable and more stringent factors for reimbursement rate methodology, in operation. In the proposed rules, Example 4 illustrated how plans and issuers would be required to ensure compliance in operation with the proposed design and application requirements for a plan’s reimbursement rate methodology NQTL.⁹⁸ These final rules redesignate proposed Example 4 as Example 1 and illustrate the application of the general rule of the design and application requirements of these final rules with respect to a plan’s reimbursement rate methodology NQTL. The language in the facts and conclusion of proposed Example 4 referencing an assumption that the plan’s methods for determining reimbursement rates for mental health and substance use disorder benefits satisfy the no more restrictive requirement has been eliminated to reflect, as discussed earlier in this preamble, that the

⁹⁸ As stated in the preamble to the proposed rules, Example 4 was based in part on guidance in FAQs Part 39, Q6, <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-39-final.pdf> and <https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-final-set-39>.

Departments decline to finalize the proposed mathematical substantially all and predominant tests in these final rules.

Accordingly, the facts of Example 1 in these final rules assume a plan's reimbursement rate methodology for outpatient, in-network providers is based on a variety of factors. As written, for mental health, substance use disorder, and medical/surgical benefits, all reimbursement rates for physicians and non-physician practitioners for the same CPT code are based on a combination of factors, such as the nature of the service, duration of the service, intensity and specialization of training, provider licensure and type, number of providers qualified to provide the service in a given geographic area, and market need (demand). In operation, the plan utilizes an additional strategy to further reduce reimbursement rates for mental health and substance use disorder non-physician providers from those paid to mental health and substance use disorder physicians by the same percentage for every CPT code but does not apply the same reductions for non-physician medical/surgical providers.

Example 1 concludes that the plan violates the rules of paragraph (c)(4). The plan reimburses non-physician providers of mental health and substance use disorder services by reducing their reimbursement rates from the rates for physician providers of such services by the same percentage for every CPT code but does not apply the same reduction to non-physician providers of medical/surgical services from the rate for physician providers of medical/surgical services. Therefore, in operation, the factors used in designing and applying the NQTL to mental health and substance use disorder benefits in the outpatient, in-network classification are not comparable to, and are applied more stringently than, the factors used in designing and applying the NQTL with respect to medical/surgical benefits in the same classification. As a result, the NQTL with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification, in violation of 26 CFR

54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4) of these final rules. This example illustrates that the plan violates the design and application requirements and does not address whether the plan complies with the relevant data evaluation requirements.

Example 2 – Strategy for exclusion for experimental or investigative treatment more stringently applied to Applied Behavior Analysis (ABA) therapy in operation. These final rules redesignate proposed Example 10 as Example 2 with modifications to the conclusion. Proposed Example 10 concluded that the plan violates the proposed no more restrictive requirements because, in operation, the plan’s exclusion for experimental or investigative treatment imposed on ABA therapy limits access to the full range of treatment options available for a condition or disorder under the plan as compared to medical/surgical benefits in the same classification. As discussed earlier in this preamble, the Departments declined to finalize the proposed mathematical substantially all and predominant tests. However, multiple commenters in response to the proposed rules expressed support for including an example that specifically addresses the exclusion of benefits to treat ASD. Therefore, in Example 2 of these final rules, the Departments are adapting proposed Example 10 to demonstrate how a strategy for a plan’s exclusion of benefits for experimental or investigative treatment that applies more stringently to ABA therapy, in operation, violates the design and application requirements, and therefore violates the requirements for NQTLs under these final rules.

In Example 2, the facts of proposed Example 10 are generally unchanged. A plan, as written, generally excludes coverage for all treatments that are experimental or investigative for medical/surgical benefits and mental health and substance use disorder benefits in the outpatient, in-network classification. As a result, the plan generally excludes, as experimental, a treatment or procedure when no professionally recognized treatment guidelines include the treatment or procedure as a clinically appropriate standard of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment’s use with respect to the

given condition or disorder. As written, the plan provides benefits for the treatment of ASD, which is a mental health condition, but, in operation, excludes coverage for ABA therapy to treat children with ASD, deeming it experimental. More than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD as including ABA therapy and more than two randomized controlled trials are available to support the use of ABA therapy as one intervention to treat certain children with ASD.

Example 2 concludes that the plan violates the design and application requirements with respect to the exclusion of ABA therapy because, in operation, the plan deviates from its strategy to exclude coverage of experimental treatment of medical conditions and surgical procedures, mental health conditions, and substance use disorders because more than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD as including ABA therapy to treat certain children with ASD and more than two randomized controlled trials are available to support the use of ABA therapy as one intervention to treat certain children with ASD. Therefore, in operation, the strategy used to design the NQTL for benefits for the treatment of ASD, which is a mental health condition for purposes of MHPAEA, in the outpatient, in-network classification is not comparable to, and is applied more stringently than, the strategy used to design and apply the NQTL for medical/surgical benefits in the same classification. As a result, the example concludes that the NQTL is more restrictive and therefore violates MHPAEA. This example illustrates that the plan violates the design and application requirements and does not address whether the plan complies with the relevant data evaluation requirements.

Example 3 – Step therapy protocol with exception for severe or irreversible consequences, discriminatory factor. The Departments received several comments asking the Departments to provide additional clarification on what would be considered discriminatory factors and evidentiary standards for purposes of determining compliance with the design and

application requirements. Accordingly, the Departments are including in these final rules a new Example 3 to provide an example of circumstances under which a plan or issuer would violate the prohibition against discriminatory factors and evidentiary standards in the context of step therapy with exceptions for severe or irreversible consequences.

The facts of Example 3 assume a plan has a step therapy protocol that requires participants and beneficiaries who are prescribed certain drugs to try and fail a generic or preferred brand name drug before the plan will cover the treatment or medication originally prescribed by a provider. The plan has an exception to this protocol that was developed solely by relying on a methodology developed by an external third-party organization. The third-party organization's methodology, which is not based on an independent professional medical or clinical standard, identifies instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences. However, with respect to a drug prescribed for a mental health condition or a substance use disorder, the third-party organization's methodology only identifies instances in which a delay in treatment could result in both severe and irreversible consequences. The plan does not take any steps to correct, cure, or supplement the methodology.

The conclusion to Example 3 explains that the plan violates the prohibition on discriminatory factors and evidentiary standards under 26 CFR 54.9812-1(c)(4)(i)(B), 29 CFR 2590.712(c)(4)(i)(B), and 45 CFR 146.136 (c)(4)(i)(B). The source upon which the factor used to apply the step therapy protocol is based is biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits because it addresses instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences, but only addresses instances in which a delay in treatment with a drug prescribed for a mental health condition or substance use disorder could result in both severe and irreversible consequences,

and the plan fails to take the steps necessary to correct, cure, or supplement the methodology so that it is not biased and is objective. Based on the relevant facts and circumstances, this source systematically disfavors access or is specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. Therefore, the factor used to design exceptions to the step therapy protocol is discriminatory, for purposes of determining comparability and stringency under the design and application requirements, and it may not be relied upon by the plan unless the plan takes the steps necessary to correct, cure, or supplement it (by, for example, taking into account instances in which a delay in treatment with a drug prescribed for a mental health condition or a substance use disorder could result in severe or irreversible consequences).

Example 4 – Use of historical plan data and steps the plan or issuer can take to correct, cure, or supplement. The Departments are including as Example 4 of these final rules a revised example illustrating how plans and issuers can correct, cure or supplement the use of historical data or other historical information from a time when the plan or coverage was not subject to MHPAEA or was in violation of MHPAEA’s requirements so that the information is not considered to be biased or not objective and can be used as the basis for a factor or evidentiary standard that is not discriminatory. The Departments stated in the preamble to the proposed rules that the proposed rules would prohibit reliance on historical plan data or other historical information from a time when the plan or coverage was not subject to MHPAEA (or was in violation of MHPAEA’s requirements) and provided an example addressing calculation of reimbursement rates based on historical data on total plan spending. Example 4 of these final rules references the fact pattern from Example 4 in the proposed rules but provides additional detail and analysis to illustrate the application of the prohibition on discriminatory factors and evidentiary standards under these final rules, including how a plan or issuer could correct, cure,

or supplement the use of such data so that the information is not considered to be biased or not objective.

Specifically, the facts of Example 4 assume a plan's methodology for calculating provider reimbursement rates relies only on historical plan data on total plan spending for each specialty, divided between mental health and substance use disorder providers and medical/surgical providers from a time where the plan was not subject to MHPAEA. The plan used these historical plan data for many years to establish base reimbursement rates in all provider specialties for which it provides medical/surgical, mental health, and substance use disorder benefits in the inpatient, in-network classification. In evaluating the use of these historical plan data in the design of the methodology for calculating provider reimbursement rates, the plan determined, based on all the relevant facts and circumstances, that the historical plan data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. To ensure this information about historical reimbursement rates is not biased and is objective, the plan supplements its methodology to develop the base reimbursement rates for mental health and substance use disorder providers in accordance with additional information, evidence, sources, and standards that reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification and to attract sufficient mental health and substance use disorder providers to the network. The relevant facts and circumstances indicate that the supplemented information, evidence, sources, or standards do not systematically disfavor access and are not specifically designed to disfavor access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

Example 4 of these final rules concludes that the plan does not violate the prohibition on discriminatory factors and evidentiary standards with respect to the plan's methodology for calculating provider reimbursement rates in the inpatient, in-network classification. The relevant

facts and circumstances indicate that the plan's use of only historical plan data to design its methodology for calculating its provider reimbursement rates in the inpatient, in-network classification would otherwise be considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits since the historical data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. However, the plan took the steps necessary to supplement the information, evidence, sources, and standards to reasonably reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification, and adjusted the methodology to increase reimbursement rates for those benefits, thereby ensuring that the information, evidence, sources, and standards relied upon by the plan for this purpose are not biased and are objective. Therefore, the factors and evidentiary standards used to design the plan's methodology for calculating provider reimbursement rates in the inpatient, in-network classification are not considered discriminatory factors and evidentiary standards.

Example 5 – Generally recognized independent professional medical or clinical standards and more stringent prior authorization requirement in operation. In the proposed rules, the Departments proposed Example 6 to illustrate the exception for impartially applied independent professional medical or clinical standards and when a plan fails to satisfy the exception. The Departments received comments requesting examples to provide further clarity on how a plan or issuer may properly rely on independent professional medical or clinical standards in the design and application of NQTLs. As described earlier in this preamble, the Departments are not finalizing this exception as proposed. Instead, these final rules specify that the use of independent professional medical or clinical standards generally will not be considered to be biased and not objective under these final rules. The Departments note that, under these final rules, the use of such standards must also comply with the other provisions of these final

rules, including the general rule in the design and application requirements and the relevant data evaluation requirements. Therefore, the Departments are modifying proposed Example 6 and redesignating it as Example 5 in these final rules, to illustrate a violation of the design and application requirements of these final rules when a plan relies on independent professional medical or clinical standards to inform a factor used to design an NQTL with respect to mental health and substance use disorder benefits that, in operation, is not comparable to, and is applied more stringently than, the same factor used to design the NQTL for medical/surgical benefits in the same classification.

In Example 5 of these final rules, the provisions of a plan state that it relies on, and does not deviate from, independent professional medical or clinical standards to inform the factor used to design prior authorization requirements for both medical/surgical and mental health and substance use disorder benefits in the prescription drug classification. In this example, the plan uses the ASAM national practice guidelines as the independent professional medical or clinical standard to inform the factors used to design and apply the prior authorization requirement for treatment of OUD. The ASAM practice guidelines do not support prior authorization every 30 days for buprenorphine/naloxone combination for treatment of OUD. However, in operation, the plan requires prior authorization for buprenorphine/naloxone combination for treatment of OUD every 30 days, which is inconsistent with independent professional medical standards on which the factor used to design the limitation is based. The plan's factor used to design and apply prior authorization requirements for medical/surgical benefits in the prescription drug classification relies on, and does not deviate from, independent professional medical or clinical standards.

The conclusion to Example 5 in these final rules states that the plan violates the requirements for NQTLs. The ASAM national practice guidelines on which the factor used to design prior authorization requirements for substance use disorder benefits is based are independent professional medical or clinical standards that are not considered to be biased or not

objective in a manner that discriminates against mental health and substance use disorder benefits under these final rules. However, the plan must comply with other requirements in these final rules for NQTLs, as applicable, with respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply an NQTL. In operation, the plan's factor used to design and apply prior authorization requirements with respect to substance use disorder benefits is not comparable to, and is applied more stringently than, the same factor used to design and apply prior authorization requirements for medical/surgical benefits, because the factor relies on, and does not deviate from, independent professional medical or clinical standards for medical/surgical benefits, but deviates from the relevant guidelines for substance use disorder benefits. As a result, the NQTL with respect to substance use disorder benefits in the prescription drug classification is more restrictive than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification.

Example 6 – Plan claims no data exist to reasonably measure impact of NQTL on access; medical necessity criteria. As described earlier in this preamble, these final rules require plans and issuers to collect and evaluate relevant data in a manner reasonably designed to assess the impact of an NQTL on relevant outcomes related to access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Additionally, these final rules provide guidance for plans and issuers to comply with the relevant data evaluation requirements when data are initially temporarily unavailable for a newly imposed NQTL or no data exist that can reasonably measure any relevant impact of an NQTL on access.⁹⁹

Under the facts of new Example 6, a plan approves or denies claims for mental health and substance use disorder benefits and for medical/surgical benefits in the inpatient, in-network and

⁹⁹ As explained earlier in this preamble, these final rules state that the provisions with respect to these types of NQTLs shall only apply in very limited circumstances and, where applicable, shall be construed narrowly, consistent with the fundamental purpose of MHPAEA. The Departments are of the view that data can be collected and evaluated for nearly all NQTLs.

outpatient, in-network classifications based on medical necessity criteria. The plan states in its comparative analysis that no data exist that can reasonably measure any relevant impact of the medical necessity criteria NQTL on access to mental health or substance use disorder benefits as compared to the NQTL's impact on access to medical/surgical benefits in the relevant classifications, without further explanation.

The example concludes that the plan violates the requirements of these final rules. The plan does not comply with the requirements under these final rules for NQTLs where no data exist that can reasonably measure any relevant impact of the NQTL on access because the plan did not include in its comparative analysis a reasoned justification as to the basis for its conclusion that there are no data that can reasonably measure the NQTL's impact, an explanation of why the nature of the NQTL prevents the plan from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the NQTL complies with the requirements of MHPAEA. For example, data the plan could have considered that could reasonably assess the NQTL's impact might include the number and percentage of claims denials, or the number and percentage of claims that were approved for a lower level of care than the level requested on the initial claim. The plan has violated the relevant data evaluation requirements, as it has not collected and evaluated relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access nor did it include sufficient information in its comparative analysis with respect to the lack of relevant data.

Example 7 – Concurrent review data collection; no material difference in access.

Example 7 in these final rules illustrates the application of the relevant data evaluation requirements to a concurrent review NQTL. This example is based on similar facts from Example 2 in the proposed rules, but language in the facts and conclusion of proposed Example 2 referencing the no more restrictive requirement have been eliminated to reflect, as discussed

earlier in this preamble, that the Departments decline to finalize the proposed mathematical substantially all and predominant tests in these final rules (that would prohibit any NQTL that is more restrictive than the most common or most frequent variation of the NQTL applied to at least two-third of medical/surgical benefits in a classification).

In this example as modified in these final rules, a plan follows a written process to apply a concurrent review NQTL to all medical/surgical benefits and mental health and substance use disorder benefits within the inpatient, in-network classification. Under this process, a first-level review is conducted in every instance in which concurrent review applies and an authorization request is approved by the first-level reviewer only if the clinical information submitted by the facility meets the plan's criteria for a continued stay. If the first-level reviewer is unable to approve the authorization request because the clinical information submitted by the facility does not meet the plan's criteria for a continued stay, it is sent to a second-level reviewer who will either approve or deny the request. The plan collects relevant data, including the number of referrals to second-level review, and the number of denials of concurrent review claims as compared to the total number of concurrent review claims in the inpatient, in-network classification. The plan also collects the number of denied claims that are overturned on appeal, separately for mental health and substance use disorder benefits and medical/surgical benefits in the inpatient, in-network classification. The plan evaluates the relevant data and determines that, based on the facts and circumstances, the data do not suggest that the concurrent review NQTL contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits in the inpatient, in-network classification. Upon requesting the plan's comparative analysis for the concurrent review NQTL and reviewing the relevant data, the Secretary does not request additional data and agrees that the data do not suggest material differences in access.

In Example 7 of these final rules, the conclusion explains that the plan does not violate the relevant data evaluation requirements as it collected and evaluated relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and considered the impact as part of its evaluation. Because the relevant data do not suggest that the NQTL contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in the inpatient, in-network classification, there is no strong indicator that the plan violates the requirements for NQTLs under these final rules. However, the plan is still required to comply with the design and application requirements under these final rules, including the prohibition on discriminatory factors and evidentiary standards.

Example 8 – Material difference in access for prior authorization requirement with reasonable action. In the proposed rules, Example 1 illustrates the effect of a disparity in the routine approval of benefits for mental health conditions and substance use disorders compared to benefits for medical/surgical conditions in a classification under the no more restrictive requirement in the proposed rules. However, as discussed earlier in this preamble, the Departments have declined to finalize the proposed mathematical substantially all and predominant tests. Therefore, the Departments are adapting proposed Example 1 for use as Example 8 of these final rules to illustrate how a plan or issuer can satisfy the requirement to take reasonable action to address any material differences in access as necessary to ensure compliance with the relevant data evaluation requirements, in the context of material differences in access in the routine approval of benefits for mental health conditions and substance use disorders compared to medical/surgical benefits in a classification.

In Example 8 of these final rules, a plan requires prior authorization that a treatment is medically necessary for all inpatient, in-network medical/surgical benefits and for all inpatient, in-network mental health and substance use disorder benefits. The plan collects and evaluates

relevant data in a manner reasonably designed to assess the impact of the prior authorization requirement on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits in the inpatient, in-network classification. The plan's written process for prior authorization states that the plan approves inpatient, in-network benefits for medical conditions and surgical procedures and mental health and substance use disorder benefits for periods of 1, 3, and 7 days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. Approvals for mental health and substance use disorder benefits are most commonly given only for 1 day, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. The relevant data show that approvals for 7 days are most common for medical conditions and surgical procedures under this plan. Based on all the relevant facts and circumstances, the difference in the data suggests that the NQTL is likely to have a negative impact on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Therefore, the differences in the data suggest that the NQTL contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits. To address these material differences, the plan consults more recent medical guidelines to update the factors that inform its medical necessity NQTLs and modifies the prior authorization NQTL so that inpatient, in-network prior authorization requests for mental health or substance use disorder benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan includes documentation of this action as part of its comparative analysis.

The conclusion to Example 8 provides that, while relevant data for the plan's prior authorization requirements suggested that the NQTL contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits in the classification, the plan has taken reasonable action, as necessary, to ensure compliance, in operation, with the requirements for NQTLs under these final rules by updating the factors that

inform its prior authorization NQTL for inpatient, in-network mental health and substance use disorder benefits, so that such benefits are approved for similar periods to what is approved for medical/surgical benefits, and documenting its action taken to address material differences in access to inpatient, in-network benefits, as required under these final rules.

Example 9 – Differences attributable to the use of independent professional medical or clinical standards. In the proposed rules, the Departments proposed to add new Example 5 to illustrate how a plan may satisfy the proposed exception for independent professional medical or clinical standards. As noted earlier in this preamble, the Departments are not finalizing that exception, and instead, under these final rules, the use of independent professional medical or clinical standards are not considered to be information, evidence, sources, or standards that are biased and not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, as long as the use of these standards to design or apply an NQTL complies with other applicable requirements. Furthermore, under these final rules, differences in access attributable to the use of independent professional medical or clinical standards for both medical/surgical benefits and mental health and substance use disorder benefits are not considered to be material. However, to the extent a plan or issuer attributes any differences in access to the application of such standards, the plan or issuer must explain its bases for reaching that conclusion in its comparative analysis. Therefore, the Departments are adapting Example 5 of the proposed rules for use as Example 9 of these final rules to illustrate the treatment of the use of independent professional medical or clinical standards.

In Example 9 of these final rules, a plan develops a medical management requirement for all inpatient, out-of-network benefits for both medical/surgical benefits and mental health and substance use disorder benefits to ensure treatment is medically necessary. The factors and evidentiary standards used to design and apply the medical management requirement rely on

independent professional medical or clinical standards that are generally recognized by health care providers and facilities in relevant clinical specialties. The processes, strategies, evidentiary standards, and other factors used in designing and applying the medical management requirement to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the requirement with respect to medical/surgical benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the medical management NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, and considers the impact as part of the plan's evaluation. Within the inpatient, out-of-network classification, the application of the medical management requirement results in a higher percentage of denials for mental health and substance use disorder claims than medical/surgical claims because the benefits were found to be medically necessary for a lower percentage of mental health and substance use disorder claims. The plan correctly determines that these differences in access are attributable to the independent professional medical or clinical standards that are used as the basis for the factors and evidentiary standards used to design or apply the NQTL and adequately explains the bases for that conclusion as part of its comparative analysis.

Example 9 concludes that the plan does not violate the requirements under these final rules for its medical management NQTL. Independent professional medical or clinical standards are not considered to be information, evidence, sources, or standards that are biased and not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits and the plan otherwise complies with the design and application requirements. Additionally, the plan does not violate the relevant data evaluation requirements because it has collected and evaluated relevant data, the differences in access are attributable to the independent professional medical or clinical standards that are used as the

basis for the factors and evidentiary standards used to design or apply the medical management NQTL, and the plan explains the bases for this conclusion in its comparative analysis. As a result, the NQTL with respect to mental health or substance use disorder benefits in the inpatient, out-of-network classification is no more restrictive than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification.

Example 10 – Material difference in access for standards for provider admission to a network with reasonable action. In the proposed rules, the Departments proposed new Example 13 to illustrate how plans and issuers may comply with the proposed relevant data evaluation requirements with respect to NQTLs related to network composition, including NQTLs for provider and facility admission to participate in a network or for continued network participation, methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of providers and facilities to provide covered services under the plan or coverage. These final rules largely adopt Example 13 as proposed, with some modifications to reflect the standards included in these final rules, and redesignate it as Example 10.

In Example 10 of these final rules, a plan applies NQTLs related to network composition in the inpatient, in-network and outpatient, in-network classifications. The plan's networks are constructed by separate service providers for medical/surgical benefits and mental health and substance use disorder benefits. The facts also assume that the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTLs related to network composition for mental health or substance use disorder benefits in the inpatient, in-network and outpatient, in-network classifications are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTLs with respect to medical/surgical benefits in the same classifications. In order to ensure, in operation, that the NQTLs are no more restrictive than the predominant

NQTLs applied to substantially all medical/surgical benefits in the classification, the plan collects and evaluates relevant data in a manner reasonably designed to assess the aggregate impact of all the NQTLs related to network composition on relevant outcomes related to access to mental health and substance use disorder benefits as compared with medical/surgical benefits and considers the impact as part of the plan's evaluation. The plan considers relevant data that is known, or reasonably should be known, including metrics relating to the time and distance from plan participants and beneficiaries to network providers in rural and urban regions; the number of network providers accepting new patients; the proportions of mental health and substance use disorder and medical/surgical providers and facilities that provide services in rural and urban regions who are in the plan's network; provider reimbursement rates (for comparable services and benchmarked to a reference standard, as appropriate); and in-network and out-of-network utilization rates (including data related to the dollar value and number of provider claims submissions). The plan determines that the relevant data suggest that the NQTLs in the aggregate contribute to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in the classifications because, based on all the relevant facts and circumstances, the differences in the data suggest that the plan's NQTLs related to network composition are likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits in the same classifications. The plan takes reasonable actions, as necessary, to address the material differences in access, to ensure compliance, in operation, with the requirements for NQTLs under these final rules, by strengthening its efforts to recruit and encourage a broad range of available providers and facilities to join the plan's network of providers, including by taking actions to increase compensation and other inducements, streamline credentialing processes, contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network, and develop a process to monitor the effects of such efforts; expanding the

availability of telehealth arrangements to mitigate overall provider shortages in certain geographic areas; providing additional outreach and assistance to participants and beneficiaries enrolled in the plan to assist them in finding available in-network providers and facilities; and ensuring that the plan's provider directories are accurate and reliable. The plan documents the efforts that it has taken to address the material differences in access that the data revealed, and also documents the reasons beyond the plan's control that the plan believes may contribute to the material differences in access, and the plan includes the documentation as part of its comparative analysis submission.

Example 10 concludes that the plan does not violate the requirements for NQTLs under these final rules. The plan complies with the design and application requirements, and also collects and evaluates relevant data, as required under these final rules, in a manner reasonably designed to assess the aggregate impact of all such NQTLs on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits. While the data suggest that the NQTLs contribute to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, the plan takes reasonable action, as necessary, to ensure compliance with these final rules. The plan also documents the actions that have been and are being taken by the plan to address material differences in access and documents the reasons beyond the plan's control that the plan believes may contribute to the material differences in access. As a result, the network composition NQTLs with respect to mental health or substance use disorder benefits in the inpatient, in-network and outpatient, in-network classifications are no more restrictive than the predominant NQTLs that apply to substantially all medical/surgical benefits in the same classifications.

Example 11 – Separate employee assistance program (EAP) exhaustion treatment limitation applicable only to mental health or substance use disorder benefits. Example 11 in the

proposed rules amended Example 6 of the 2013 final regulations. These final rules retain this example as proposed with minor, non-substantive changes.

Specifically, in Example 11, an employer maintains both a major medical plan and an EAP. The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions. These sessions, together with other benefits provided by the EAP, are not significant benefits in the nature of medical care. Participants are eligible for mental health or substance use disorder benefits under the major medical plan only after exhausting the counseling sessions provided by the EAP, and no similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical plan.

Example 11 concludes that the requirement that limits eligibility for mental health and substance use disorder benefits under the major medical plan until benefits under an EAP are exhausted is an NQTL subject to MHPAEA. Because the limitation does not apply to medical/surgical benefits, it violates the prohibition on a separate NQTL applicable only to mental health or substance use disorder benefits. The Departments have also included language to note that under other Departmental regulations,¹⁰⁰ the EAP does not qualify as excepted benefits because participants in the major medical plan are required to use and exhaust benefits under the EAP (making the EAP a gatekeeper) before they are eligible for benefits under the plan.

Example 12 – Separate exclusion for treatment in a residential facility applicable only to mental health and substance use disorder benefits. Under Example 12 of these final rules, which is substantively identical to Example 12 in the proposed rules and only includes minor, non-substantive changes, a plan generally covers inpatient, in-network and inpatient, out-of-network treatment without any limitations on setting, including skilled nursing facilities and rehabilitation hospitals, provided other medical necessity standards are satisfied. The plan has an exclusion for

¹⁰⁰ 26 CFR 54.9831-1(c)(3)(vi)(B)(I), 29 CFR 2590.732(c)(3)(vi)(B)(I) and 45 CFR 146.145(b)(3)(vi)(B)(I).

treatment at residential facilities, which the plan defines as an inpatient benefit for mental health and substance use disorder benefits. This exclusion was not generated through any broader NQTL (such as medical necessity or other clinical guideline).

Example 12 concludes that the plan violates these final rules. The exclusion of residential treatment is a separate NQTL applicable only to mental health and substance use disorder benefits in the inpatient, in-network and inpatient, out-of-network classifications because the plan does not apply a comparable exclusion with respect to any medical/surgical benefits in the same benefit classification.

Example 13 – Impermissible NQTL imposed following a final determination of noncompliance and direction by the Secretary. In the proposed rules, Example 7 provides that a plan that continues to impose an NQTL after the Secretary issues a final determination of noncompliance with the NQTL comparative analysis documentation requirements and directs the plan not to impose the NQTL by a certain date, would not comply with the requirements applicable to NQTLs. These final rules retain this example with modifications to add specificity and reflect the substantive provisions of the final rule and redesignate it as Example 13.

In this example, following an initial request by the Secretary for a plan's comparative analysis of the plan's exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification, the plan submits a comparative analysis for the NQTL. The comparative analysis included insufficient information to conduct an appropriate comparison of the NQTL. After review of the comparative analysis, as well as additional information submitted by the plan after the Secretary determines that the plan has not submitted sufficient information to be responsive to the request, the Secretary makes an initial determination that the comparative analysis fails to demonstrate that the processes, strategies, evidentiary standards, and other factors used in designing and applying the exclusion to mental health or substance use disorder benefits in the inpatient, in-network classification are

comparable to, and applied no more stringently than, those used in designing and applying the NQTL to medical/surgical benefits in the classification. Although the plan submits a corrective action plan and additional comparative analyses within 45 calendar days after the initial determination, it does not eliminate or alter the exclusion or alter the processes, strategies, evidentiary standards, and other factors used in designing and applying the exclusion. Moreover, the additional comparative analysis still does not include sufficient information. The Secretary determines that the additional comparative analyses do not demonstrate compliance with the requirements for NQTLs under MHPAEA. Accordingly, the plan receives a final determination of noncompliance with the statutory comparative analysis documentation requirements from the Secretary, which concludes that the plan did not demonstrate compliance through the comparative analysis process. After considering the relevant facts and circumstances, and considering the interests of plan participants and beneficiaries, as well as feedback from the plan, the Secretary directs the plan not to impose the NQTL by a certain date, unless and until the plan demonstrates compliance to the Secretary or takes appropriate action to remedy the violation. The plan makes no changes to its plan terms by that date and continues to impose the exclusion of benefits for failure to complete a course of treatment in the inpatient, in-network classification.

This Example 13 concludes that, by continuing to impose the exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification after the Secretary directs the plan not to impose this NQTL, the plan violates the requirements of these final rules related to the effect of a final determination of noncompliance.

4. Prohibition on Financial Requirements and Treatment Limitations Applicable Only to Mental Health or Substance Use Disorder Benefits - 26 CFR 54.9812-1(c)(2)(i)

and (c)(4)(iv), 29 CFR 2590.712(c)(2)(i) and (c)(4)(iv), and 45 CFR 146.136(c)(2)(i) and (c)(4)(iv)

The Departments proposed to amend the general parity requirement set forth in 26 CFR 54.9812-1(c)(2)(i), 29 CFR 2590.712(c)(2)(i), and 45 CFR 146.136(c)(2)(i) by adding a sentence to reiterate that a plan or issuer may not impose any financial requirement or treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and not to any medical/surgical benefits in the same benefit classification. The preamble to the proposed rules noted that the 2013 final regulations do not explicitly incorporate the statutory prohibitions on separate financial requirements and treatment limitations that are imposed only with respect to mental health or substance use disorders in Code sections 9812(a)(3)(A)(i) and (ii), ERISA sections 712(a)(3)(A)(i) and (ii), and PHS Act sections 2726(a)(3)(A)(i) and (ii), respectively, but noted that financial requirements and quantitative treatment limitations imposed only with respect to mental health or substance use disorder benefits generally could not comply with the parity requirements contained in paragraph (c)(3) of 26 CFR 54.9812-1, 29 CFR 2590.712, and 45 CFR 146.136. Additionally, the Departments referred to an example in the 2013 final regulations that demonstrates and affirms that an NQTL applied only to mental health or substance use disorder benefits would not be permissible.¹⁰¹ The Departments noted in the proposed rules that these amendments would directly incorporate the statutory prohibitions by expressly stating that plans and issuers are not permitted to impose any type of financial requirement or treatment limitation that applies only to mental health or substance use disorder benefits and not to medical/surgical benefits in the same classification.

Additionally, since the 2013 final regulations state that the application of paragraph (c)(2) to NQTLs is addressed in paragraph (c)(4) of the regulations, the Departments also proposed to

¹⁰¹ See 26 CFR 54.9812-1(c)(4)(iii) Example 6, 29 CFR 2590.712(c)(4)(iii) Example 6, and 45 CFR 146.136(c)(4)(iii) Example 6.

add similar language to the proposed rules for NQTLs at 26 CFR 54.9812-1(c)(4)(vi), 29 CFR 2590.712(c)(4)(vi), and 45 CFR 146.136(c)(4)(vi), which cross-reference the language proposed to be added to 26 CFR 54.9812-1(c)(2)(i), 29 CFR 2590.712(c)(2)(i), and 45 CFR 146.136(c)(2)(i). The Departments proposed that a plan or issuer may not apply any NQTL that is applicable only with respect to mental health or substance use disorder benefits and not with respect to any medical/surgical benefits in the same benefit classification. The Departments noted that an exclusion of benefits for a mental health condition or substance use disorder in a classification that is merely an expression of another NQTL, such as medical necessity requirements or experimental or investigational exclusions, that is applied with respect to medical/surgical benefits in the same classification would not be considered a separately applicable treatment limitation. As a result, such an NQTL would be evaluated to determine whether such NQTL complies with all applicable requirements of these final rules.

Many commenters supported reiterating the statutory requirement that a plan or issuer must not impose a financial requirement or treatment limitation that is applicable only to mental health or substance use disorder benefits and specifying that if an exclusion of a mental health or substance use disorder treatment or service is not due to the application of another NQTL to both mental health or substance use disorder benefits and medical/surgical benefits in a classification, such exclusion would be subject to this prohibition. Commenters also agreed with the Departments that, if an exclusion of benefits for a mental health condition or substance use disorder is not generated through a process, strategy, or factor, or informed by an evidentiary standard of a broader NQTL like medical necessity, such an exclusion would need to be evaluated for parity compliance (and would therefore be prohibited, provided it does not apply to medical/surgical benefits). One commenter requested the Departments clarify that a specific NQTL need not be applicable to medical/surgical benefits in the same classification to overcome the notion that the limitation is separately applicable.

The Departments agree with commenters that the proposed prohibition on NQTLs applicable only to mental health or substance use disorder benefits is consistent with the statute, and that an exclusion of benefits for a mental health condition or substance use disorder otherwise covered under the plan or coverage not generated through a process, strategy, or factor, or informed by an evidentiary standard of a broader NQTL like medical necessity should be evaluated for MHPAEA compliance. This exclusion is prohibited as an impermissible separate treatment limitation if a comparable exclusion does not apply to medical/surgical benefits in the classification. Additionally, as evaluation of a plan's or issuer's compliance with MHPAEA is generally assessed within a classification of benefits, the prohibition on separately applicable financial requirements or treatment limitations applies with respect to benefits in the same benefit classification. Therefore, the Departments are finalizing these amendments as proposed at 26 CFR 54.9812-1(c)(2)(i) and (c)(4)(iv), 29 CFR 2590.712(c)(2)(i) and (c)(4)(iv), and 45 CFR 146.136(c)(2)(i) and (c)(4)(iv) to reiterate that a plan or issuer may not impose any financial requirement or treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and not with respect to any medical/surgical benefits in the same benefit classification.

5. Other Amendments

a. Meaningful Benefits

The Departments proposed to amend 26 CFR 54.9812-1(c)(2)(ii)(A), 29 CFR 2590.712(c)(2)(ii)(A), and 45 CFR 146.136(c)(2)(ii)(A) to specify that, if a plan (or health insurance coverage) provides any benefits for a mental health condition or substance use disorder in any classification of benefits, benefits for that mental health condition or substance use disorder must be provided in every classification in which medical/surgical benefits are provided. The proposed rules proposed that for purposes of this provision, if a plan (or health insurance coverage) provides any benefits for a mental health condition or substance use disorder

in any classification of benefits, the plan or issuer would not be considered to provide benefits for the mental health condition or substance use disorder in every classification in which medical/surgical benefits are provided unless the plan or issuer provides meaningful benefits for treatment for that condition or disorder in each classification, as determined in comparison to the benefits provided for medical conditions and surgical procedures in such classification. The Departments noted in the preamble to the proposed rules that this requirement would ensure that, when plans and issuers cover benefits for a range of services or treatments for medical/surgical conditions in a classification, plans and issuers cannot provide, for example, only one limited benefit for a mental health condition or substance use disorder in that classification. The Departments requested comments on this provision of the proposed rules, including whether and how to define “meaningful benefits” and other potential alternatives.

Many commenters expressed support for this provision of the proposed rules. Several of these commenters noted that this requirement is essential to ensure that plans and issuers are no longer able to deny reimbursement of fundamental evidence-based services for the treatment of mental health conditions and substance use disorders in a way that similar services would never be excluded for medical/surgical care.

Conversely, some commenters opposed adopting any “meaningful benefit” or similar standard in these final rules. Several commenters argued that this proposed requirement exceeds the Departments’ statutory authority, and that by requiring “meaningful benefits,” the Departments would convert MHPAEA into a mandate to cover mental health and substance use disorder benefits. Other commenters stated that the approach would require plans and issuers to compare specific treatments, which is inconsistent with congressional intent to preserve the ability of a plan or issuer to determine whether a specific treatment is medically necessary or appropriate, instead of comparing coverage for medical/surgical benefits and mental health or substance use disorder benefits more generally. Additionally, one commenter stated this

provision would significantly broaden the scope and complexity of a plan's or issuer's compliance analysis and limit flexibility in benefit design. Some commenters noted that the meaningful benefits standard, as proposed, might adversely affect the operation of closed panel plans, as the provision of any services outside the network could require such plans to evaluate and expand the scope of covered mental health and substance use disorder benefits, or alternatively, restrict out-of-network benefits.

Commenters also expressed concern that the term "meaningful benefits" may not include services such as coordinated specialty care for first episode psychosis, and without a clear definition of the term, such services would not be covered for privately insured individuals. Another commenter stated that the proposed meaningful benefit standard may overlook and devalue the mental health and substance use disorder services provided by primary care physicians and pediatricians, who are generally considered to be medical/surgical providers.

The Departments received many comments on how to define the term "meaningful benefits," as well as potential alternatives, including whether it would be more practical to require plans and issuers to provide "substantial coverage" of mental health and substance use disorder benefits or benefits for the "primary or most common or frequent types of treatment for a covered condition or disorder" in each classification in which medical/surgical benefits are provided. Many commenters generally recommended defining "meaningful benefits" based on independent medical and clinical guidelines or primary evidence-based treatment based on independent standards of current medical practice. Some commenters recommended that "meaningful benefits" be defined as the full continuum of services that are consistent with independent professional medical or clinical standards (or, equivalently, the term "generally accepted standards of care"). Other commenters recommended that these final rules require coverage of at least one primary treatment for a mental health condition or substance use disorder in a classification or coverage that aligns with coverage under the State's designated

EHB-benchmark plan. A few commenters recommended that the definition of “meaningful benefits” or primary treatment be further developed through additional notice and comment rulemaking or a request for information.

The Departments recognize, as commenters stated, that additional clarifications are warranted regarding the definition of the term “meaningful benefits.” With regard to comments stating that this provision of the proposed rules is a benefit mandate that would require plans and issuers to cover specific treatments, as well as comments that raised concerns about specific mental health and substance use disorder services not being considered meaningful benefits (and therefore not being covered by plans and issuers), the Departments reiterate that this requirement does not require plans and issuers to cover mental health and substance use disorder benefits independently or irrespective of what is provided with respect to medical/surgical benefits.

After considering comments received, the Departments are finalizing the proposed meaningful benefits standard, with modifications and clarifications. These final rules require that, if a plan (or health insurance coverage) provides any benefits for a mental health condition or substance use disorder in any classification of benefits, it must provide meaningful benefits for that mental health condition or substance use disorder in every classification in which medical/surgical benefits are provided. For this purpose, whether the benefits provided are meaningful benefits is determined in comparison to the benefits provided for medical conditions and surgical procedures in the classification, and requires, at a minimum, coverage of benefits for that condition or disorder in each classification in which the plan (or coverage) provides benefits for one or more medical conditions or surgical procedures. Additionally, a plan (or coverage) does not provide meaningful benefits under these final rules unless it also provides benefits for a core treatment for that condition or disorder in each classification in which the plan (or coverage) provides benefits for one or more medical conditions or surgical procedures.

The Departments note that, while these final rules only require plans and issuers to cover a minimum of one core treatment for a covered mental health condition or substance use disorder in every classification of benefits in which the plan (or coverage) provides benefits for a core treatment for one or more medical conditions or surgical procedures, plans and issuers are strongly encouraged to provide more robust coverage to ensure that participants and beneficiaries have access to the mental health and substance disorder care they need. The Departments incorporate this requirement in 26 CFR 54.9812-1(c)(2)(ii), 29 CFR 2590.712(c)(2)(ii), and 45 CFR 146.136(c)(2)(ii) of these final rules, as suggested by commenters, to ensure that plans and issuers offering mental health or substance use disorder benefits do not provide coverage for the full range of medical/surgical benefits in a classification, yet cover only one or a few isolated ancillary benefits for a covered mental health condition or substance use disorder in the same classification. As noted earlier in this preamble, a commenter expressed the concern that this requirement would broaden the scope and complexity of analyzing MHPAEA NQTL compliance and limit benefit design. However, as noted above, this provision amends the general requirement and limits the ability of a plan or issuer to implement a benefit design that provides robust benefits for medical conditions and surgical procedures while offering minimal benefits for mental health conditions and substance use disorders. This requirement, in combination with the other amendments to these final rules, will help to better ensure equitable access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

For purposes of these final rules, a core treatment for a condition or disorder is a standard treatment or course of treatment, therapy, service, or intervention indicated by generally recognized independent standards of current medical practice. This definition of “meaningful benefits” takes an approach that is similar to the suggestion made by multiple commenters, as noted earlier in this preamble, that meaningful benefits be defined as the primary treatment for a condition or disorder based on generally recognized independent standards of current medical

practice. However, instead of defining “meaningful benefits” as coverage for the primary treatment for a condition or disorder in a classification, these final rules require the coverage of a core treatment because, from a medical or clinical perspective, there may not be a single primary treatment in many cases for a given condition or disorder (even where there are evidence-based treatments, services, therapies, and standards of care).

These final rules do not set forth specific requirements for plans and issuers to determine what constitutes a core treatment for any particular condition or disorder, but plans and issuers, in determining a core treatment for a condition or disorder in this context, should rely on current evidence-based medical and clinical information. The Departments note that a core treatment for a particular condition or disorder may not necessarily refer to a single item or service but may instead encompass a suite of items and services that together constitute a core treatment, depending on the relevant generally recognized independent standards of current medical practice. In such a case, the Departments expect that under this provision, plans and issuers will cover all components of at least one core treatment if the items and services provided as part of the treatment span a number of classifications, provided the plan or coverage provides benefits for one or more core treatments for any medical conditions or surgical procedures in those classifications. For example, one core treatment for major depressive disorder generally includes prescription drugs and psychotherapy. However, a core treatment may also include only prescription drugs or only psychotherapy (and in cases of severe depression, may also include inpatient hospitalization or other types of residential or outpatient treatment). The Departments note that a core treatment, with respect to a classification, may include the same item or service in other benefit classifications. For example, for major depressive disorder, psychotherapy could be a core treatment with respect to both the outpatient, in-network and outpatient, out-of-network classifications. In response to commenter requests for examples of meaningful benefits, the Departments have modified proposed Examples 5 and 6, and added examples that further

illustrate the application of the meaningful benefit standard, as discussed in more detail later in this preamble.

The Departments also recognize the workability concerns raised by commenters with respect to the proposed meaningful benefits standard in the proposed rules. In response to these comments, the Departments include language in these final rules to provide that, if there is no core treatment for a mental health condition or substance use disorder with respect to a classification, the plan (or coverage) is not required to provide benefits for a core treatment for such condition or disorder in that classification. Instead, the plan (or coverage) must provide benefits for such condition or disorder in every classification in which medical/surgical benefits are provided. Additionally, under these final rules, if the plan (or coverage) does not provide meaningful benefits for any medical condition or surgical procedure in a classification, the plan (or coverage) is not required to provide meaningful benefits for any mental health conditions or substance use disorders in the classification. This language further makes clear that the requirement to provide coverage of meaningful benefits for a condition or disorder is not a coverage mandate, but rather another approach to ensuring parity between mental health or substance use disorder benefits and medical/surgical benefits in a classification.

The Departments also stated in the preamble to the proposed rules that they recognize that the meaningful benefits proposal is related to an issue characterized as “scope of services” or “continuum of care,” as addressed in the preamble to the 2013 final regulations.¹⁰² “Scope of services,” when used in this context, generally refers to the types of treatment and treatment settings that are covered by a plan or coverage. The Departments requested comments on whether additional guidance is needed regarding how the proposed meaningful benefits standard would interact with the approach related to scope of services adopted under the 2013 final regulations.

¹⁰² See 78 FR 68240, 68246-68247 (Nov. 13, 2013).

Commenters suggested the Departments add “scope of services” or “scope of covered services” to the illustrative, non-exhaustive list of NQTLs. These commenters noted the importance of psychiatric care being fully integrated with the rest of medicine in primary care settings and in hospitals. Despite the language in the 2013 final regulations on intermediate services,¹⁰³ these commenters highlighted that plans and issuers sometimes exclude fundamental services and do not assess those exclusions as NQTLs. These commenters noted that identifying “scope of services” or “scope of covered services” as a covered NQTL would remove ambiguity and require plans and issuers to determine whether an exclusion of mental health or substance use disorder benefits met the NQTL comparability and stringency test.

The Departments acknowledge these comments and the importance of psychiatric care being fully integrated in primary care settings and in hospitals but decline to add scope of services as an NQTL in the illustrative list in these final rules. Like the 2013 final regulations, these final rules are not intended to mandate coverage of any particular benefits. These final rules continue to require mental health and substance use disorder benefits and medical/surgical benefits to be assigned to the six classifications set forth in the regulations. For intermediate services like residential treatment, partial hospitalization, and intensive outpatient treatment, the Departments continue to require plans and issuers to assign covered intermediate mental health and substance use disorder benefits to the existing six benefit classifications in the same way that they assign comparable intermediate medical/surgical benefits to these classifications.¹⁰⁴ The

¹⁰³ *Ibid.* In the preamble to the 2013 final regulations, the Departments stated that plans and issuers must assign covered intermediate mental health and substance use disorder benefits to the existing six benefit classifications in the same way that they assign comparable intermediate medical/surgical benefits to these classifications. The 2013 final regulations also included additional examples illustrating the application of the NQTL rules to plan exclusions affecting the scope of services and clarified that plan or coverage restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of treatment must comply with the NQTL parity standard under the final rules.

¹⁰⁴ *Id.* at 68247. For example, as described in the preamble to the 2013 final regulations, if a plan or issuer classifies care in skilled nursing facilities or rehabilitation hospitals as inpatient benefits, then the plan or issuer must likewise treat any covered care in residential treatment facilities for mental health or substance use disorders as an inpatient benefit. In addition, if a plan or issuer treats home health care as an outpatient benefit, then any covered intensive outpatient mental health or substance use disorder services and partial hospitalization must be considered outpatient benefits as well.

Departments point to the examples in these final rules that address coverage restrictions based on geographic location, facility types, provider specialty, and other criteria that limit the scope or duration of benefits. Plans and issuers are required to comply with the NQTL requirements with respect to these types of restrictions. Further, the Departments note that exclusions of services to treat a condition or disorder otherwise covered by the plan or coverage are NQTLs that must comply with the provisions applicable to NQTLs under the final rules (including that there are no separate NQTLs that apply only to mental health or substance use disorder benefits in a classification).

In response to questions about whether the No Surprises Act's requirements that certain out-of-network items and services be covered by plans and issuers might adversely affect the operation of closed panel plans by effectively requiring the coverage of out-of-network mental health or substance use disorder benefits (including in the context of the meaningful benefits standard in these final rules), the Departments note that nothing in these final rules requires a plan or coverage that provides coverage for medical/surgical benefits in the inpatient, out-of-network and outpatient, out-of-network classifications only to the extent required under Code sections 9816 and 9817, ERISA sections 716 and 717, and PHS Act sections 2799A-1 and 2799A-2 to provide additional mental health or substance use disorder benefits in the inpatient, out-of-network and outpatient, out-of-network classifications in accordance with this section. This approach is consistent with language in the 2013 final regulations which stated that compliance with PHS Act section 2713 (requiring coverage for recommended preventive services without any cost-sharing requirements) should not require that the full range of benefits for a mental health condition or substance use disorder be provided under MHPAEA. The proposed amendments to 26 CFR 54.9812-1(c)(2)(ii), 29 CFR 2590.712(c)(2)(ii), and 45 CFR 146.136(c)(2)(ii) would also make explicit the Departments' interpretation that the requirement to provide coverage for mental health and substance use disorder benefits in each classification

in which medical/surgical benefits are provided applies on a condition or disorder basis, an interpretation that the Departments have held since the 2010 interim final rules implementing MHPAEA.¹⁰⁵

The Departments solicited comments on the provisions of the proposed rules on classifications of benefits, including whether additional flexibility is needed to account for benefits that are difficult to place into classifications under the current structure, and whether additional guardrails or protections should be required. The Departments received very few comments on this issue. Most of the comments received related to the classification of certain benefits as medical/surgical instead of mental health or substance use disorder. One comment suggested that a new classification of “urgent/crisis care” should be added to encompass both medical/surgical urgent care and mental health or substance use disorder crisis services. Because additional classifications are not required or necessary, the Departments are finalizing these amendments as proposed. Plans and issuers are reminded that the list of the current classifications in these final rules is exhaustive. Classification of benefits as medical/surgical benefits instead of mental health or substance use disorder benefits is discussed in more detail earlier in this preamble. The Departments will consider whether and to what extent additional guidance may be needed to address the application of MHPAEA to urgent/crisis care.

In the proposed rules, the Departments proposed to add two examples to 26 CFR 54.9812-1(c)(2)(ii)(C), 29 CFR 2590.712(c)(2)(ii)(C), and 45 CFR 146.136(c)(2)(ii)(C) to illustrate the application of these proposed amendments. The Departments are finalizing these examples with modifications to align with these final rules and are providing additional clarity on the application of the meaningful benefits standard to plans and issuers by redesignating proposed Example 6 as Example 7, and adding new Examples 6 and 8.

¹⁰⁵ 75 FR 5410, 5413 (Feb. 2, 2010).

In proposed Example 5, a plan generally covers treatment for ASD, a mental health condition,¹⁰⁶ and covers outpatient, out-of-network developmental evaluations for ASD but excludes all other benefits for outpatient treatment for ASD, including ABA therapy, when provided on an out-of-network basis. The preamble of the proposed rules stated that, based on generally recognized independent standards of current medical practice consulted, ABA therapy is the primary treatment for ASD in children. In this proposed example, the plan generally covers the full range of outpatient treatments and treatment settings, including primary treatments, for medical conditions and surgical procedures when provided on an out-of-network basis. The proposed example concluded that the plan violates the proposed meaningful benefits standard because, by not providing benefits for ABA therapy, it fails to provide meaningful benefits for ASD in the outpatient, out-of-network classification, but generally covers the full range of medical/surgical benefits in the classification.

In proposed Example 6, a plan generally covers diagnosis and treatment for eating disorders, a mental health condition, but specifically excludes coverage for nutrition counseling to treat eating disorders, including in the outpatient, in-network classification. The example in the proposed rules noted that nutrition counseling is the primary treatment for eating disorders in the outpatient, in-network classification and stated that the plan generally provides benefits for the primary treatments for medical conditions and surgical procedures in the outpatient, in-network classification. The proposed example concluded that the plan violates the proposed meaningful benefits standard because, by not providing benefits for nutrition counseling, it fails to provide meaningful benefits for the treatment of eating disorders in the outpatient, in-network classification, as determined in comparison to the benefits provided for medical/surgical

¹⁰⁶ As stated earlier in this preamble, the proposed rules stated, and these final rules continue to state, that for purposes of MHPAEA, ASD is a mental health condition under generally recognized independent standards of current medical practice. Therefore, benefits for this condition are considered mental health benefits, and are subject to the protections of MHPAEA and its implementing regulations.

conditions in the classification. The Departments noted that, if the plan covers medical/surgical benefits for nutrition counseling, the plan would also violate the prohibition on separate NQTLs applicable only to mental health or substance use disorder benefits.

Several commenters generally expressed support for the proposed Examples 5 and 6, which illustrated clear instances where exclusions of key services for ASD and eating disorders violate MHPAEA, noting that these examples remove any ambiguity whether such exclusions are inconsistent with MHPAEA's requirements. One commenter expressed concerns about references to ABA therapy specifically because referring to a specific treatment may be limiting as evidence evolves regarding ASD. This commenter also cited a relatively weak evidence base for ABA therapy as a reason why the example should not specifically reference ABA therapy. Another commenter requested that Example 6 define "primary treatments" and "meaningful benefits" based on independent medical and clinical guidelines. A few commenters suggested that the Departments use the term "medical nutrition therapy" instead of nutrition counseling, to better reflect the clinical term used in treatment codes. Another commenter suggested providing an additional example related to the treatment of OUD, to reinforce the clear requirement to cover opioid treatment program services as part of the "meaningful" coverage of substance use disorder benefits in all classifications in which meaningful medical/surgical services are covered.

After considering comments, the Departments are finalizing Examples 5 and 6 in the proposed rules with modifications, to make the examples consistent with the clarifications described earlier in this preamble stating that a plan or issuer will be required to provide meaningful benefits for a mental health condition or substance use disorder in a classification if it provides meaningful benefits for one or more medical conditions or surgical procedures in the same classification. These final rules also make minor clarifying changes to reflect more appropriate clinical terminology and introduce two new, additional examples. In each example in these final rules that illustrates the meaningful benefits standard, the group health plan is subject

to the requirements of MHPAEA and provides both medical/surgical benefits and mental health and substance use disorder benefits. Additionally, these final rules note that references in these examples to any particular core treatment are included for illustrative purposes only and are not intended to limit coverage in any way. The Departments remind plans and issuers that they must consult generally recognized independent standards of *current* medical practice to determine the applicable core treatment, therapy, service, or intervention for any covered condition or disorder, and note that, as medical evidence evolves, the core treatment options for any condition or disorder may change.

In Example 5 of these final rules, a plan covers treatment for ASD. As explained earlier in this preamble and in the proposed rules, for purposes of MHPAEA, ASD is a mental health condition under generally recognized independent standards of current medical practice.¹⁰⁷ Specifically, the plan covers outpatient, out-of-network developmental screenings for ASD, but excludes all other benefits for outpatient treatment for ASD, including ABA therapy, when provided on an out-of-network basis. The plan generally covers the full range of outpatient treatments (including core treatments) and treatment settings for medical conditions and surgical procedures when provided on an out-of-network basis. Under the generally recognized independent standards of current medical practice consulted by the plan, developmental screenings alone that are covered for diagnostic purposes, without any coverage for a therapeutic intervention, do not constitute a core treatment for ASD. Example 5 concludes that the plan violates these final rules. Although the plan covers benefits for ASD, in the outpatient, out-of-network classification, it only covers developmental screenings, so it does not cover a core treatment for ASD in the classification. Since the plan generally covers the full range of medical/surgical benefits including a core treatment for one or more medical conditions or

¹⁰⁷ DSM (5th ed.), Section II: Diagnostic Criteria and Codes, Autism Spectrum Disorder.

surgical procedures in the classification, it fails to provide meaningful benefits for treatment of ASD in the classification, as required under these final rules.

New Example 6 of these final rules starts with the same facts as Example 5 and illustrates how these final rules apply where a plan or issuer does not cover a core treatment for any medical conditions or surgical procedures in a classification. The facts of new Example 6 state that the plan is a health maintenance organization (HMO) that does not cover the full range of medical/surgical benefits, including a core treatment for any medical conditions or surgical procedures in the outpatient, out-of-network classification (except as required under Code sections 9816 and 9817, ERISA sections 716 and 717, and PHS Act sections 2799A-1 and 2799A-2), but covers benefits for medical conditions and surgical procedures in the inpatient, in-network; outpatient, in-network; emergency care, and prescription drug classifications. Example 6 concludes that the plan does not violate the rules in 26 CFR 54.9812-1(c)(2)(ii), 29 CFR 2590.712(c)(2)(ii), and 45 CFR 146.136(c)(2)(ii). Because the plan does not provide meaningful benefits including a core treatment for any medical condition or surgical procedure in the outpatient, out-of-network classification (except as required under Code sections 9816 and 9817, ERISA sections 716 and 717, and PHS Act sections 2799A-1 and 2799A-2), the plan is not required to provide meaningful benefits, for any mental health conditions or substance use disorders in that classification.¹⁰⁸ The Departments note that, nevertheless, the plan must provide meaningful benefits for each mental health condition and substance use disorder for which the plan provides benefits in every classification in which meaningful medical/surgical benefits are provided. Additionally, the Departments note that plans and issuers must comply with other

¹⁰⁸ As discussed earlier in this preamble, the Departments note that this conclusion would hold if the plan provides benefits for a core treatment for a medical/surgical condition in the outpatient, out-of-network classification, solely to meet requirements under the provisions of the No Surprises Act.

requirements of these final rules, as applicable, including the prohibition on NQTLs applicable only to mental health and substance use disorder benefits.¹⁰⁹

In Example 7 of these final rules, which was redesignated from Example 6 in the proposed rules, a plan provides extensive benefits, including for core treatments for many medical conditions and surgical procedures in the outpatient, in-network classification, including nutrition counseling for diabetes and obesity. The plan also generally covers diagnosis and treatment for eating disorders, which are mental health conditions, including coverage for nutrition counseling¹¹⁰ to treat eating disorders in the outpatient, in-network classification. Under this example, nutrition counseling is a core treatment for eating disorders, in accordance with generally recognized independent standards of current medical practice consulted by the plan. Example 7 concludes that the plan does not violate the meaningful benefits standard in these final rules. The coverage of diagnosis and treatment for eating disorders, including nutrition counseling, in the outpatient, in-network classification results in the plan providing meaningful benefits for the treatment of eating disorders in the classification, as determined in comparison to the benefits provided for medical conditions and surgical procedures in the classification.

In response to commenters who requested an additional example illustrating what plans and issuers must do to provide meaningful benefits for the treatment of OUD, the Departments are also finalizing new Example 8. In this new example, a plan provides extensive benefits for

¹⁰⁹ For example, if the plan excludes coverage for ABA therapy and the exclusion does not comply with the provisions applicable to NQTLs under the final rules—including the design and application requirements and the relevant data evaluation requirements (if the exclusion was generated through a broader NQTL such as medical necessity or other clinical guideline that also applies to medical/surgical benefits in the relevant classification), or the requirement that there are no separate NQTLs that apply only to mental health or substance use disorder benefits in a classification—the plan violates the rules of 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4).

¹¹⁰ The proposed rules and these final rules refer to benefits for “nutrition counseling.” The Departments acknowledge several commenters who noted that other terminology may be more appropriate, such as “medical nutrition therapy” or “medical nutrition therapy provided by a dietitian” using specific CPT codes. The Departments intend that references to nutritional counseling for eating disorders be interpreted broadly to include these and other appropriate types of treatment for eating disorders.

the core treatments for many medical conditions and surgical procedures in the outpatient, in-network and prescription drug classifications. The plan provides coverage for diagnosis and treatment for OUD, a substance use disorder, in the outpatient, in-network classification, by covering counseling and behavioral therapies, also referred to as psychosocial treatments. Additionally, the plan provides coverage for diagnosis and treatment for OUD, in the prescription drug classification, by covering medications to treat opioid use disorder (MOUD). Under this example, counseling and behavioral therapies and MOUD, in combination, are one of the core treatments for OUD, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

Example 8 concludes that the plan does not violate these final rules. The coverage of counseling and behavioral therapies and MOUD, in combination, in the outpatient, in-network classification and prescription drug classification, respectively, results in the plan providing meaningful benefits for the treatment of OUD in the outpatient, in-network and prescription drug classifications.

b. Classification of Benefits

The 2013 final regulations set forth the only classifications of benefits that may be used in applying the parity rules for financial requirements and treatment limitations and listed specific instances when a plan or issuer may divide benefits into sub-classifications beyond the six classifications permitted in paragraph (c)(2)(ii)(A) of the 2013 final regulations. The Departments proposed to reiterate at 26 CFR 54.9812-1(c)(3)(iii), 29 CFR 2590.712(c)(3)(iii), and 45 CFR 146.136(c)(3)(iii) that a plan or issuer may not divide benefits into any sub-classifications other than those specifically permitted under the regulations. The Departments did not propose any substantive changes to the existing sub-classifications or to permit any new sub-classifications. The Departments also proposed non-substantive changes to 26 CFR 54.9812-

1(c)(3)(iv), 29 CFR 2590.712(c)(3)(iv), and 45 CFR 146.136(c)(3)(iv) to label the tables in the examples, update references in the examples, and redesignate the examples as paragraphs.

A few commenters expressed concerns about the classification of certain types of benefits and providers into existing classifications and sub-classifications, including intensive outpatient treatment, partial hospitalization programs, and other team-based models of care. Some commenters requested additional clarification, including a standard definition for the outpatient sub-classifications, citing the fact that some plans and issuers use differing variations to define the outpatient, office visit sub-classification. One commenter requested that the Departments indicate that the sub-classifications applicable to financial requirements and quantitative treatment limitations under paragraph (c)(3)(iii) of the 2013 final regulations may also be used for NQTLs.

As discussed earlier in this preamble, plans and issuers must assign covered intermediate mental health and substance use disorder benefits to the existing six benefit classifications in the same way that they assign comparable intermediate medical/surgical benefits to these classifications. Additionally, plans and issuers that opt to use sub-classifications for outpatient benefits must assign covered outpatient benefits to the permissible outpatient sub-classifications for mental health and substance use disorder benefits in the same way they assign comparable medical/surgical benefits. The Departments are finalizing the clarification that a plan or issuer is not permitted to divide benefits into any sub-classifications other than those specifically permitted under the regulations,¹¹¹ as well as the clarification that plans and issuers may use the permissible sub-classifications under the 2013 final regulations when applying all of the rules for financial requirements and treatment limitations, including NQTLs.¹¹² Consistent with the proposed rules, the Departments are not making any substantive changes to the existing sub-

¹¹¹ 26 CFR 54.9812-1(c)(3)(iii), 29 CFR 2590.712(c)(3)(iii), and 45 CFR 146.136(c)(3)(iii).

¹¹² 26 CFR 54.9812-1(c)(2)(ii)(A), 29 CFR 2590.712(c)(2)(ii)(A), and 45 CFR 146.136(c)(2)(ii)(A).

classifications or to permit any new sub-classifications of benefits in these final rules. The Departments are also finalizing the non-substantive changes to 26 CFR 54.9812-1(c)(3)(iv), 29 CFR 2590.712(c)(3)(iv), and 45 CFR 146.136(c)(3)(iv), for which no comments were received.

The Departments noted in the preamble to the proposed rules that they have received questions and requests for guidance on how to comply with MHPAEA's requirements with respect to telehealth benefits, including where telehealth fits into the existing classifications and sub-classifications of benefits and whether changes are necessary to account for telehealth benefits. The Departments did not propose any changes in the proposed rules with respect to telehealth benefits and instead stated that they expected plans and issuers to treat telehealth benefits the same way they treat those benefits when provided in person in determining the classification or sub-classifications in which a particular benefit belongs. The Departments requested comments on whether changes to the framework and existing regulations implementing MHPAEA were necessary to account for telehealth benefits.

Several commenters stated that the expansion of telehealth services can supplement a plan's or issuer's network where there are in-person provider shortages and expressed support for treating telehealth benefits the same way those benefits are treated when provided in person. Some commenters discussed the growth and sustained usage of telehealth services since the start of the COVID-19 pandemic, particularly for mental health and substance use disorder services. Commenters stressed that telehealth is particularly valuable in rural and medically underserved areas. However, commenters stressed that telehealth may not be appropriate for all patients and does not fully replace in-person mental health and substance use disorder care. The Departments reiterate that plans and issuers are expected to treat telehealth benefits the same way they treat those benefits when provided in person in determining the classification or sub-classifications in which a particular benefit belongs.

As discussed earlier in the preamble, several commenters requested the Departments take into account telehealth in the relevant data evaluation requirements, as well as the requirements for standards related to network composition; however, the Departments are not addressing any specific data metrics for telehealth in these final rules. After reviewing the comments received on this issue, the Departments are not making changes in these final rules to address how to classify telehealth benefits. The Departments understand that telehealth plays a vital role in the provision of health care, particularly following the COVID-19 pandemic, and may support access to services for those with transportation barriers. When evaluating MHPAEA compliance, plans and issuers must include any covered telehealth benefits in the six classifications used to apply the parity requirements. The Departments also understand that telehealth can be used by plans and issuers as a tool to address provider shortages. These final rules also acknowledge telehealth can be leveraged to mitigate provider shortages in a geographic area and that leveraging telehealth is a potential reasonable action that can be used to address material differences in in-network access.

c. Availability of Plan Information

Treasury and DOL proposed to amend 26 CFR 54.9812-1(d)(3) and 29 CFR 2590.712(d)(3) by adding cross-references to proposed 26 CFR 54.9812-2 and 29 CFR 2590.712-1 to clarify that the comparative analyses and any other applicable information required under the CAA, 2021 are considered to be instruments under which a plan is established or operated, and therefore ERISA plans generally must furnish those documents to plan participants and beneficiaries upon request within 30 days, as required under section 104 of ERISA and 29 CFR 2520.104b-1. Additionally, the Departments proposed to amend 26 CFR 54.9812-1(d)(3), 29 CFR 2590.712(d)(3), and 45 CFR 146.136(d)(3) to clarify that the comparative analyses and any other applicable information required under the CAA, 2021 and the proposed rules qualify as documents, records, and other information relevant to the

claimant's claim for benefits to which plans and issuers must provide reasonable access upon request and free of charge. The Departments noted that this clarification is consistent with proposed 26 CFR 54.9812-2(e)(2), 29 CFR 2590.712-1(e)(2), and 45 CFR 146.137(e)(2), which generally would require plans and issuers to make available the comparative analyses required to be performed and documented under the CAA, 2021 when requested by participants and beneficiaries in ERISA plans, including when requested by a participant or beneficiary (or a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit determination related to mental health or substance use disorder benefits. The Departments noted in the preamble to the proposed rules that participants and beneficiaries in ERISA plans should be able to request copies of comparative analyses to ensure they are informed about their health plans or group health insurance coverage. Additionally, the Departments noted that these comparative analyses would be relevant to a claimant's claim for benefits and should therefore be available to participants or beneficiaries, and providers or other individuals acting as a participant's or beneficiary's authorized representative.

The Departments received several comments on this aspect of the proposed rules. A few commenters recommended that the Departments add language to the end of paragraph (d)(3) of 26 CFR 54.9812-1, 29 CFR 2590.712, and 45 CFR 146.136 making clear that no part of the comparative analyses or other applicable information required by 26 CFR 54.9812-2, 29 CFR 2590.712-1, or 45 CFR 146.137 may be withheld when requested, including because the information is proprietary, has commercial value, or is commercially protected. One of these commenters also urged the Departments to conform this provision with the standard proposed in 26 CFR 54.9812-2(e), 29 CFR 2590.712-1(e), and 45 CFR 146.137(e), so that individuals can have information at the time of the denial, which is needed to assess whether to raise a parity compliance claim in an internal grievance or appeal.

After considering comments, the Departments are finalizing the amendments to 26 CFR 54.9812-1(d)(3), 29 CFR 2590.712(d)(3), and 45 CFR 146.136(d)(3) as proposed, with a correction. The final rules remove the phrase “upon appeal of an adverse benefit determination” and replace it with “who have received an adverse benefit determination” in the third sentence of 26 CFR 54.9812-1(d)(3), 29 CFR 2590.712(d)(3), and 45 CFR 146.136(d)(3) to conform with the requirements under the DOL claims procedure rule at 29 CFR 2560.503–1 and rules issued by the Departments at 26 CFR 54.9815-2719, 29 CFR 2590.715-2719, and 45 CFR 147.136, which set forth rules regarding claims and appeals. The Departments also decline to exempt plans and issuers from providing certain types of information as part of their comparative analyses, to ensure transparency when an individual (or their authorized representative) requests a comparative analysis. As stated earlier in this preamble, this information is relevant to a claimant’s claim for benefits and should therefore be made available.

d. Other Provisions

The proposed rules included proposed amendments to 26 CFR 54.9812-1(e)(4), 29 CFR 2590.712(e)(4), and 45 CFR 146.136(e)(4) to include a reference to 26 CFR 54.9812-2(g), 29 CFR 2590.712-1(g), and 45 CFR 146.137(g) and to reflect current HHS regulations at 45 CFR 156.115(a)(3). The preamble to the proposed rules noted that existing regulations at 26 CFR 54.9812–1(e)(4), 29 CFR 2590.712(e)(4), and 45 CFR 146.136(e)(4) state that nothing in paragraphs (f) and (g) of the 2013 final regulations related to MHPAEA’s small employer exemption and increased cost exemption, respectively, changes the requirement under HHS regulations at 45 CFR 147.150 and 156.115, providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market providing mental health and substance use disorder services, including behavioral health treatment services, must comply with the provisions of 45 CFR 146.136 to satisfy the requirement to provide EHB. The preamble further stated that HHS has updated 45 CFR 156.115(a)(3) to state

that provision of EHB means that a health plan provides benefits that “[w]ith respect to the mental health and substance use disorder services, including behavioral health treatment services, required under § 156.110(a)(5), comply with the requirements under section 2726 of the Public Health Service Act and its implementing regulations.”¹¹³ The Departments did not receive comments on this provision. Therefore, to be consistent with the language contained in 45 CFR 156.115(a)(3), and to ensure that the cross-reference between the Departments’ MHPAEA implementing regulations and HHS’ EHB implementing regulations includes the requirement to comply with the provisions on comparative analyses, the Departments are finalizing this change as proposed with minor edits for precision, and to reflect that the requirement would only apply to a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market that is required to provide mental health and substance use disorder services, including behavioral health treatment services, as part of EHB required under 45 CFR 156.110(a)(5) and 156.115(a).

The proposed rules also included several technical edits to update paragraph (c)(3)(i) of the 2013 final regulations to add citations, include additional specificity in citations, and strike an outdated reference to limitations on annual deductibles for non-grandfathered health plans in the small group market at PHS Act section 2707(b) and ACA section 1302(c). The Departments did not receive any comments on these provisions and are finalizing as proposed.

The Departments are finalizing proposed technical amendments to 26 CFR 54.9812-1(c)(3)(iii)(A) and (B), 29 CFR 2590.712(c)(3)(iii)(A) and (B), and 45 CFR 146.136(c)(3)(iii)(A) and (B) to update citations. No comments were received on these technical amendments. In finalizing these provisions, the Departments are also restoring parenthetical

¹¹³ Patient Protection and Affordable Care Act; Updating Payment Parameters, Section 1332 Waiver Implementing Regulations, and Improving Health Insurance Markets for 2022 and Beyond, 86 FR 53412 (Sept. 27, 2021), <https://www.federalregister.gov/documents/2021/09/27/2021-20509/patient-protection-and-affordable-care-act-updating-payment-parameters-section-1332-waiver>.

references to health insurance coverage. Re-insertion of the phrase “health insurance coverage” is not intended to be a substantive change from the proposed rules, but rather corrects this omission and is consistent with the text of the 2013 final regulations.

B. New Regulations at 26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137

The CAA, 2021 amended MHPAEA, in part, to expressly require plans and issuers that offer coverage that provides both medical/surgical benefits and mental health or substance use disorder benefits and impose NQTLs on mental health or substance use disorder benefits to perform and document comparative analyses of the design and application of NQTLs, and make their comparative analyses and certain information available to the Departments or applicable State authorities upon request. The Departments proposed to codify this requirement.

Many commenters expressed support for codification of this requirement with several of these commenters noting that such detailed requirements are necessary to clarify what plans’ or issuers’ analyses must contain, as well as to hold plans and issuers accountable in following such requirements.

Many other commenters criticized the proposed content elements and requested specific changes to the rules as proposed to assist plans and issuers in complying with the requirement to perform and document comparative analyses. Several commenters requested examples of a compliant comparative analysis to assist in understanding what documentation, in the Departments’ view, is required to meet the standards. Another commenter stated that critical components of the terms, such as what a test comprises, the standards for meeting that test, and compiling the proper information are subject to interpretation, which can lead to regulators and auditors having different perspectives on the requirements, creating substantial uncertainty for plans and issuers that are attempting to comply. Several commenters also expressed a desire for additional clarification regarding the proposed content elements with respect to specific NQTLs. One commenter was concerned that the proposed rules did not provide clarity on how to apply

the new comparative analysis requirements to complex NQTLs, such as those related to network administration.

After reviewing comments, the Departments are finalizing the codification of the new statutory requirement that plans and issuers that offer coverage that provides both medical/surgical benefits and mental health or substance use disorder benefits and impose NQTLs on mental health or substance use disorder benefits must perform and document a comparative analysis of the design and application of each such NQTL, with modifications in response to comments as noted. This finalized provision aligns the regulations with the statutory requirements under MHPAEA, as amended by the CAA, 2021. In response to commenter concerns that the proposed rules did not clarify how a plan or issuer should apply the new comparative analysis requirements to factors and evidentiary standards used to design and apply NQTLs that are especially complex (including those related to network composition), the Departments disagree that the proposed rules and these final rules do not rationally relate to factors and evidentiary standards used to design and apply NQTLs like standards related to network composition or methods for determining out-of-network rates. Using the definitions of the terms “processes,” “strategies,” “evidentiary standards,” and “factors” under these final rules to inform the content elements required in a comparative analysis, these final rules provide sufficient guidance for plans and issuers to perform and document their comparative analyses of all NQTLs.

Additionally, these final rules also provide additional guidance on how a plan or issuer with a typical plan or coverage design should collect and evaluate data for NQTLs related to network composition (which must be included in the comparative analysis) under the relevant data evaluation requirements, and provides examples of reasonable actions that plans and issuers may take (and document in the comparative analysis) if such data suggest that NQTLs related to network composition contribute to material differences in access to mental health and substance

use disorder benefits as compared to medical/surgical benefits in a classification. The Departments acknowledge that a plan or issuer imposing a complex NQTL with respect to mental health and substance use disorder benefits by relying on a large number of complicated factors and evidentiary standards will likely require more resources to perform and document their comparative analysis in a manner that is compliant with these final rules. The Departments also appreciate that some of the required content for comparative analyses are described broadly and therefore could lead to the Departments and applicable State authorities taking different approaches in determining what constitutes a sufficient comparative analysis. However, these broad descriptions are necessary to ensure that these final rules set forth a single set of content elements that are flexible enough to apply to the wide variety of different NQTLs imposed by plans and issuers with respect to mental health and substance use disorder benefits.

The Departments are not providing an example of a comparative analysis that complies with these final rules, but continue to consider what additional resources and guidance are necessary to assist the regulated community in complying with MHPAEA and these final rules. A plan or issuer that analyzes the design and application of an NQTL along with the relevant data and considers it in the manner described earlier in this preamble will be well positioned to perform and document a comparative analysis in a manner consistent with these final rules. The Departments also note, as stated earlier in this preamble, that they intend to update the MHPAEA Self-Compliance Tool for plans and issuers to determine which data to collect and evaluate. The Departments note that what constitutes a compliant comparative analysis will depend on all the relevant facts and circumstances, including the provisions of the plan or coverage and the relevant NQTL. The Departments remain committed to providing additional guidance to assist with the implementation of these final rules.

1. Content of Comparative Analyses - 26 CFR 54.9812-2(c), 29 CFR 2590.712-1(c), and 45 CFR 146.137(c)

The Departments proposed requirements at 26 CFR 54.9812-2(c), 29 CFR 2590.712-1(c), and 45 CFR 146.137(c) governing the content of the comparative analyses required by Code section 9812(a)(8), ERISA section 712(a)(8), and PHS Act section 2726(a)(8). Specifically, the Departments proposed that each comparative analysis would include, at a minimum, with respect to each NQTL imposed under the plan or coverage on mental health and substance use disorder benefits, six elements:

- (1) a description of the NQTL;
- (2) the identification and definition of the factors used to design or apply the NQTL;
- (3) a description of how factors are used in the design or application of the NQTL;
- (4) a demonstration of comparability and stringency, as written;
- (5) a demonstration of comparability and stringency, in operation; and
- (6) findings and conclusions.

In addition to proposing to require the inclusion of specific elements in each comparative analysis, the proposed rules would require each plan or issuer to prepare and make available to the Departments, upon request, a written list of all NQTLs imposed under the plan or coverage and a general description of any information considered or relied upon by the plan or issuer in preparing the comparative analysis for each NQTL.

Several commenters expressed general support for the proposed elements that plans and issuers would be required to include in their comparative analyses under the proposed rules. Some commenters highlighted that the clarity the proposed rules provided would help to reduce confusion as to how plans and issuers should perform and document their comparative analyses, and others reasoned that, by clarifying the comparative analysis content requirements under the proposed rules, regulators will be able to better determine compliance with MHPAEA.

Some commenters, however, stated that the proposed rules did not provide enough clarity, which they stated may make complying with the requirements more challenging. These

commenters stated that providing a list of all NQTLs imposed under a plan or coverage would be challenging without either a definitive list of all NQTLs or requiring that plans and issuers perform and document comparative analyses only for NQTL types that the Departments define through regulations or guidance. As discussed earlier in the preamble, several commenters requested that the Departments provide an exhaustive list of NQTLs for which a comparative analysis would be required.

Commenters also expressed concerns about whether plans and issuers would be able to access the information and data necessary to perform and document a sufficient comparative analysis that includes all of the proposed content requirements. Several of these commenters mentioned difficulty acquiring the necessary information and data from their service providers and business partners, while other commenters stated that the proposed content requirements for comparative analyses are superfluous, unhelpful, or unreasonably burdensome. Some commenters described concerns related to cost and feasibility of preparing comparative analyses that would comply with the proposed content requirements.

After reviewing comments, the Departments are finalizing the requirement that a comparative analysis include, at a minimum, the six content elements listed in the proposed rules, consistent with the statute, with several modifications. This section of the preamble to these final rules discusses the comments received with respect to each content element in the proposed rules and the modifications made to each content element in these final rules.

With respect to the requirement to prepare and make available, upon request, a written list of all NQTLs imposed under the plan or coverage and commenters who noted that this requirement would be challenging to meet without a definitive list of all NQTLs, as stated earlier in this preamble, the Departments decline to provide an exhaustive list of NQTLs in these final rules or separate guidance. The Departments also note that, like the substantive requirements for NQTLs, the comparative analysis requirements of MHPAEA are not limited to a list of specific

NQTLs, but apply to all NQTLs that limit the scope or duration of treatment under a plan or coverage. As a result, these final rules require that, in addition to the comparative analysis for each NQTL, each plan or issuer must prepare and make available to the Secretary, upon request, a written list of all NQTLs imposed under the plan or coverage.

Additionally, for ERISA-covered plans, the written list must be provided to the named fiduciaries of the plan who are required to include a certification as part of each comparative analysis, as discussed later in this preamble. However, because the Departments recognize that a sufficient comparative analysis will include descriptions of the information, evidence, sources, and standards, as well as factors and evidentiary standards, that the plan or issuer considered or relied upon as part of the content elements, these final rules eliminate the separate requirement that proposed to require plans and issuers to provide a general description of any information considered or relied upon by the plan or issuer in preparing a comparative analysis for an NQTL.

The Departments are aware of reports that some self-insured plans have been unsuccessful in receiving comparative analyses (or the information required to perform and document comparative analyses) requested from their TPAs or other service providers. The Departments emphasize that, as of the date of the publication of these final rules, the statutory requirement to perform and document comparative analyses has been applicable to plans and issuers for over 3 years. The Departments have previously stated that TPAs and other service providers are expected to work closely with plans and issuers to support their needs by providing data and other information about the design and application of NQTLs applicable to mental health and substance use disorder benefits and to medical/surgical benefits so that comparative analyses can be performed and documented (regardless of whether the Departments or an applicable State authority have requested them). Because plans and issuers are the entities required by statute to perform and document comparative analyses and there is no exception to the requirement when necessary information cannot be obtained from another entity, plans and

issuers must work with their TPAs and service providers to obtain the information they need for their comparative analyses. Any ERISA-governed group health plans that contract with service providers refusing or otherwise failing to provide the requisite information should notify DOL.

Additionally, as noted earlier in this preamble, the Departments acknowledge the challenges, cost, and complexity of collecting and evaluating data, but are of the view that it is important to include specific content requirements in these final rules, including those related to relevant data to measure the impact of an NQTL on access to mental health and substance use disorder benefits. However, in recognition of these challenges and to align with other changes made in these final rules the Departments have modified certain specific provisions within some of the listed content elements as described in the following paragraphs.

a. Description of the NQTL

For each comparative analysis, the proposed rules would require a plan or issuer to identify the NQTL that is the subject of the comparative analysis, including the specific terms of the plan or coverage or other relevant terms regarding the NQTL, the policies or guidelines (internal or external) in which the NQTL appears or is described, and the applicable sections of any other relevant documents, such as provider contracts that describe the NQTL, consistent with the statute. This would include the documents that contain the specific language of the NQTL that the plan or issuer imposes. The plan or issuer would also be required to identify all mental health or substance use disorder benefits and medical/surgical benefits to which the NQTL applies, including a list identifying which of those benefits are considered to be mental health and substance use disorder benefits and which benefits are considered to be medical/surgical benefits (consistent with the proposed definitions of those terms). Additionally, each plan or issuer would be required to include in its comparative analysis a description of which benefits are included in each classification of benefits. Finally, under the proposed rules, the plan or issuer would be required to identify the predominant NQTL applicable to substantially all

medical/surgical benefits in each classification, including an explanation of how the plan or issuer determined which variation is the predominant NQTL and how the plan identified the variations of the NQTL.

The Departments received few comments on this proposed first content element. One commenter suggested an alternative approach, arguing that, instead of requiring that plans and issuers provide all policies, guidelines, provider contracts, and any other documents where the NQTL “appears or is described,” plans and issuers should be required under these final rules to provide only the documents, policies, or procedures that govern the NQTL.

After reviewing comments, the Departments are finalizing the requirement that a comparative analysis include a description that identifies the NQTL, identifies all mental health or substance use disorder benefits and medical/surgical benefits to which the NQTL applies, and describes which benefits are included in each classification. The Departments emphasize that these final rules still require a plan or issuer to identify the specific terms of the plan or coverage or other relevant terms regarding the NQTL, including the policies or guidelines (internal or external) in which the NQTL appears or is described and the applicable sections of any other relevant documents, such as provider contracts, that describe the NQTL. Under these final rules, the entire policy, guideline, or document is not required to be included in a comparative analysis, but could be requested by the Departments in the course of reviewing a comparative analysis. The Departments decline to require the inclusion of only the documents that govern the NQTL, because that might not include all the policies or guidelines that determine how the NQTL is designed or applied with respect to mental health or substance use disorder benefits.

Additionally, as noted earlier in these final rules, the Departments are not finalizing the proposed mathematical substantially all and predominant tests. Therefore, these final rules do not finalize the proposed content requirement that the description of the NQTL in a comparative analysis identify the predominant NQTL applicable to substantially all medical/surgical benefits

in each classification, including an explanation of how the plan or issuer determined which variation is the predominant NQTL and how the plan or issuer identified the variations of the NQTL.¹¹⁴

b. Identification and Definition of the Factors and Evidentiary Standards
Used to Design or Apply the NQTL

Under the second proposed content element, a plan or issuer would be required to identify and define all of the factors considered or relied upon to design or apply the NQTL. The plan or issuer would be required to identify all of the factors considered, as well as the evidentiary standards considered or relied upon to design or apply each factor and the evidence or sources from which each evidentiary standard was derived, in determining which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the NQTL. The plan or issuer would also be required to define each factor, by including a detailed description of the factor, and providing a description of each evidentiary standard (and the source of each evidentiary standard) identified. The Departments stressed in the preamble to the proposed rules that when identifying the evidence or sources from which an evidentiary standard is derived, a plan or issuer should be prepared to provide the copies of the actual evidence or source used, as well as the date and relevant citation for the correct version of the document used.

The Departments received few comments on this content element. One commenter noted that the requirement to provide detailed descriptions of each factor, including evidence and sources relied upon with data and relevant citations, may be challenging for plans and issuers to operationalize. One commenter highlighted that it may be difficult to identify evidence and sources for factors that are processes, such as provider referral requirements, requirements to

¹¹⁴ However, as discussed earlier in this preamble, the Departments are of the view that the concept of material differences in access helps to give meaning to the concepts of “substantially all” and “predominant” from the statutory language in the context of NQTLs.

submit information for clinical review, or the development and approval of a treatment plan, and that processes used to apply the NQTL “in operation” should be analyzed under a separate step of the comparative analysis. Another commenter stated that the requirement to do a historical analysis of the factors utilized by plans and issuers, including dating and providing citations for sources (from the time they decided to impose the NQTL), would be burdensome, and recommended such a requirement be eliminated or that the Departments accept references to factors that are generally accepted business standards without the need for specific dates and citations.

After reviewing comments, the Departments are finalizing the requirement that the comparative analysis identify and define all of the factors considered or relied upon to design or apply the NQTL to mental health or substance use disorder benefits and medical/surgical benefits as proposed, with minor non-substantive changes and a modification to align with changes made in these final rules to the prohibition on discriminatory factors and evidentiary standards. Specifically, these final rules clarify that a plan or issuer must identify every factor and the evidentiary standards considered or relied upon to design or apply each factor, instead of all of the factors considered, consistent with other provisions of these final rules. These final rules also add a new paragraph 26 CFR 54.9812-2(c)(2)(ii)(C), 29 CFR 2590.712-1(c)(2)(ii)(C), and 45 CFR 146.137(c)(2)(ii)(C) to make clear that plans and issuers must describe any steps taken to correct, cure, or supplement any information, evidence, sources, or standards that are the basis for a factor or evidentiary standard and that would otherwise have been considered biased or not objective in the absence of such steps. Additionally, as discussed earlier in this preamble, these final rules also make minor modifications to better distinguish evidentiary standards from factors within the definitions of those terms, and clarify that, while this content element requires a plan or issuer to include a description of each evidentiary standard used to design or apply each factor, this information is part of the required detailed description of each factor.

While the Departments acknowledge that identifying and defining all factors takes time for a plan or issuer to complete (for newly applied and existing NQTLs), the Departments note that this requirement was not new when it was included in the proposed rules. The CAA, 2021 specifically requires the identification and definition of factors relied upon to design and apply the NQTL,¹¹⁵ and has been applicable to plans and issuers since February 10, 2021. Identification and definition of the factors considered in the design and application of an NQTL was also previously addressed in FAQs Part 45.¹¹⁶ It is important for comparative analyses to include detailed information about factors, evidentiary standards, and their sources when a plan or issuer starts to perform and document its comparative analysis, to support the plan's or issuer's analysis of how factors and evidentiary standards are used to design and apply NQTLs. Such analysis should include support for the factors utilized from the time a plan or issuer decided to impose, or continues to impose, an NQTL on the relevant mental health and substance use disorder benefits, as well as medical/surgical benefits. To the extent a plan or issuer cannot support its use of factors and evidentiary standards, including by providing information on the sources of the factors and evidentiary standards considered and relied on by plans and issuers (from the time they decided to impose the NQTL), it is unclear how such plan or issuer can ensure that the factors and evidentiary standards are comparable and no more stringently designed and applied for mental health and substance use disorder benefits, than for medical/surgical benefits, as required under the statute (and the fourth and fifth content elements of a comparative analysis under these final rules).

¹¹⁵ Code section 9812(a)(8)(A)(iii), ERISA section 712(a)(8)(A)(iii), and PHS Act section 2726(a)(8)(A)(iii).

¹¹⁶ <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-45.pdf> and <https://www.cms.gov/ccio/resources/fact-sheets-and-faqs/downloads/mhpaea-faqs-part-45.pdf>. Additionally, the 2020 MHPAEA Self-Compliance Tool includes robust guidance related to requirements for NQTLs. Step two of the analysis outlined in the 2020 MHPAEA Self-Compliance Tool for NQTLs suggests identifying the factors considered in the design of the NQTL. See EBSA, Self-Compliance Tool for the Mental Health Parity and Addiction Equity Act (MHPAEA) (2020), <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/self-compliance-tool.pdf>.

Without such information, a comparative analysis likely would not accurately describe factors and their sources and would not demonstrate that, when factors are used to design or apply an NQTL to mental health or substance use disorder benefits, they are comparable to, and not more stringently applied, than they are when used to design or apply an NQTL to medical/surgical benefits. The absence of this information would also make it difficult for the Departments and applicable State authorities to confirm compliance with MHPAEA. The Departments stress that to the extent a plan or issuer applies factors that are processes, such as provider referral requirements, requirements to submit information for clinical review, or the development and approval of a treatment plan, such processes include both as written and in operation components. In addition, for these processes, a plan or issuer should be prepared to identify any sources utilized in determining the appropriateness of such requirements. To properly evaluate the comparability and stringency of such factors, it is important that any sources utilized be specifically identified in a comparative analysis. As stated earlier in this preamble, if a plan's or issuer's comparative analysis is requested by the Departments, the plan or issuer generally has multiple opportunities to engage with the Departments on these requirements.

c. Description of How Factors are used in the Design and Application of the NQTL

Under the third proposed content element, a plan or issuer would be required to provide a description of how each factor identified and defined in the second content element of the comparative analysis is used in the design or application of an NQTL to mental health and substance use disorder benefits and medical/surgical benefits in a classification. This would include a detailed explanation of how each factor identified and defined in the comparative analysis is used to determine which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the NQTL. The description would also include an

explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the NQTL, including in the determination of whether and how mental health or substance use disorder benefits or medical/surgical benefits are subject to the NQTL.

In instances in which the application of the factor depends on specific decisions made in the administration of benefits, the comparative analysis would be required to provide information on the nature and timing of the decisions, and the professional designations and qualifications of each decision maker. The proposed rules further provided that, to the extent that more than one factor is identified and defined with respect to an NQTL, the comparative analysis would be required to explain how such factors relate to each other; the order in which all the factors are applied, including when they are applied; whether and how any factors are given more weight than others; and the reasons for the ordering or weighting of the factors. The analysis would also be required to address any deviation(s) or variation(s) from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which each evidentiary standard was derived), such as how the factor is used differently to apply the NQTL to mental health and substance use disorder benefits as compared to medical/surgical benefits, and a description of how the plan or issuer establishes such deviations or variations. The Departments noted that the terms “deviations” or “variations” in this context referred to any differences in how a factor is applied with respect to an NQTL.

The Departments received few comments on this content element. One commenter requested that the Departments clarify the requirement to document the qualifications of staff as well as for the professional designations and qualifications of each decision maker involved in the application of a given NQTL factor, requesting that the Departments describe how the requirement to document the professional designations and qualifications of each decision maker

should be appropriately applied to health plan operations, and specifically Pharmacy and Therapeutics (P&T) committees.

After reviewing comments, the Departments are finalizing, with minor non-substantive changes, the requirement that plans and issuers provide a description of how each factor identified and defined in the second content element of the comparative analysis is used in the design or application of an NQTL to mental health and substance use disorder benefits and medical/surgical benefits in a classification. This includes the requirement to include a detailed explanation of how each identified and defined factor is used to determine which benefits are subject to the NQTL, and an explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the NQTL, including in the determination of whether and how benefits are subject to the NQTL. If the application of a factor depends on specific decisions made in the administration of benefits, the comparative analysis must also provide information on the nature and timing of the decisions, and the professional designations and qualifications of each decision maker. Additionally, if there is more than one factor, the comparative analysis must explain how all of the factors relate to each other; the order in which all the factors are applied, including when they are applied; whether and how any factors are given more weight than others; and the reasons for the ordering or weighting of the factors. Finally, the comparative analysis must address any deviations or variations from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which each evidentiary standard was derived), such as how the factor is used differently to apply the NQTL to mental health or substance use disorder benefits as compared to medical/surgical benefits, and a description of how the plan or issuer establishes such deviations or variations. As used in this context, the terms “deviations” or “variations” in these final rules refer to any differences in how a factor is applied with respect to an NQTL.

In response to the request for how the requirement to document professional designations and qualifications applies to health plan operations, including P&T committees, the Departments emphasize that these committees must have members with similar expertise for mental health conditions and substance use disorders as for medical conditions and surgical procedures. This may not necessarily require the same number of members with expertise relevant to mental health conditions and substance use disorders as it does for medical conditions and surgical procedures, but plans and issuers should ensure that members of a P&T committee include individuals with similar expertise with respect to these conditions and disorders.

d. Demonstration of Comparability and Stringency, As Written

Under the fourth proposed content element, plans and issuers would be required to evaluate whether, in any classification, under the terms of the plan (or health insurance coverage) as written, any processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to medical/surgical benefits. The proposed rules would require plans and issuers to include in their comparative analyses, with respect to the NQTL and the factors used in designing and applying the NQTL, documentation of each factor identified and defined in the comparative analysis that was applied to determine whether the NQTL applies to mental health or substance use disorder benefits and medical/surgical benefits in a classification. This would include, as relevant, quantitative data, calculations, or other analyses showing whether, in each classification in which the NQTL applies, mental health or substance use disorder benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard and the evaluation of relevant data to determine that the NQTL would or would not apply. In addition, such documentation would be required to include records maintained by the plan or issuer

documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application. Such records could include meeting minutes, or calculations related to quantitative factors, such as costs.

Plans and issuers would also be required to include in their comparative analyses, in each classification in which the NQTL applies, a comparison of how the NQTL, as written, is applied to mental health or substance use disorder benefits and to medical/surgical benefits, including the specific provisions of any forms, checklists, procedure manuals, or other documentation used in designing and applying the NQTL or that address the application of the NQTL. Additionally, the plan or issuer would be required to include documentation in its comparative analysis demonstrating how the factors are comparably applied, as written, to mental health or substance use disorder benefits and medical/surgical benefits in each classification, to determine which benefits are subject to the NQTL. If there is any deviation(s) or variation(s) in the application of a factor, the plan or issuer would be required to include in its comparative analysis an explanation of the reason(s) for such deviation(s) or variation(s) in the application of a factor used to apply the NQTL, or the application of the NQTL, to mental health or substance use disorder benefits as compared to medical/surgical benefits in the same classification, and how the plan or issuer establishes such deviation(s) or variation(s), including in the definition of the factors, the evidentiary standards used to define the factors, and the sources from which the evidentiary standards were derived; in the design of the factors or evidentiary standards; or in the application or design of the NQTL. In the preamble to the proposed rules, the Departments noted that the terms “deviations” or “variations” in this context refer to any differences in how a factor is applied with respect to an NQTL.

Multiple commenters expressed support for the requirement to demonstrate comparability and stringency as written through the proposed requirements for the fourth content element. However, other commenters raised concerns about the proposal, with some requesting additional

clarification or guidance to assist with achieving compliance. For example, one commenter requested that the Departments clarify the difference between the proposed requirement that plans and issuers provide documentation that demonstrates how factors are comparably applied in step 4 of the comparative analysis content requirements, and the service-by-service documentation requirement for each factor under step 3 of the analysis, which requires a description of how factors are used in the design and application of the NQTL.

Another commenter expressed concerns about how this content element may create operational challenges due to its breadth and how it would require plans to also consider other factors that were considered and not applied. Other commenters suggested ways that the Departments might ease the burden of the proposed fourth content element requirements on plans and issuers. One comment included a recommendation that the Departments clarify that plans and issuers can document each factor that was applied, including quantitative data, at the issuer level, rather than at the plan or coverage level. Another commenter encouraged the Departments to limit documentation requirements and enforcement to apply only to the comparability of the NQTL, as written and in operation; to acknowledge that subject matter experts may rely on professional knowledge, experience, and judgment to evaluate the evidentiary standard for identified factors; and to not require the use of quantitative data, calculations, or other analyses. Another commenter stated that the requirement to provide records documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application, was inconsistent with the descriptions elsewhere of requiring a “general description” of the factors relied upon, and therefore urged the Departments to eliminate the requirement to include the actual evidence and related records in the comparative analysis itself.

The Departments note that, while the third content element requires a plan or issuer to provide details on how each factor (and evidentiary standards or other information or sources) is

used in the design and application of an NQTL, that content element does not require an evaluation of whether the use of those factors complies with MHPAEA. Instead, these final rules require a demonstration of comparability and stringency, both as written and in operation, in the fourth and fifth content requirements for a comparative analysis, respectively. Additionally, the Departments are of the view that a plan or issuer cannot effectively demonstrate comparability and stringency, as written and in operation, without sufficiently identifying and defining each factor (in the second content element), and explaining how each factor is used to design and apply an NQTL (in the third content element).

After reviewing comments, these final rules retain all of the proposed substantive features of the fourth content element requirements, which require that plans and issuers evaluate whether, in any classification, under the terms of the plan (or health insurance coverage) as written, any processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL with respect to medical/surgical benefits. As finalized, this provision includes a technical modification to a citation that accounts for the reorganization of language in 26 CFR 54.9812-1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii) and also now specifies that the comparative analysis must include a comparison of how the NQTL, as written, is designed and applied to mental health or substance use disorder benefits and to medical/surgical benefits, instead of only as applied.¹¹⁷ The

¹¹⁷ As explained earlier in this preamble, these final rules amend the general rule in the design and application requirements, to align the language of the 2013 final regulations with the Departments' interpretation that a plan or issuer must consider the comparability and relative stringency of any processes, strategies, evidentiary standards, or other factors, used in both designing and applying NQTLs to mental health or substance use disorder benefits as compared to medical/surgical benefits in a classification. These final rules revise the regulatory text to make this requirement with respect to designing the NQTL explicit and for consistency with the statutory language added by the CAA, 2021.

requirements related to demonstrating comparability and stringency as written under the fourth content element are otherwise being finalized as proposed.

The Departments note that this content requirement does not require the use of quantitative data, calculations, or other analyses, nor does it prohibit plans from relying on professional knowledge, experience, and judgment to evaluate the evidentiary standard for the identified factors. Instead, this content element is meant to show how the factors described in the third content element used in designing and applying an NQTL to mental health and substance use disorder benefits are comparable to, and applied no more stringently than, the factors used in designing and applying the NQTL to medical/surgical benefits in the same classification, as written. Despite the potential operational challenges associated with the breadth of this content element, the Departments are of the view that it is a vital component of comparative analyses and is necessary to demonstrate compliance with MHPAEA as written, consistent with the statute.¹¹⁸ The Departments note that, as discussed earlier in this preamble, these final rules eliminate the duplicative requirement from the proposed rules that plans and issuers include a general description of any information considered or relied upon in preparing the comparative analysis for each NQTL. The final rules also eliminate a duplicative reference to the evaluation of relevant data in the fourth content element for comparative analyses, which is addressed as part of the fifth content element.

The Departments recognize that a factor may be considered, but not used, to apply an NQTL to a specific benefit; however, to the extent such factor is used to design or apply the NQTL to mental health and substance use disorder benefits, it must be addressed in the plan's or issuer's comparative analysis, including in this fourth content element. The Departments are of the view that, to the extent an issuer or TPA uses factors or evidentiary standards to design and apply an NQTL consistently for multiple plans and coverage they administer, nothing in these

¹¹⁸ Code section 9812(a)(8)(A)(iv), ERISA section 712(a)(8)(A)(iv), and PHS Act section 2726(a)(8)(A)(iv).

final rules specifically prohibits the issuer or TPA from performing and documenting a comparative analysis at the level of the issuer (or TPA). However, to the extent relevant data exists at the level of the plan or coverage that measures access to mental health or substance use disorder benefits in a manner that is different than data at the level of the issuer or TPA, the Departments of are the view that a plan's or issuer's comparative analysis must account for that data, as described later in this preamble.

The Departments note that it is possible that the reasons for any deviations or variations in the application of a factor used to apply the NQTL, or the application of the NQTL, might include steps to correct, cure, or supplement information, evidence, sources, or standards that would otherwise be considered biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. To the extent a plan or issuer has adequately documented such steps as part of its comparative analysis, as required in the second content element of these final rules requiring the identification and definition of the factors used to design or apply the NQTL, the plan or issuer is not required to address such steps again in the fourth content element if otherwise applicable, and instead may include references to the description of such steps in the second content element, as appropriate.

e. Demonstration of Comparability and Stringency, In Operation

The Departments proposed that plans and issuers be required to evaluate in a comparative analysis whether, in any classification, under the terms of the plan (or health insurance coverage) in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits. A comprehensive explanation would be required to include an explanation of any methodology and underlying data used to demonstrate the application of the NQTL in operation, and the sample

period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the NQTL is applicable.

To comply with the proposed fifth content element, plans and issuers would also be required to identify the relevant data collected and evaluated in their comparative analyses and provide an evaluation of the outcomes that resulted from the application of the NQTL to mental health or substance use disorder benefits and medical/surgical benefits to demonstrate compliance with the design and application requirements. Additionally, the comparative analysis would be required to include a detailed explanation of material differences in outcomes that are not attributable to differences in the comparability or relative stringency of the NQTL as applied to mental health or substance use disorder benefits and medical/surgical benefits, as well as the basis for concluding that material differences in outcomes are not attributable to differences in the comparability or relative stringency of the NQTL. Finally, under this content element, the comparative analysis would be required to include a discussion of any measures that have been or are being implemented by the plan or issuer to mitigate any material differences in access with respect to mental health or substance use disorder benefits as compared to medical/surgical benefits.

Many commenters expressed support for the proposed requirement and standards for the demonstration of comparability and stringency in operation captured in the proposed fifth content element, especially with respect to NQTLs related to network composition and the use and application of clinical guidelines. Commenters supported the proposed requirements for detailed comparative analyses because they reasoned that these requirements would help regulators understand participant and beneficiary access to mental health and substance use disorder services under real conditions as opposed to only looking to written plan terms and policies. Some commenters also included recommendations for additional data transparency

requirements to ensure compliance and ease the burden on the Departments in enforcing MHPAEA's requirements. Several commenters also indicated a desire for additional clarification regarding this proposed content element. For example, one commenter noted that the fifth content element requires the demonstration of comparability and stringency in operation to be comprehensive, without discussion of what that term means.

After reviewing comments, the Departments are finalizing the proposed requirements for the fifth content element with several clarifications and modifications. The Departments are finalizing the requirement that the comparative analysis must evaluate whether, in any classification, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than those used with respect to medical/surgical benefits. However, the Departments have removed the references to the terms of the plan (or health insurance coverage) from this requirement, in recognition of the fact that the operations of the plan (or health insurance coverage) may not necessarily be reflected in its terms.

The Departments are also finalizing the requirement that the comparative analysis must include a comprehensive explanation addressing the comparability and stringency of these processes, strategies, evidentiary standards, and other factors. These final rules require that this explanation address how the plan or issuer "evaluates whether" (instead of "ensures that"), in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits in a classification are comparable to, and are applied no more stringently than, those used in designing and applying the NQTL with respect to medical/surgical benefits.

In these final rules, the Departments finalize with additional clarifications the proposal that, as part of the proposed fifth content element, a comprehensive explanation of how the plan

or issuer evaluates in-operation compliance with the design and application requirements of MHPAEA would include an explanation of the methodology and underlying data used to demonstrate the application of the NQTL, as well as the sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the NQTL is applicable. These final rules also include language to align with changes made to address a lag between when an NQTL is newly designed and applied and when relevant data are available, as well as some limited circumstances in which no data exist that can reasonably assess any relevant impact of an NQTL on access to benefits. Specifically, with respect to an NQTL for which relevant data are temporarily unavailable, the Departments clarify that the comparative analysis must include a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed.

With respect to an NQTL for which no data exist that can reasonably assess any relevant impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, the fifth content element requires the plan or issuer to include as part of the comparative analysis a reasoned justification as to the basis for the conclusion that there are no data that can reasonably measure the NQTL's impact, an explanation of why the nature of the NQTL prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure that the NQTL complies with all applicable requirements. As noted earlier in this preamble, the Departments recognize that plans and issuers may encounter difficulties when attempting to collect and evaluate relevant data in certain circumstances, and, accordingly, intend to review the explanation provided in a plan's or issuer's comparative analysis to understand those difficulties in determining whether the plan or issuer is

in compliance with these final rules. However, the Departments reiterate their intention that the provisions of these final rules regarding the unavailability of data shall only apply in very limited circumstances and, where applicable, shall be construed narrowly.

The Departments are finalizing the proposed requirements for the fifth content element that a comparative analysis must include identification of the relevant data collected and evaluated, as well as documentation of the outcomes that resulted from the application of the NQTL to mental health or substance use disorder benefits and medical/surgical benefits, including the evaluation of relevant data as described earlier in this preamble. This also includes a reasoned justification and analysis that explains whether, and if so, why the plan or issuer concluded that differences in relevant data do or do not suggest the NQTL contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits.

The Departments recognize that, for NQTLs related to network composition, under these final rules, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the aggregate impact of all such NQTLs on access to mental health and substance use disorder benefits and medical/surgical benefits. Therefore, for NQTLs related to network composition, comparative analyses should analyze their impact as a whole. Plans and issuers may also, however, indicate in these comparative analyses where one particular NQTL may affect differences in access.

Furthermore, in response to comments, these final rules provide more specifics on the requirement for the fifth content element to provide a detailed explanation of any material differences in access demonstrated by the outcomes evaluated, by requiring a reasoned explanation of any material differences in access that are not attributable to differences in the comparability or relative stringency of an NQTL as applied to mental health or substance use disorder benefits and medical/surgical benefits. This explanation should include a detailed

discussion of any considerations beyond a plan's or issuer's control that contribute to the existence of material differences, as well as a detailed explanation of the bases for concluding that material differences are not attributable to differences in the comparability or relative stringency of the NQTL. The Departments note that such an explanation should be comprehensive and include evidence to support the conclusion that considerations beyond a plan's or issuer's control contribute to the existence of material differences in access.

Additionally, these final rules add that, to the extent differences in access to mental health or substance use disorder benefits are attributable to independent professional medical or clinical standards or fraud and abuse measures, and such standards or measures are used as the basis for a factor or evidentiary standard used to design or apply an NQTL, comparative analyses must include documentation explaining how any such differences in access are attributable to those standards or measures. By requiring plans and issuers to analyze and explain material differences in access as demonstrated by outcomes, the Departments aim to encourage plans and issuers to examine closely and critically the extent to which access to benefits is shaped by particular NQTLs so that they can take effective, reasonable actions as necessary to mitigate material differences.

Finally, these final rules specify that, in demonstrating comparability and stringency in operation under the fifth content element in these final rules, plans and issuers must discuss in their comparative analyses the actions that have been or are being taken by the plan or issuer, as necessary, to address any material differences in access. Under these final rules, this discussion must include, as applicable, a reasoned explanation of any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits that persist despite reasonable actions that have been or are being taken. Additionally, for a plan or issuer designing and applying one or more NQTLs related to network composition, to comply with this aspect of the fifth content element, the comparative analysis must include a discussion

of the actions that have been or are being taken, as necessary, to address material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits, including those listed in these final rules as examples of possible actions that a plan or issuer could take to comply,¹¹⁹ if any such material differences exist. The Departments recognize that plans and issuers may already be aware of material differences in access to mental health or substance use disorder benefits and, as a result, may have taken actions to comply with MHPAEA's requirements. The Departments are of the view that comparative analyses should address any such actions taken to address material differences in access and their effectiveness, to improve access to mental health and substance use disorder care for participants and beneficiaries and demonstrate compliance with MHPAEA.

f. Findings and Conclusions

Under the sixth and final proposed content element, a plan or issuer would be required to include in its comparative analysis its findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTL to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation. For this purpose, the comparative analysis would be required to include any findings or conclusions indicating that the plan or coverage is not (or might not be) in compliance with the provisions of the proposed rules for NQTLs, including any actions the plan or issuer has taken or intends to take to address any potential areas of concern or noncompliance. The comparative analysis would be required to include a reasoned and detailed discussion of those findings and conclusions, as well as citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions.

¹¹⁹ See 26 CFR 54.9812-1(c)(4)(iii)(C), 29 CFR 2590.712(c)(4)(iii)(C), and 45 CFR 146.136(c)(4)(iii)(C).

Additionally, the proposed rules would require that the comparative analysis include the date of the analysis and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis. If the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, the comparative analysis would be required to include an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of each NQTL applicable to both mental health or substance use disorder benefits and medical/surgical benefits. For plans subject to ERISA, the comparative analysis would be required to include a certification by one or more named fiduciaries who have reviewed the analysis, stating whether they found the comparative analysis to be in compliance with the content requirements of the proposed rules.

With respect to the requirements regarding reliance on an evaluation by an expert, one commenter was supportive of the rule as proposed, and another recommended that the Departments not require that the comparative analyses include the name of the expert so that experts would not be dissuaded from providing their expertise to avoid public identification.

Some commenters were supportive of the fiduciary certification requirement for plans subject to ERISA, with one stating that this would help to ensure that plan fiduciaries meet their obligations to review comparative analyses and monitor their plans for compliance. Many other commenters expressed concern, with some reasoning that requiring a named fiduciary to review and certify that a comparative analysis complies with the content requirements of the proposed rules would put an unrealistic expectation on that fiduciary to understand the required nuance and complexity of the proposed rules. Other commenters opined that the requirement would create an unnecessary burden. These commenters stressed that the requirement would increase compliance costs (as fiduciaries would have to contract with additional service providers to

assess compliance) without increasing access to benefits. Other commenters highlighted that Congress knew how to provide for a certification or attestation requirement but refrained from doing so for the MHPAEA comparative analysis. These comments urged against including the fiduciary certification requirement.

The Departments are of the view that requiring plans and issuers to address the findings and conclusions of both comparability and stringency of processes, strategies, evidentiary standards and other factors in their comparative analysis is necessary and appropriate to increase and ensure compliance with MHPAEA. The Departments' experience enforcing the current regulatory framework has shown that, too often, plans and issuers design and apply NQTLs without considering the impact those NQTLs have on access to mental health and substance use disorder benefits as compared to medical/surgical benefits for participants and beneficiaries. In practice, the Departments have encountered many NQTLs that often impose a greater burden on access to mental health and substance use disorder benefits than medical/surgical benefits. Therefore, the Departments are finalizing, with modifications, the requirements for the sixth content element that requires plans and issuers to address the findings and conclusions as to the comparability and relative stringency of the processes, strategies, evidentiary standards, and other factors used in designing and applying NQTLs in their comparative analyses. The requirement under these final rules that plans and issuers must include any findings and conclusions is consistent with the statutory text, and these final rules also specify that these findings and conclusions must be included whether or not the plan or coverage is or is not (or might or might not be) in compliance. The Departments stress that, while these final rules require an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied on their evaluation (if at all), these final rules do not require the name of the expert in the comparative analysis. These final rules also make additional minor technical edits to the sixth content requirement, for clarity.

In response to comments expressing concern with the named fiduciary certification requirement for plans subject to ERISA in the proposed rules, DOL is modifying this requirement. These final rules continue to require, for plans subject to ERISA, the comparative analysis to include a certification by one or more named fiduciaries. However, instead of requiring noted fiduciaries to state whether they found the comparative analysis to be in compliance with the content requirements, these final rules require certification confirming the fiduciary's engagement in a prudent process to select one or more qualified service providers to perform and document a comparative analysis in connection with the imposition of any NQTLs that apply to mental health and substance use disorder benefits under the plan in accordance with MHPAEA and its implementing regulations, as well as satisfaction of the duty to monitor those service providers. For this purpose, DOL expects that a plan fiduciary making such a certification will, at a minimum, review the comparative analysis prepared by or on behalf of the plan with respect to an NQTL applicable to mental health and substance use disorder benefits and medical/surgical benefits; ask questions about the analysis and discuss it with service providers, as necessary, to understand the findings and conclusions documented in the analysis; and ensure that a service provider responsible (in whole or in part) for performing and documenting a comparative analysis provides assurance that, to the best of its ability, the NQTL and associated comparative analysis complies with the requirements of MHPAEA and its implementing regulations. While not required, a plan fiduciary may alternatively provide a certification that each comparative analysis is in compliance with the content requirements, consistent with the proposed certification requirement in the proposed rules.¹²⁰ Because the statute expressly places the obligation on the plan (or issuer) to ensure compliance with

¹²⁰ See 88 FR 51552, 51651 (Aug. 3, 2023), setting forth the proposed requirement that one or more named fiduciaries who have reviewed a comparative analysis provide a certification stating whether they found the comparative analysis to be in compliance with the content requirements of the regulations.

MHPAEA, these final rules align with the duties ERISA imposes on plan fiduciaries under part 4 of ERISA.

2. Requirement to Provide Comparative Analyses and Notices to the Department and Other Individuals and Entities - 26 CFR 54.9812-2(d) and (e), 29 CFR 2590.712-1(d) and (e), and 45 CFR 146.137(d) and (e)

Effective February 10, 2021, plans and issuers have been required, consistent with the statute, to perform and document comparative analyses and make them available to the Departments or applicable State authorities upon request.¹²¹ The proposed rules would require that plans and issuers make a comparative analysis available and submit it upon request to the relevant Secretary (as well as applicable State authorities and participants and beneficiaries in certain circumstances), explain that additional information may be required to be provided after a comparative analysis is deemed insufficient, and outline requirements for plans and issuers after an initial determination of noncompliance and a final determination of noncompliance. Some commenters were supportive of the proposed requirements, though others offered suggestions for improving the various elements, as described later in this preamble.

Once a comparative analysis is requested, plans and issuers would be required to provide a comparative analysis within 10 business days of receipt of a request from the relevant Secretary (or an additional period of time specified by the relevant Secretary). Some commenters remarked that 10 business days is not sufficient to provide a comparative analysis upon request. While a few commenters requested that the Departments allow plans and issuers at least 30 days to provide the requested information, others requested a 60-day period to provide an updated comparative analysis. Several commenters highlighted that plans and issuers might not anticipate

¹²¹ Code section 9812(a)(8), ERISA section 712(a)(8), and PHS Act section 2726(a)(8). This requirement was reiterated in FAQs Part 45, <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-45.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/MHPAEA-FAQs-Part-45.pdf>.

what is regarded as an NQTL by the Departments and requested that the Departments provide additional time to respond to a request for a comparative analysis for an NQTL that was not on an illustrative list of NQTLs provided by the Departments.

After reviewing comments, the Departments are finalizing, as proposed, the requirement that plans and issuers make available a comparative analysis and submit it to the relevant Secretary within 10 business days of receipt of a request from the relevant Secretary (or an additional period of time specified by the relevant Secretary). Plans and issuers are statutorily obligated to perform and document their NQTL comparative analyses, and to be ready to make them available in response to a request, regardless of whether the plan or issuer has actually received a request from the Departments or an applicable State authority, and have been since February 10, 2021. While these final rules specify content elements that comparative analyses must contain, the Departments have expected, and will continue to expect, that plans and issuers perform and document their NQTL comparative analyses without waiting for a request from the Departments or an applicable State authority. Where plans and issuers have performed and documented their NQTL comparative analyses, additional time will not generally be required to respond to an initial request. The language allowing an additional period of time specified by the Secretary for a plan or issuer to submit a comparative analysis to the Secretary provides sufficient flexibility to plans and issuers where the Departments determine it to be appropriate.

Under the proposed rules, in instances in which the Secretary determines that the plan or issuer has not submitted sufficient information for the Secretary to review the requested comparative analysis, the Secretary will specify to the plan or issuer the additional information the plan or issuer must submit to the Secretary to be responsive to the request. The plan or issuer would be required to furnish this additional information to the relevant Secretary within 10 business days after the relevant Secretary specifies the additional information to be submitted (or an additional period of time specified by the relevant Secretary). The Departments noted in the

preamble to the proposed rules that a request for additional information by the relevant Department or an applicable State authority may include a request for data to analyze the assertions made in the comparative analyses, consistent with existing authority. This additional information or data may relate to the data required by the Departments to be collected and evaluated under the relevant data evaluation requirements. A few commenters stated that 10 business days was not enough time to respond with supplemental information, calling the timeframe overly restrictive and unrealistically short. One requested 60 days to respond to such a request instead of 10 business days as proposed.

After reviewing comments, the Departments are finalizing with minor technical edits the requirement that plans and issuers furnish the additional requested information to the relevant Secretary within 10 business days after the relevant Secretary specifies the additional information to be submitted (or an additional period of time specified by the relevant Secretary). The Departments acknowledge that in some, but not all, cases, 10 business days may not be enough time to respond with supplemental information and recognize that not all requests for supplemental information are equal in terms of the volume and complexity of the information requested, which is why these final rules allow for additional time to be specified by the relevant Secretary (for example, where the volume or complexity of the additional information requested would take more time to collect and provide). The Departments emphasize that additional information must be provided within 10 *business* days, rather than calendar days, and are of the view that, in the majority of cases, 10 business days should be sufficient. However, unless otherwise specified, the other timelines associated with the comparative analysis requirements generally refer to calendar days.

In instances where the relevant Secretary has reviewed a plan's or issuer's comparative analyses (and any additional information submitted upon request), and made an initial determination that the plan or issuer is not in compliance with the requirements related to

NQTLs, the Departments proposed to require the plan or issuer to respond to the relevant Secretary, specifying the actions it will take to come into compliance. The plan or issuer would also be required to provide to the relevant Secretary additional comparative analyses meeting the requirements of the proposed rules that demonstrate compliance with MHPAEA. The plan or issuer would be required to submit these responses to the relevant Secretary not later than 45 calendar days after the relevant Secretary's initial determination that the plan or issuer is not in compliance.

One commenter stated that the proposed penalties for noncompliance are not strict enough to discourage noncompliant issuer behavior and stated that, without strict enforcement penalties, issuers will continue to attempt to skirt the law. Additionally, as discussed earlier in the preamble, other commenters urged the Departments to provide procedural guardrails and due process protections for plans and issuers prior to the final determination of noncompliance, suggesting that the plan or issuer should have an opportunity to meet with the DOL or HHS national office, review the determination, and work together to achieve compliance.

After reviewing comments, the Departments are finalizing this requirement with minor edits. These final rules clarify, however, that the plan or issuer must respond to the initial determination by the Secretary, instead of more generally requiring the plan or issuer to respond to the Secretary, as proposed, to better match the statutory text. In response to the commenter who criticized the penalties for noncompliance, the Departments note that they do not have the statutory authority to increase penalties for violations of MHPAEA, but, as discussed earlier in this preamble, have stepped up enforcement efforts and anticipate continuing to prioritize enforcement of these requirements.

As discussed earlier in the preamble, the statute establishes the comparative analysis request process, as well as the penalties for failing to comply, and, working within this process, the Departments have worked with many plans and issuers to achieve compliance, often without

issuing a final determination of noncompliance, as described at length in our MHPAEA Reports to Congress.¹²² The Departments expect that this approach will continue to work after the issuance of these final rules. To the extent possible, the Departments expect to continue to work with plans and issuers to ensure compliance, without need of issuance of a final determination of noncompliance.

If the relevant Department makes a final determination that the plan or issuer is not in compliance with MHPAEA (after issuance of an initial determination of noncompliance, a failure by the plan or issuer to sufficiently respond to the initial determination and specify the actions the plan or issuer will take to bring the plan or coverage into compliance, and a failure to provide additional sufficient comparative analyses within the 45-calendar-day corrective action period), the plan or issuer must, within 7 calendar days of the receipt of the final determination of noncompliance, provide a standalone notice that is not combined with any other notices or disclosures, as required under applicable Federal or State law, to all participants and beneficiaries enrolled in the plan or coverage that the plan or issuer has been determined to not be in compliance with the requirements of the proposed rules. The plan or issuer would also be required to provide a copy of the notice to the relevant Secretary, any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within the same timeframe. The Departments noted in the preamble to the proposed rules that this notice gives participants and beneficiaries (or their authorized representatives) critically important information for the pursuit and protection of their own benefit claims and rights and provides a powerful incentive for the plan or issuer to take necessary corrective actions to come into compliance following an initial determination of noncompliance. The proposed rules set forth

¹²² See, e.g., 2023 MHPAEA Comparative Analysis Report to Congress (July 2023), <https://www.dol.gov/sites/dolgov/files/ebsa/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf>. Other reports are available at <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/reports>.

requirements for the content of this notice and the manner in which it would be required to be provided, including that the notice be written in plain language and in a manner calculated to be understood by the average plan participant. The notice would also be required to include the following statement prominently displayed on the first page, in no less than 14-point font:

“Attention! The [Department of Labor/Department of Health and Human Services/Department of the Treasury] has determined that [insert the name of group health plan or health insurance issuer] is not in compliance with the Mental Health Parity and Addiction Equity Act.”

The proposed rules would also require the notice contain a summary of any changes the plan or issuer has made as part of its corrective action plan specified to the Secretary following the initial determination of noncompliance, including an explanation of any opportunity for a participant or beneficiary to have a claim for benefits reprocessed. Additionally, the notice would be required to include a summary of the Secretary’s final determination that the plan or issuer is not in compliance, including any provisions or practices identified to be in violation of MHPAEA, any additional corrective actions identified by the Secretary in the final determination notice, and information on how participants and beneficiaries can obtain a copy of the final determination of noncompliance from the plan or issuer. This notice would also be required to include any other actions the plan or issuer is taking to come into compliance with MHPAEA, information on when the plan or issuer will take (or has taken) such actions, and a clear and accurate statement explaining whether the Secretary has concurred with those actions. Finally, the proposed rules would require that the notice include contact information for questions and complaints, with a statement explaining how participants and beneficiaries can obtain more information about the notice, including a phone number and an email or web portal address for the plan or issuer, and contact information for the relevant Department.

Under the proposed rules, a plan or issuer would be required to make the notice available in paper form. The plan or issuer may alternatively make the notice available electronically (such as by email or an internet posting) if the format is readily accessible, the notice is provided in paper form free of charge upon request, and, in a case in which the electronic form is an internet posting, the plan or issuer timely notifies participants and beneficiaries in paper form (such as a postcard) or email that the documents are available on the internet, provides the internet address, and notifies participants and beneficiaries that the documents are available in paper form upon request. The Departments noted that this approach is similar to standards for when a plan or issuer is permitted to provide a copy of its plan's or coverage's summary of benefits and coverage with respect to participants and beneficiaries who are eligible but not enrolled for coverage.¹²³ For ERISA plans, the plan or issuer would also be required to ensure that the notice is provided to any service provider involved in the claims process and any fiduciary responsible for deciding benefit claims within 7 calendar days of receipt of the final determination of noncompliance, so that the service provider or fiduciary can appropriately take the violation into account in deciding claims in compliance with the requirements of 29 CFR 2590.712(c)(4) and in accordance with section 404(a)(1)(D) of ERISA.

Multiple commenters recommended that the requirement for plans and issuers to include information in the notice about any opportunity for a participant or beneficiary to have claims reprocessed be revised to instead place affirmative obligations on plans and issuers who receive a final determination of noncompliance to identify affected participants or beneficiaries, reprocess claims, and take other necessary steps to rectify harms. One commenter further suggested that plans or issuers be required to describe the process they will follow and the time frames for reprocessing claims in the notice of noncompliance. Another commenter opposed the

¹²³ See 26 CFR 54.9815-2715(a)(4)(ii)(B), 29 CFR 2590.715-2715(a)(4)(ii)(B), and 45 CFR 147.200(a)(4)(ii)(B).

requirement that a plan deemed noncompliant send a notice to all beneficiaries, arguing that it amounted to public shaming and that it was beyond the scope of the authorizing statute.

Several commenters suggested that the notice should be provided to participating providers, as such providers may have experienced issues submitting claims to plans and issuers for reimbursement, including improper denials, and stopped submitting further claims. One commenter requested that these final rules be accompanied by guidance and online compliance resources developed by the Departments to help the affected plans and issuers draft their notices of noncompliance.

Several commenters expressed concern that providing notice within 7 calendar days would not be feasible, particularly with the level of information that a plan or issuer is required to compile and provide. Some commenters requested a 30-day period to provide this notice and others requested a 45-day period.

After reviewing comments, the Departments are finalizing with minor clarifications the provision that a plan or issuer must notify all participants and beneficiaries enrolled in the plan or coverage that the plan or issuer has been determined to not be in compliance with the requirements of MHPAEA if the Secretary makes a final determination of noncompliance, as required by the statute. The Departments highlight that the statute specifies the notice be provided within 7 days, and the Departments lack the statutory authority to extend this timeframe, such as to 30 or 45 days, as suggested by commenters. However, in response to comments, these final rules provide that plans and issuers have 7 business days instead of 7 calendar days to notify participants and beneficiaries of a final determination of noncompliance, to provide plans and issuers additional time to prepare the notice of final determination as required under these final rules.

The Departments also note that the relevant statutory language requires notice to be sent to “all individuals enrolled in the plan or applicable health insurance coverage offered by the

issuer,” which includes participants and beneficiaries, rather than attending providers. However, if a single notice is provided to a participant and any beneficiaries at the participant’s last known address, the requirement to provide notice to participants and beneficiaries is considered satisfied, unless the plan or issuer knows (or reasonably should have known) that the beneficiary’s last known address is different, in which case a notice is required to be provided to the beneficiary at the beneficiary’s last known address.

The Departments are also finalizing the requirement for ERISA-covered plans that the plan or issuer must provide a copy of the notice to any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within 7 business days of receipt of the final determination of noncompliance. DOL recognizes that, depending on the nature of the NQTL and the final determination of noncompliance, not all such determinations will impact adjudicated claims, but is of the view that it is important for such information to be disclosed to relevant service providers and fiduciaries, so they can properly consider whether such changes are required.

The Departments are finalizing the proposed notice content requirements and stress that the notice must describe any other actions the plan or issuer is taking to come into compliance with MHPAEA. Generally, when noncompliance has been identified, the Departments will require plans and issuers to take steps to identify affected participants, reprocess claims, and take other necessary steps to rectify harms; however, the specific steps a plan or issuer will be required to take in response to a final determination of noncompliance will depend on the facts and circumstances of the violations. While these final rules generally require a plan or issuer to include an explanation of any opportunity for a participant or beneficiary to have a claim for benefits reprocessed (or, as explained below, submitted) in a notice describing a final determination of noncompliance, the Departments do not intend that provision to imply that

plans and issuers will not be obligated to take any other particular actions intended to provide appropriate corrections to affected individuals or otherwise remediate potential harms.

As noted throughout this preamble to these final rules, the Departments are committed to ensuring that participants and beneficiaries have access to the mental health and substance use disorder benefits covered under their plan or coverage and are not adversely affected by violations of MHPAEA. The Departments are, however, modifying the requirement that plans and issuers must include a clear and accurate statement as to whether the Secretary has indicated that those actions, if completed, will result in compliance, to reflect that the Secretary may not be able to know whether the actions taken or being taken will bring the plan into compliance. Instead, under these final rules, plans and issuers must indicate whether the relevant Secretary has concurred with those actions. The Departments are also modifying the requirement that the notice include a description of any opportunity for a participant or beneficiary to have a claim for benefits reprocessed to include any opportunity to submit a new claim, to account for participants and beneficiaries who did not initially file a claim for a mental health or substance use disorder benefit that could have been covered.

In the proposed rules, the Departments solicited comment on other measures to increase transparency and better inform the general public regarding final agency determinations of noncompliance of plans or issuers with MHPAEA. One commenter suggested that to improve transparency, all informational materials published to the public following final agency determinations of noncompliance should clearly state the name of the insurer who holds contracts with the TPA or MBHO if a TPA or MBHO is found to be in violation of MHPAEA. The commenter also recommended that the Departments require all States to make notices of MHPAEA violations publicly available via State agency websites and other avenues easily accessible by beneficiaries within a reasonable timeframe after determinations of noncompliance

with MHPAEA are made. The Departments acknowledge these comments and will continue to consider them.

In addition to making the comparative analyses available upon request to the relevant Secretary, the Departments proposed to codify a requirement that plans and issuers make available the comparative analyses when requested by any applicable State authority, as well as participants and beneficiaries (including a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit determination related to mental health or substance use disorder benefits and, for ERISA-covered plans, participants and beneficiaries at any time, under authority under ERISA section 104. The Departments noted that, while the proposed rules would codify the statutory requirement to make comparative analyses available to the applicable State authority upon request, the proposed rules would not otherwise apply the timeframes and processes regarding the Secretarial request process to requests for comparative analyses made by applicable State authorities. The Departments requested comments on these proposals, including whether the proposed requirements should apply to plans and issuers with respect to a request made by the applicable State authority for an NQTL comparative analysis, including the proposed notice requirement following a final determination of noncompliance.

Some commenters recommended that the Departments emphasize that health insurance issuers have an unambiguous duty to share their MHPAEA comparative analyses with applicable State authorities upon request even if the relevant Secretary has not also made the same request. Commenters also recommended that the Departments work closely with State insurance authorities to incentivize and facilitate the implementation of comparable review and notice standards. Several other commenters requested the Departments include applicable State authorities in proposed 26 CFR 54.9812-2(b), 29 CFR 2590.712-1(b), and 45 CFR 146.137(b), to make clear that States have the authority to request comparative analyses. Some commenters

noted that some issuers refuse to provide comparative analyses to the applicable State authority upon request. Commenters requested guidance concerning requests from participants, beneficiaries, and authorized representatives who have received an adverse benefit determination related to mental health and substance use disorder benefits, including one commenter requesting guidance on how participants, beneficiaries, and their authorized representatives may report potential violations of MHPAEA, and another commenter that requested clear guidelines regarding when the issuance of an adverse benefit determination triggers a requirement by the plan to disclose its comparative analyses, upon request.

After reviewing comments, the Departments are finalizing as proposed the requirement that plans and issuers must make available a copy of the comparative analysis when requested by any applicable State authority, a participant or beneficiary (or a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit determination related to mental health or substance use disorder benefits, and, for ERISA-covered plans, participants and beneficiaries generally, who may request the comparative analysis at any time under ERISA section 104. The Departments are of the view that it is important that participants and beneficiaries are able to access comparative analyses of NQTLs imposed on mental health and substance use disorder benefits under their plan or coverage. In implementing MHPAEA, the Departments have heard repeated complaints that plans and issuers fail to disclose information on the processes, strategies, evidentiary standards, and other factors used to design and apply an NQTL, including the relevant comparative analyses to participants and beneficiaries, despite clear statements by the Departments regarding this requirement.¹²⁴ The

¹²⁴ See, e.g., 26 CFR 54.9812-1(d)(3), 29 CFR 2590.712(d)(3), and 45 CFR 146.136(d)(3); FAQs About Affordable Care Act Implementation Part V and Mental Health Parity Implementation (Dec. 22, 2010), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-v.pdf> and <https://www.hhs.gov/guidance/document/affordable-care-act-implementation-faqs-set-5>; FAQs About Affordable Care Act Implementation Part 31, Mental Health Parity Implementation and Women's Health and Cancer Rights Action Implementation (Apr. 20, 2016), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebbsa/our-activities/resource-center/faqs/aca-part-31.pdf> and <https://www.hhs.gov/guidance/document/affordable-care-act->

Departments are concerned that limiting the ability of participants and beneficiaries (or their authorized representatives) to request the comparative analyses to only those situations where there is an adverse benefit determination related to mental health or substance use disorder benefits, would frustrate participants' and beneficiaries' ability to get the information they need about their mental health and substance use disorder benefits to effectuate their rights, including in situations where they forgo submitting a claim for benefits. The Departments remain committed to responding to inquiries and complaints about compliance with MHPAEA, and participants, beneficiaries, and enrollees, as well as their authorized representatives, may contact EBSA at 1-866-444-3272 or <https://www.dol.gov/agencies/ebsa/about-ebsa/ask-a-question/ask-ebsa> or HHS at 1-800-985-3059 or <https://www.cms.gov/medical-bill-rights/help/submit-a-complaint>.

As specified earlier in the preamble, the statute requires that plans and issuers must provide a copy of the comparative analysis to any applicable State authority upon request. The statute does not require applicable State authorities to follow the same procedure to review and request comparative analyses as that applicable to the Departments, and, therefore, these final rules do not include “applicable State authorities” in the regulatory text that describes this procedure. However, these final rules at 26 CFR 54.9812-2(e), 29 CFR 2590.712-1(e), and 45 CFR 146.137(e) provide that a health insurance issuer in a State must provide the comparative analysis to the applicable State authority (that is, the State insurance commissioner or official or officials designated by the State to enforce the requirements of title XXVII of the PHS Act for the State involved with respect to such issuer) upon request. Additionally, compliance with MHPAEA is not determinative of compliance with other State or Federal laws. Applicable State

implementation-faqs-set-31; FAQs About Mental Health Parity Implementation and the Consolidated Appropriations Act, 2021 Part 45 (Apr. 2, 2021), <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-45.pdf> and <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/MHPAEA-FAQs-Part-45.pdf>.

authorities retain independent authority over issuers of group and individual health insurance coverage and may request or require additional information under their own authorities. Issuers of group and individual health insurance coverage must also comply with State insurance laws, to the extent they do not prevent the application of the requirements of MHPAEA.

C. Applicability - 26 CFR 54.9812-1(i), 29 CFR 2590.712(i), and 45 CFR 146.136(i) and 26 CFR 54.9812-2(g), 29 CFR 2590.712-1(g), and 45 CFR 146.137(g)

The Departments proposed to amend 26 CFR 54.9812–1(i)(1), 29 CFR 2590.712(i)(1), and 45 CFR 146.136(i)(1) to specify that, except as provided in paragraph (i)(2), the proposed rules applicable to group health plans (and health insurance coverage offered by an issuer in connection with such plans)¹²⁵ would apply on the first day of the first plan year beginning on or after January 1, 2025. The Departments acknowledged in the preamble of the proposed rules that the proposed requirements would take time for plans and issuers to implement. Therefore, the Departments sought to strike an appropriate balance for the date by which plans and issuers must comply with final rules. The Departments noted that until the proposed applicability date, plans and issuers would be required to continue to comply with the most recent MHPAEA regulations codified in the CFR,¹²⁶ as applicable. The Departments similarly proposed that the requirements in 26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137 of the proposed rules, governing the requirements for comparative analyses under MHPAEA, would apply for plan years beginning on or after January 1, 2025. However, the Departments reminded plans and issuers that the statutory provisions added to MHPAEA by the CAA, 2021 are self-implementing

¹²⁵ Coverage offered by Medicaid managed care organizations, CHIP, and Medicaid Alternative Benefit Programs are subject to separate mental health parity regulations at codified at 42 CFR Parts 438, 440, 456, and 457. *See* Medicaid and Children’s Health Insurance Programs; Mental Health Parity and Addiction Equity Act of 2008; Application of Mental Health Parity Requirements to Coverage Offered by Medicaid Managed Care Organizations, the Children’s Health Insurance Program (CHIP), and Alternative Benefit Plans; Final Rule. 81 FR 18390 (Mar. 30, 2016), <https://www.federalregister.gov/documents/2016/03/30/2016-06876/medicaid-and-childrens-health-insurance-programs-mental-health-parity-and-addiction-equity-act-of>.

¹²⁶ 26 CFR 54.9812-1, revised as of April 1, 2023, 29 CFR 2590.712, revised as of July 1, 2022, and 45 CFR 146.136, revised as of October 1, 2021.

and took effect on February 10, 2021. As such, the proposed delayed applicability date for the comparative analysis requirements in the proposed rules would not alter a plan's or issuer's obligations under the statute. The Departments solicited comments on the proposed applicability dates.

Several commenters stated that the proposals put forward sweeping changes to the existing rules. To allow time for implementation, commenters requested that the applicability date of the final rules for plans and issuers be for plan years beginning on or after January 1, 2026, or 2 years following publication of the final rules. Several commenters requested an implementation period ranging from 1 to 2 years. Some of these commenters additionally requested a 1-year good faith enforcement safe harbor to allow plans and issuers additional time to comply with the new requirements. Another commenter requested that the proposed rules be effective in 2024, in order to not delay access to vital mental health and substance use disorder benefits.

In order to effectuate these final rules in a timely manner and to ensure that participants and beneficiaries seeking benefits to treat mental health conditions or substance use disorders do not face a greater burden on access to mental health and substance use disorder benefits than medical/surgical benefits, while acknowledging the challenges to plans and issuers of implementing some of the requirements in these final rules, the Departments are finalizing the applicability provision, with some modifications. Accordingly, these final rules apply to group health plans (and health insurance coverage offered by an issuer in connection with a group health plan) on the first day of the first plan year beginning on or after January 1, 2025, except for the meaningful benefits standard, the prohibition on discriminatory factors and evidentiary standards, the relevant data evaluation requirements, and the related requirements in the provisions for comparative analyses, which apply on the first day of the first plan year beginning on or after January 1, 2026. Until these rules are applicable, plans and issuers must continue to

comply with the regulations implementing MHPAEA as in effect prior to the effective date of these final rules, and must comply with the statutory provisions of MHPAEA, as amended by the CAA, 2021, both before and after these final rules become applicable. The Departments remind plans and issuers that guidance provided in FAQs Part 45 addresses what information plans and issuers should make available under MHPAEA, as amended by the CAA, 2021, in response to the Departments' request for comparative analyses and can be relied on pending the applicability dates of these final rules.

In response to the comments raising concerns about the magnitude of the changes of the proposed requirements in the proposed rules, particularly in relation to the amount of data collection and analysis that would be required and the time needed by plans and issuers to implement these changes, the Departments are delaying the applicability date with respect to certain provisions in these final rules, as discussed in this section of the preamble.

As part of the request to the Departments to extend the applicability date of these final rules, several commenters raised concerns regarding the amount of new documentation and the time necessary to implement the relevant data evaluation requirements, which, as noted earlier in this preamble, require plans and issuers to collect and evaluate data in a manner that is not currently required. The Departments acknowledge that the relevant data evaluation requirements and the related requirements in the provisions requiring the comparative analyses to demonstrate comparability and stringency, in operation, impose specific new obligations that plans and issuers must comply with in order to demonstrate that an NQTL with respect to mental health or substance use disorder benefits in any classification is no more restrictive in operation than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification. These final rules identify examples of relevant data that a plan or issuer may be required to collect, but ultimately the plan or issuer will need to determine which data must be collected and analyzed to comply with these final rules, whether any differences reflected in the

data are material, and what reasonable actions to take, as necessary, when there are material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in the same classification. Similarly, the Departments recognize that the meaningful benefits standard under these final rules could impose new obligations for plans and issuers, which may require changes to benefit design that may be difficult to implement within a short period of time after the issuance of these final rules. Additionally, the Departments acknowledge that the prohibition on discriminatory factors may require plans and issuers to evaluate their NQTLs to determine whether such limitations are based on prohibited factors or evidentiary standards and whether changes need to be made to such factors or evidentiary standards in order to comply with these final rules.

The Departments agree with commenters that this process will take time and that plans and issuers will face difficulty complying with these requirements by the start of a plan year beginning on or after January 1, 2025. Therefore, the Departments are delaying the applicability date for the meaningful benefits standard under 26 CFR 54.9812-1(c)(2)(ii)(A), 29 CFR 2590.712(c)(2)(ii)(A), and 45 CFR 146.136(c)(2)(ii)(A); the prohibition on discriminatory factors and evidentiary standards under 26 CFR 54.9812-1(c)(4)(i)(B), 29 CFR 2590.712(c)(4)(i)(B), and 45 CFR 146.136(c)(4)(i)(B); the relevant data evaluation requirements under 26 CFR 54.9812-1(c)(4)(iii), 29 CFR 2590.712(c)(4)(iii), and 45 CFR 146.136(c)(4)(iii); and the related requirements in the provisions for comparative analyses;¹²⁷ to apply on the first day of the first plan year beginning on or after January 1, 2026. The Departments emphasize that plans and issuers must continue to comply with the 2013 final regulations until the respective applicability dates in these final rules. For example, even though the prohibition on discriminatory factors does not apply to plans and issuers until plan years beginning on or after

¹²⁷ 26 CFR 54.9812-2(c)(2)(ii)(C), (c)(5)(i)(C) and (D), and (c)(5)(ii) through (v); 29 CFR 2590.712-1(c)(2)(ii)(C), (c)(5)(i)(C) and (D), and (c)(5)(ii) through (v); and 45 CFR 137(c)(2)(ii)(C), (c)(5)(i)(C) and (D), and (c)(5)(ii) through (v).

January 1, 2026, plans and issuers should still be prepared to demonstrate that the factors used to design or apply an NQTL to mental health and substance use disorder benefits are comparable to and applied no more stringently than the factors used to design and apply an NQTL to medical/surgical benefits in the same classification in accordance with the 2013 final regulations. The Departments expect that plans and issuers will utilize the delayed applicability period to work in good faith to update systems and processes to comply with the new requirements of these final rules. Accordingly, the Departments encourage plans and issuers to start working to ensure that they are in a position to comply with all aspects of these final rules in a timely manner, including by working to comply with the meaningful benefits standard, the prohibition on discriminatory factors and evidentiary standards, and the relevant data evaluation requirements, as well as the associated comparative analysis requirements, no later than for plan years beginning on or after January 1, 2026.

D. Severability - 26 CFR 54.9812-1(j), 29 CFR 2590.712(j), and 45 CFR 146.136(j) and 26 CFR 54.9812-2(h), 29 CFR 2590.712-1(h), and 45 CFR 146.137(h)

The Departments proposed severability clauses in the proposed rules to capture the Departments' intent that, to the extent a reviewing court holds that any provision of the final rules is unlawful by its terms or as applied to any person or circumstance, or stayed pending further agency action, the provision would be construed so as to continue to be given the maximum effect permitted by law. The Departments expressed their view that if the proposed rules were finalized as proposed or as a substantially similar version, such rules would provide comprehensive protections that implement MHPAEA's requirements. The Departments noted that the aim of the proposed rules is to ensure that individuals with mental health conditions and substance use disorders benefit from the full protections afforded to them under MHPAEA, and that separate elements of the proposed rules would individually contribute to furthering that aim. Therefore, the Departments proposed that if a court were to hold that any provisions were invalid

or unenforceable, any affected provisions would be severable from the rest of the proposed rules, if finalized, and would not affect any other provisions or their application to persons not similarly situated or to dissimilar circumstances.

The Departments did not receive any comments relating to the proposed severability provisions and are finalizing these provisions without change. The Departments note that, while the requirements under 26 CFR 54.9812-1(c)(4)(i) and (iii), 29 CFR 2590.712(c)(4)(i) and (iii), and 45 CFR 146.136(c)(4)(i) and (iii) are part of a comprehensive regulatory scheme, the provisions are separate aspects of the parity analysis and can continue to apply independently if other provisions of these final rules are invalidated. While the Departments have made some changes from the proposed rules in these final rules, as discussed earlier in this preamble, the Departments are not of the view that these changes affect the severability of the provisions of these final rules.

E. Request for Information

In the preamble to the proposed rules, the Departments requested information on ways to improve the coverage of mental health and substance use disorder benefits through other consumer protection laws, including the ACA. The Departments requested comments on ways to incentivize TPAs to facilitate compliance with MHPAEA on behalf of the plans that they design and administer and methods to enhance access to mental health and substance use disorder benefits through the Departments' implementation of PHS Act section 2706(a), the provider nondiscrimination requirements. The Departments also requested comments on ways that they could improve the coverage of and enhance access to mental health and substance use disorder benefits through their implementation of the provider directory requirements under Code section 9820(a) and (b), ERISA section 720(a) and (b), and PHS Act section 2799A-5(a) and (b), the requirements for telehealth, and the ways in which the Departments could leverage ERISA's and the ACA's existing claims procedure requirements to help facilitate access to mental health and

substance use disorder benefits. Finally, the Departments requested information on whether HHS and the Treasury should consider potential amendments to the minimum value rule and on how behavioral health crisis services fit within the existing MHPAEA classifications or the EHB categories.

The Departments appreciate the many comments received in response to the request for information and will use the comments to inform potential future rulemaking and guidance.

III. Overview of the Final Rules – Department of HHS

A. Sunset of MHPAEA Opt-Out for Self-Funded Non-Federal Governmental Plans

Prior to the enactment of the CAA, 2023 on December 29, 2022, sponsors of self-funded non-Federal governmental plans were permitted to elect to exempt those plans from (opt out of) compliance with the MHPAEA requirements, among other specified requirement categories, in title XXVII of the PHS Act.¹²⁸

The CAA, 2023 included a provision that sunsets the election option with respect to MHPAEA.¹²⁹ Specifically, that provision amended PHS Act section 2722(a)(2) to specify that no MHPAEA opt-out election may be made on or after the date of the enactment of the CAA, 2023, and that, subject to certain exceptions, no MHPAEA opt-out election expiring on or after the date that is 180 days after the date of such enactment may be renewed.¹³⁰

The CAA, 2023 included an exception for certain collectively bargained plans with an opt-out election in effect for MHPAEA that allows for a longer transition to come into compliance with MHPAEA. Specifically, the CAA, 2023 added language to PHS Act section 2722(a)(2) indicating that a self-funded non-Federal governmental plan that is subject to multiple collective bargaining agreements of varying lengths that has a MHPAEA opt-out election in

¹²⁸ PHS Act section 2722(a)(2); 45 CFR 146.180.

¹²⁹ Division FF, Title I, Subtitle C, Chapter 3, section 1321, Pub. L. 117-328, 136 Stat. 4459 (Dec. 29, 2022).

¹³⁰ PHS Act section 2722(a)(2)(F)(i).

effect as of the date of enactment of the CAA, 2023, that expires on or after the date that is 180 days after the enactment of the CAA, 2023, may extend such election until the date on which the term of the last such agreement expires.¹³¹

As a result of the CAA, 2023 amendments to PHS Act section 2722(a)(2), self-funded non-Federal governmental plan sponsors may elect to opt out of only the following three PHS Act requirement categories: standards relating to benefits for newborns and mothers (PHS Act section 2725), required coverage for reconstructive surgery following mastectomies (PHS Act section 2727), and coverage for dependent students on a medically necessary leave of absence (PHS Act section 2728).

In the proposed rules, HHS proposed to amend 45 CFR 146.180 to align with the CAA, 2023 amendments to PHS Act section 2722(a)(2). Specifically, HHS proposed to redesignate paragraphs (a)(3) through (7) as paragraphs (a)(4) through (8) and add a new paragraph (a)(3) specifying that a sponsor of a self-funded non-Federal governmental plan may not elect to exempt its plans from any of the MHPAEA requirements on or after December 29, 2022 (the date of enactment of the CAA, 2023) through the process specified in 45 CFR 146.180. HHS also proposed to add new paragraph (f)(4)(iii) specifying that in the case of a self-funded non-Federal governmental plan that is subject to multiple collective bargaining agreements of varying lengths and that has an election with respect to any of the MHPAEA requirements in effect as of December 29, 2022, through the process specified in 45 CFR 146.180, that expires on or after June 27, 2023 (the date that is 180 days after the date of enactment of the CAA, 2023), the plan may extend such election until the date on which the term of the last such agreement expires. HHS also proposed to make conforming edits to paragraph (a)(2), paragraphs (a)(5)(i), (a)(5)(ii), and (a)(6)(ii), as proposed to be redesignated, and paragraph (f)(1). HHS proposed that the

¹³¹ PHS Act section 2722(a)(2)(F)(ii).

amendments to 45 CFR 146.180 would apply on the effective date of the final rule.¹³² HHS sought comments on these proposed amendments, including whether additional guidance or clarifications were necessary to implement the sunset of the MHPAEA opt-out election provision.

Several commenters expressed support for the proposal to codify the sunset for sponsors of self-funded non-Federal governmental plans to opt out of compliance with the MHPAEA requirements. Many of these commenters recommended prioritizing MHPAEA compliance reviews of these plans as soon as their respective opt-outs are no longer valid. Furthermore, some commenters suggested these plans should immediately be requested to submit the NQTL comparative analyses required under PHS Act section 2726(a)(8)(A) to ensure compliance with MHPAEA. One commenter encouraged HHS to oversee self-funded non-Federal governmental plans to ensure full MHPAEA compliance by such plans that previously opted out of compliance with the MHPAEA requirements.

HHS appreciates the support for the proposed amendments to codify the sunset of the option for self-funded non-Federal governmental plans to elect to opt out of compliance with the MHPAEA requirements. HHS did not receive any comments objecting to the proposed amendments to 45 CFR 146.180 and is finalizing those amendments as proposed in these final rules. HHS is committed to ensuring that self-funded non-Federal governmental plans that previously opted out of compliance with MHPAEA come into compliance with MHPAEA requirements. In determining the degree to which HHS will prioritize compliance reviews, NQTL comparative analysis reviews, and enforcement of MHPAEA with respect to self-funded non-Federal governmental plans once the plans' respective opt-outs sunset, HHS will weigh all

¹³² The statutory provisions implemented by 45 CFR 146.180 became effective December 29, 2022 (the date of enactment of the CAA, 2023).

relevant considerations, such as the number of complaints of MHPAEA noncompliance with respect to such plans.

One commenter suggested HHS implement a tiered approach to penalty assessment for compliance with MHPAEA that employs varying levels of penalties which consider the severity of and frequency of violations. This approach, according to the commenter, would encourage greater compliance as non-Federal governmental entities diligently work to modify their health plans, and would mitigate detrimental fiscal impacts that would reduce the ability of non-Federal governmental entities to both recruit and retain a strong workforce and continue to provide necessary services to residents.

With respect to penalties for violations of MHPAEA and other PHS Act requirements, HHS has determined that the enforcement processes and procedures set forth in existing regulations are sufficient to address the tiered approach to penalty assessment recommended by the commenter. The HHS enforcement processes and procedures applicable to self-funded non-Federal governmental plans are set forth at 45 CFR 150.301 through 150.347. Rather than specifying a specific set penalty amount for any and all violations, the regulations at 45 CFR 150.317, 150.319, 150.321, and 150.323 specify the factors HHS uses in determining the amount of any penalty, including the entity's previous record of compliance and the gravity of the violation; mitigating circumstances; aggravating circumstances; and other matters as justice may require.¹³³ These factors allow HHS to structure penalties in a manner that encourages compliance while taking into account the relevant facts and circumstances.

One commenter requested that HHS provide guidance on how self-funded non-Federal governmental plans can leverage the expertise of TPAs to comply with MHPAEA.

¹³³ HHS proposed amendments to the provisions in 45 CFR part 150 related to enforcement processes and procedures and penalties for noncompliance. 86 FR 51730 (Sept. 16, 2021).

HHS acknowledges that most self-funded group health plans contract with one or more TPAs to administer, and in some cases, to design plan benefits. To the extent a self-funded non-Federal governmental plan that contracts with a TPA has previously elected to opt out of MHPAEA compliance, HHS urges the sponsors of such plans to work with their TPAs to ensure that, under the plan's contract with the administrator, if the TPA is required to administer benefits, it collects and analyzes data, and provides data to the sponsor in such a way that will enable the sponsor to comply with all the requirements of MHPAEA. HHS also notes that Federal regulations at 45 CFR 150.305 identify the entity liable for civil money penalties for noncompliance with applicable PHS Act requirements, including MHPAEA. Under the regulations, if a non-Federal governmental plan is sponsored by two or more employers and fails to comply with an applicable PHS Act requirement, the plan is subject to a civil money penalty, irrespective of whether the plan is administered by a health insurance issuer, an employer sponsoring the plan, or a TPA.¹³⁴ If a non-Federal governmental plan is sponsored by a single employer and fails to comply with an applicable PHS Act requirement, the employer is subject to a civil money penalty, irrespective of whether the plan is administered by a health insurance issuer, the employer, or a TPA.¹³⁵

B. Applicability of MHPAEA to Individual Health Insurance Coverage

The HHS regulation implementing MHPAEA for individual health insurance coverage is codified at 45 CFR 147.160. The regulation currently provides that the group market regulation implementing MHPAEA at 45 CFR 146.136 applies to health insurance coverage offered by a health insurance issuer in the individual market in the same manner and to the same extent as such provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market, for policy years beginning on or

¹³⁴ 45 CFR 150.305(b).

¹³⁵ 45 CFR 150.305(c).

after the applicability date set forth in 45 CFR 146.136(i). Therefore, through cross-reference, the proposed amendments to 45 CFR 146.136 would apply in the same manner to health insurance issuers offering individual health insurance coverage. Further, HHS proposed to include a cross reference in 45 CFR 147.160 to the comparative analysis requirements that were proposed in 45 CFR 146.137. The cross reference would similarly make clear that the comparative analysis requirements apply to health insurance issuers offering individual health insurance coverage in the same manner that those provisions apply to group health plans and health insurance issuers offering coverage in connection with such plans. HHS proposed that these provisions would apply to health insurance issuers offering individual health insurance coverage for policy years beginning on or after January 1, 2026. Finally, for greater clarity and precision and to align with the statutory terminology, HHS proposed to modify the regulation text to refer to “individual health insurance coverage offered by a health insurance issuer” as opposed to “health insurance coverage offered in the individual market.”

Commenters expressed support for HHS’ proposal to apply the proposed amendments to 45 CFR 146.136 in the same manner to individual health insurance coverage. HHS is finalizing this proposal as proposed.

HHS received one comment supporting its proposal to include a cross reference in 45 CFR 147.160 to the comparative analysis requirements that were proposed in 45 CFR 146.137 to make clear that the comparative analysis requirements apply to health insurance issuers offering individual health insurance coverage in the same manner that those provisions apply to group health plans and health insurance issuers offering coverage in connection with such plans, and did not receive any comments opposing that proposal. HHS did not receive any comments on its proposal to modify the regulation text to refer to “individual health insurance coverage offered by a health insurance issuer” as opposed to “health insurance coverage offered in the individual market.” HHS is finalizing these proposals as proposed.

With respect to HHS' proposal that these provisions would apply to individual health insurance coverage for policy years beginning on or after January 1, 2026, one commenter stated that this applicability date should align with the applicability date for self-funded non-Federal governmental plans to come into compliance with MHPAEA's requirements under PHS Act section 2726 and its implementing regulations, while other commenters requested that the applicability date for individual health insurance coverage be delayed until January 1, 2027. As stated in the proposed rules, non-grandfathered individual health insurance coverage must be offered on a calendar year basis. Premium rates must be submitted to the applicable regulator and finalized prior to January 1 of each calendar year and rates cannot be modified during the year. The proposed applicability date is intended to provide time for issuers offering individual health insurance coverage to account for the effects of these rules following publication of the final rules, which precludes alignment with the applicability date for self-funded non-Federal governmental plans, and prior to when rates and benefits must be finalized and approved for the following calendar year. In addition, HHS declines to delay the applicability date until January 1, 2027, in order to ensure the protections of these final rules apply in a timely manner. Therefore, with respect to its proposal that these provisions would apply to individual health insurance coverage, HHS is finalizing the applicability date of January 1, 2026, as proposed.

Until the applicability date, issuers are required to continue to comply with the most recent MHPAEA regulations codified in the CFR¹³⁶ and must comply with the statutory provisions of MHPAEA, as amended by the CAA, 2021, both before and after these final rules become applicable. HHS reminds issuers that the guidance in FAQs Part 45 addresses what information plans and issuers should make available under MHPAEA, as amended by the CAA,

¹³⁶ Specifically, issuers must continue to comply with 45 CFR 147.160, incorporating 45 CFR 146.136, each revised as of October 1, 2023.

2021, in response to the Departments’ request for comparative analyses and can be relied on pending the applicability date of these final rules.

IV. Regulatory Impact Analysis

Summary – Departments of Health and Human Services and Labor

The Departments¹³⁷ have examined the impacts of these final rules as required by Executive Order 12866,¹³⁸ Executive Order 13563,¹³⁹ Executive Order 14094,¹⁴⁰ the Paperwork Reduction Act of 1995,¹⁴¹ the Regulatory Flexibility Act,¹⁴² section 202 of the Unfunded Mandates Reform Act of 1995,¹⁴³ Executive Order 13132,¹⁴⁴ and the Congressional Review Act.¹⁴⁵

1. Executive Orders 12866 and 13563 – Departments of Health and Human Services and Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Under Executive Order 12866, “significant” regulatory actions are subject to review by the Office of Management and Budget (OMB). As amended by Executive Order 14094,¹⁴⁶ entitled “Modernizing Regulatory Review,” section 3(f) of the Executive order defines a “significant regulatory action” as any regulatory action that is likely to result in a rule that may:

¹³⁷ The Department of the Treasury is not included as part of the Departments in the regulatory impact analysis.

¹³⁸ Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993).

¹³⁹ Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 18, 2011).

¹⁴⁰ Modernizing Regulatory Review, 88 FR 21879 (Apr. 6, 2023).

¹⁴¹ 44 U.S.C. 3506(c)(2)(A) (1995).

¹⁴² 5 U.S.C. 601 *et seq.* (1980).

¹⁴³ 2 U.S.C. 1501 *et seq.* (1995).

¹⁴⁴ Federalism, 64 FR 153 (Aug. 4, 1999).

¹⁴⁵ 5 U.S.C. 801 *et seq.* (1996).

¹⁴⁶ Modernizing Regulatory Review, 88 FR 21879 (Apr. 6, 2023).

- (1) have an annual effect on the economy of \$200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, Territorial, or Tribal governments or communities;
- (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- (3) materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

Based on the Departments' estimates, OMB's OIRA has determined this rulemaking is significant per section 3(f)(1) as measured by the \$200 million or more in any one year. Therefore, the Departments have provided an assessment of the potential costs, benefits, transfers, and alternatives associated with these final rules, and OMB has reviewed these final rules.

2. Introduction and Need for Regulations

Mental health is crucial to a person's overall well-being, and access to quality mental health and substance use disorder treatment is as essential for health as access to medical/surgical treatment.¹⁴⁷ According to the NSDUH, in 2022, 50.6 percent of adults in the United States with

¹⁴⁷ Commonwealth Fund, *Behavioral Health Care in the United States: How It Works and Where It Falls Short* (Sept. 7, 2022), <https://www.commonwealthfund.org/publications/explainer/2022/sep/behavioral-health-care-us-how-it-works-where-it-falls-short>.

any mental illness had received treatment within the past year; 66.7 percent of adults with a serious mental illness had received treatment.¹⁴⁸

Failure to treat mental health conditions or substance use disorders can be costly. For example, depression is associated with increased risk of cardiovascular disease, diabetes, stroke, Alzheimer's disease, suicidality, and osteoporosis, and an untreated substance use disorder may result in hospital emergency room care for a drug overdose.¹⁴⁹ One study examined the costs and benefits of 58 grants provided through the Garrett Lee Smith Memorial Suicide Prevention Program (GPP) between 2005 and 2009, which provides Federal funding to States, Tribes, and colleges for community-based suicide prevention programs. The study estimated that the programs resulting from GPP funding prevented 79,379 suicide attempts and resulted in \$4.50 in medical cost savings for each dollar invested.¹⁵⁰

Individuals with mental health conditions or substance use disorders have faced stigma, discrimination, and other barriers inside and outside of the health care system, which can operate as impediments to seeking and obtaining treatment. In 2022, approximately 27 percent of adults 18 and older with any mental illness in the past year who did not receive mental health treatment reported a perceived unmet need for treatment.¹⁵¹ Individuals reported a variety of reasons for not receiving treatment: 59 percent thought it would cost too much; 26 percent were concerned their information would not be kept private; 20 percent were unable to get an opening in the treatment program or with the health care professional they wanted to see; 16 percent thought it

¹⁴⁸ SAMHSA, *Center for Behavioral Health Statistics and Quality*, National Survey on Drug Use and Health, Table 6.21B (2022), <https://www.samhsa.gov/data/sites/default/files/reports/rpt42728/NSDUHDetailedTabs2022/NSDUHDetailedTabs2022/NSDUHDetTabsSect6pe2022.htm>.

¹⁴⁹ Government Accountability Office (GAO), *Behavioral Health: Research on Health Care Costs of Untreated Conditions is Limited*, GAO-19-274 (Feb. 2019), <https://www.gao.gov/assets/gao-19-274.pdf>.

¹⁵⁰ Lucas Godoy Garraza, Christine Walrath, Simone Peart Boyce, & David Goldston, *An Economic Evaluation of the Garrett Lee Smith Memorial Suicide Prevention Programs*, 48(1) *Suicide and Life-Threatening Behavior* (2018), <https://onlinelibrary.wiley.com/doi/10.1111/sltb.12321>.

¹⁵¹ SAMHSA, *Center for Behavioral Health Statistics and Quality*, National Survey on Drug Use and Health, Figure 64 (2022), <https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf>.

may cause their community to have a negative opinion about them; and 15 percent thought it might impact their job, parental rights or housing.¹⁵²

The Departments are particularly concerned with access barriers for individuals seeking mental health or substance use disorder treatments. A 2022 Harris Poll sponsored by the National Council for Mental Wellbeing found that 21 percent of adults with unmet mental health care needs in the past year and 28 percent of those with unmet substance use disorder care needs in the past year reported that their inability to get an immediate appointment had prevented them from getting needed care.¹⁵³

Obtaining appointments with primary care physicians instead of behavioral health specialists can be significantly easier. According to the 2023 KFF Employer Health Benefits Survey, 91 percent of firms that offer physical health benefits believe there is a sufficient number of primary care providers in the plans' network, whereas only 67 percent and 59 percent, respectively, believe there is a sufficient number of mental health providers and substance use disorder providers.¹⁵⁴ However, while up to 70 percent of all primary care visits include a behavioral health component,¹⁵⁵ research suggests that primary care providers face significant barriers to delivering these services, including insufficient resources, inadequate related knowledge, and limited time with patients.¹⁵⁶

¹⁵² SAMHSA, *Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, Table A.47B* (2022), <https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf>. Respondents could indicate multiple reasons for not receiving treatment and so response categories are not mutually exclusive.

¹⁵³ National Council for Mental Wellbeing, *2022 Access to Care Survey Results* (May 11, 2022), <https://www.thenationalcouncil.org/wp-content/uploads/2022/05/2022-Access-To-Care-Survey-Results.pdf>.

¹⁵⁴ KFF, *2023 Employer Health Benefits Survey* (Oct. 18, 2023), <https://www.kff.org/report-section/ehbs-2023-section-13-employer-practices-telehealth-provider-networks-coverage-limits-and-coverage-for-abortion/>.

¹⁵⁵ Health Affairs, *Combating a Crisis by Integrating Mental Health Services and Primary Care*, *Health Affairs Forefront* (July 8, 2022), <https://www.healthaffairs.org/doi/10.1377/forefront.20220706.603540>.

¹⁵⁶ Danielle F. Loeb, Elizabeth A. Bayliss, Ingrid A. Binswanger, Carey Candrian, & Frank V. Degruy, *Primary Care Physician Perceptions on Caring for Complex Patients with Medical and Mental Illness*, 27(8) *Journal of General Internal Medicine* pp. 945-952 (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3403152/>; Lusine Poghosyan, Allison A. Norful, Affan Ghaffari, Maureen George, Shruti Chhabra, Mark Olfson, *Mental Health Delivery in Primary Care: The Perspectives of Primary Care Providers*, 33(5) *Archives of Psychiatric Nursing* pp. 63-67 (Oct. 2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7077950>.

In seeking out specialists, individuals tend to face less adequate mental health provider networks than medical/surgical provider networks through their plan or coverage. A 2024 study of 2019-2021 claims and enrollment data for employer-sponsored health plans reported that office visits with psychiatrists and psychologists occurred out-of-network 8.9 and 10.6 times more, respectively, than those with medical/surgical specialist physicians.¹⁵⁷ According to a 2021 study, which compared the experiences of patients receiving both specialty mental health and medical/surgical care, patients who were receiving mental health treatment from only a mental health practitioner were more likely to rate their plan's mental health network as inadequate compared with their plan's medical/surgical provider network.¹⁵⁸ The study referenced research that found specialty mental health networks tend to be narrower due to a growing workforce shortage of mental health providers, a high demand for mental health services, and specialty mental health practitioners opting out of participating in provider networks due to low reimbursements for mental health services compared with other specialties. These factors have consequentially resulted in higher out-of-network utilization rates for mental health care services.^{159,160,161}

Use of out-of-network providers can place additional burdens on families seeking mental health and substance use disorder treatments. A 2022 study of families experiencing out-of-network behavioral health expenditures in their employer-sponsored insurance claims found that

¹⁵⁷ Tami L. Mark & William Parish, *Behavioral Health Parity – Pervasive Disparities in Access to In-Network Care Continue*, RTI International (2024), <https://dpjh8a19zd3a4.cloudfront.net/publication/behavioral-health-parity-pervasive-disparities-access-network-care-continue/fulltext.pdf>.

¹⁵⁸ Susan H. Busch & Kelly Kyanko, *Assessment of Perceptions of Mental Health vs Medical Health Plan Networks Among US Adults with Private Insurance*, 4(10) *JAMA Network Open* (2021).

¹⁵⁹ Davenport, Stoddard, Travis Gray, & Stephen P. Melek, *Addiction and Mental Health vs. Physical Health: Widening Disparities in Network Use and Provider Reimbursement*, Milliman (Nov. 20, 2019), <https://www.milliman.com/en/insight/addiction-and-mental-health-vs-physical-health-widening-disparities-in-network-use-and-p/>.

¹⁶⁰ Tara F. Bishop, Joanna K. Seirup, Harold Alan Pincus, & Joseph S. Ross, *Population of US Practicing Psychiatrists Declined, 2003–13, Which May Help Explain Poor Access to Mental Health Care*, 35(7) *Health Affairs (Millwood)* (2016) pp. 1271-1277.

¹⁶¹ Daria Pelech & Tamara Hayford, *Medicare Advantage and Commercial Prices for Mental Health Services*, 38(2) *Health Affairs (Millwood)* (2019) pp. 262-267.

roughly half of the families were subject to “balance billing,” with the yearly mean total for those families being \$861. This study, however, focused on out-of-network claims submitted by providers to insurers, which suggests that, for individuals seeking treatment from behavioral health care from providers not accepting insurance, the out-of-pocket costs could be even greater.¹⁶²

Despite access barriers to seeking mental health and substance use disorder treatment, the need for these services has only increased. An estimated 37 percent of U.S. adults reported being diagnosed with a mental health condition in 2023, a 5-percentage-point increase from pre-pandemic levels in 2019.¹⁶³ Research suggests that the need for mental health services has also increased among children and adolescents. For instance, a 2022 study using 2009 to 2019 data from the NSDUH found that the prevalence of a major depressive episode among adolescents aged 12 to 17 increased by 7.7 percentage points, from approximately 8.1 percent in 2009 to 15.8 percent in 2019. The study found that the increase in prevalence of major depressive episodes was even higher among female adolescents, finding a 12.0-percentage-point increase.¹⁶⁴

The enactment of MHPAEA, as well as the CAA, 2021¹⁶⁵ and associated regulations and guidance issued by the Departments, were intended to assist plans and issuers in improving their policies and procedures to ensure parity between mental health and substance use disorder benefits and medical/surgical benefits, particularly with regards to applying NQTLs.¹⁶⁶

¹⁶² Sarah A. Friedman, Haiyong Xu, Francisca Azocar, & Susan L. Ettner, *Quantifying Balance Billing for Out-of-Network Behavioral Health Care in Employer-Sponsored Insurance*, 73(9) *Psychiatric Services* pp. 1019–1026 (2022).

¹⁶³ American Psychological Association, *Stress in America 2023: A Nation Recovering from Collective Trauma* (Nov. 2023), <https://www.apa.org/news/press/releases/stress/2023/collective-trauma-recovery>.

¹⁶⁴ Michael Daly, *Prevalence of Depression Among Adolescents in the US from 2009 to 2019: Analysis of Trends by Sex, Race/Ethnicity, and Income*, 70 *Journal of Adolescent Health* 3 pp. 496-499 (2022). Additional information regarding these trends in mental health services among children and adolescents is addressed earlier in this preamble.

¹⁶⁵ Pub. L. 116-260 (Dec. 27, 2020).

¹⁶⁶ NQTLs consist of any limitations on the scope and duration of benefits that are not expressed numerically. Because they are non-quantitative, it can be difficult to measure their impact on restricting access and whether they are applied in parity across mental health and substance use disorder benefits and medical/surgical benefits.

However, as documented in the past two Reports to Congress^{167,168} and discussed later in this regulatory impact analysis, the Departments have found from their initial reviews that plans and issuers failed to comply with these requirements.

In order to address these issues and improve the health and well-being of both individuals and their communities, the Departments are committed to promoting equal access to treatment for mental health conditions and substance use disorders. These final rules, by clarifying requirements for comparative analyses and setting forth additional requirements for how NQTLs must be designed and applied for group health plans and health insurance coverage, will serve to improve compliance with MHPAEA by plans and issuers. This will in turn promote more equitable access to affordable and comprehensive care for individuals with mental health conditions and substance use disorders and reduce barriers to mental health and substance use disorder treatments, resulting in greater access and utilization of these services as well as better patient outcomes.

2.1 History of MHPAEA Related Government Actions

To implement the requirements of MHPAEA, the Departments published a request for information soliciting comments on issues under MHPAEA in 2009¹⁶⁹ and interim final regulations in 2010.¹⁷⁰ After considering the comments and other feedback received from interested parties, the Departments published the 2013 final regulations.¹⁷¹ In subsequent years, the Departments provided extensive guidance and compliance assistance materials to the regulated community, State regulators, and other interested parties to facilitate the implementation and enforcement of MHPAEA, including the 2020 MHPAEA Self-Compliance

¹⁶⁷ 2022 MHPAEA Report to Congress, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf>.

¹⁶⁸ 2023 MHPAEA Comparative Analysis Report to Congress, www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

¹⁶⁹ 74 FR 19155 (Apr. 28, 2009).

¹⁷⁰ 75 FR 5410 (Feb. 2, 2010).

¹⁷¹ 78 FR 68240 (Nov. 13, 2013).

Tool, which provided a basic framework for plans and issuers to assess whether their NQTLs satisfy MHPAEA's parity requirements. The Departments also have provided materials to educate consumers, their family members, and policymakers about parity for mental health and substance use disorder benefits,¹⁷² and may develop new materials and undertake additional educational efforts as necessary after the publication of these final rules.

The CAA, 2021 amended MHPAEA, in part, by expressly requiring group health plans and health insurance issuers that provide both medical and surgical benefits and mental health or substance use disorder benefits and impose NQTLs on mental health or substance use disorder benefits to perform and document their comparative analyses of the design and application of NQTLs. Plans and issuers must provide those analyses to the Departments or applicable State authorities, upon request. Moreover, the CAA, 2021 compels the Departments to request and evaluate no fewer than 20 NQTL comparative analyses per year and submit to Congress and make available to the public an annual report summarizing the Departments' review process and findings. Shortly after the enactment of the amendments to MHPAEA made by the CAA, 2021, the Departments issued FAQs Part 45 to help plans and issuers comply with the comparative analysis requirements.¹⁷³

As documented in the 2022 MHPAEA Report to Congress,¹⁷⁴ the Departments found that under the first year of the CAA, 2021, none of the NQTL comparative analyses they reviewed

¹⁷² SAMHSA, *Know Your Rights: Parity for Mental Health and Substance Use Disorder Benefits* (2022), <https://store.samhsa.gov/product/know-your-rights-parity-mental-health-and-substance-use-disorder-benefits/pep21-05-00-003>; SAMHSA, *The Essential Aspects of Parity: A Training Tool for Policymakers*(2022), <https://store.samhsa.gov/product/essential-aspects-parity-training-tool-policymakers/pep21-05-00-001>; DOL, *Understanding Your Mental Health and Substance Use Disorder Benefits*, <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/publications/understanding-your-mental-health-and-substance-use-disorder-benefits>.

¹⁷³ FAQs about Mental Health and Substance Use Disorder Parity Implementation and the Consolidated Appropriations Act, 2021 Part 45 (Apr. 2, 2021), <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-45.pdf> and <https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/mhpaea-faqs-part-45.pdf>.

¹⁷⁴ *2022 MHPAEA Report to Congress*, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf>.

contained sufficient information and documentation from plans and issuers upon initial receipt. Similarly, the 2023 MHPAEA Comparative Analysis Report to Congress¹⁷⁵ notes that nearly all the comparative analyses reviewed by the Departments contained insufficient information upon initial receipt and identified common deficiencies in the comparative analyses prepared by plans and issuers. Moreover, despite plans' and issuers' longstanding obligations under MHPAEA to ensure that the processes, strategies, evidentiary standards, and other factors used to apply NQTLs are equitable, it was apparent upon review of the analyses, that plans and issuers had not carefully designed and implemented their NQTLs to be compliant with MHPAEA prior to the enactment of the CAA, 2021. Many plans and issuers appeared to generate their analyses for the first time in response to the Departments' requests, rather than in advance, as required by law and as a critical part of the design and application of a MHPAEA-compliant NQTL. Consequently, the comparative analyses appeared to focus on finding after-the-fact rationales for decisions and designs involving NQTLs, rather than reflecting proper attention to MHPAEA compliance in the first place.

The Departments are committed to ensuring parity in access to mental health and substance use disorder benefits as compared to medical/surgical benefits. By issuing these final rules, the Departments will provide additional guidance to affected parties to facilitate compliance with MHPAEA and to help ensure that individuals with mental health conditions and substance use disorders benefit from the full protections required by law consistent with the fundamental purpose of MHPAEA.

2.2. Current Regulatory Actions

These final rules amend existing regulatory definitions and add new definitions of key terms, including “factors,” “processes,” “strategies,” and “evidentiary standards.” They also add

¹⁷⁵ 2023 MHPAEA Comparative Analysis Report to Congress, www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

more specificity as to what conditions or disorders plans and issuers must treat as mental health conditions and substance use disorders for purposes of MHPAEA to be consistent with generally recognized independent standards of current medical practice. These final rules also clarify the way the parity requirements apply to NQTLs, including by prohibiting discriminatory factors and evidentiary standards, and provide additional examples of the application of MHPAEA to NQTLs to improve the understanding and ability of the regulated community to comply with the law. Additionally, these final rules require that plans and issuers provide meaningful benefits for covered mental health conditions and substance use disorders in each classification in which meaningful medical/surgical benefits are provided.

Under these final rules, plans and issuers are required to collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits. These final rules provide guidance for how to comply with the relevant data evaluation requirements in limited circumstances where data is initially and temporarily unavailable for new and newly imposed NQTLs and where no data exists that can reasonably measure any relevant impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits. In those instances, the plan or issuer must include specific information in their comparative analyses, as explained earlier in this preamble.

These final rules also set forth specific content requirements for comparative analyses required by the CAA, 2021, and outline the process for plans and issuers to provide their comparative analyses to the Departments or an applicable State authority upon request. Additionally, in these final rules, HHS finalizes regulatory amendments to implement a provision in the CAA, 2023 that sunsets the election option for sponsors of self-funded non-Federal governmental plans to opt out of requirements under MHPAEA.

In their reviews of plans' and issuers' comparative analyses under the requirements of the

CAA, 2021, the Departments identified exclusions related to treatment for ASD with ABA therapy and OUD with medication assisted treatment, as well as gatekeeping provisions for treatment applied with respect to mental health or substance use disorder benefits but not to medical/surgical benefits, such as requiring referrals for appointments and prior authorization for mental health and substance use disorder outpatient services, resulting in corrections by the plans and issuers.¹⁷⁶ However, the comparative analyses alone are often less effective in identifying substantive parity violations for more complex NQTLs, such as those related to network composition. The Departments expect that these additional requirements will provide plans and issuers with a better understanding of the requirements of MHPAEA with respect to NQTLs and improve how they measure, compare, and demonstrate parity, while clarifying appropriate ways for plans and issuers to modify their policies and procedures to meet parity requirements. As such, these final rules will help plans and issuers comply with these requirements, increase the ability of plans and issuers to provide compliant comparative analyses during future reviews or investigations, and result in improved access to treatment and coverage of mental health conditions and substance use disorders, as intended by MHPAEA.

3. Baseline

The baseline for this analysis includes the MHPAEA statute, as amended, implementing regulations, and subsequent guidance. Benefits, costs, and transfers are measured as changes from the baseline under these final rules. For example, the CAA, 2021 requires that plans and issuers perform and document NQTL comparative analyses. Starting 45 days after the enactment of the CAA, 2021, plans and issuers were required to make their comparative analyses available to the Departments or an applicable State authority upon request. Plans and issuers are further required to make these comparative analyses and other applicable information required by the

¹⁷⁶ 2023 MHPAEA Comparative Analysis Report to Congress, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf>.

CAA, 2021 available upon request to participants, beneficiaries, and enrollees in all non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage (including a provider or other person acting as a participant's, beneficiary's, or enrollee's authorized representative) in connection with an adverse benefit determination, as well as to participants and beneficiaries in plans subject to ERISA.¹⁷⁷

The 2022 and 2023 MHPAEA Reports to Congress documented that many comparative analyses prepared by plans and issuers prior to these final rules were deficient even after multiple requests for correction by the Departments.^{178,179} In addition, at least some plans and issuers failed to conduct the required comparative analyses until after the Departments requested them, rather than performing and documenting them prospectively within 45 days following the enactment of the CAA, 2021.

The Departments' view is that plans and issuers that were already timely fulfilling the comparative analysis requirements outlined in CAA, 2021 will incur only incremental costs to comply with these final rules. Plans and issuers not already meeting those requirements may, on the other hand, face significant costs to come into compliance with the CAA, 2021 comparative analysis requirements and these final rules. However, because those actions to comply with the CAA, 2021 comparative analysis requirements would need to occur absent these final rules, those costs are included in the baseline.

Therefore, this regulatory impact analysis does not include benefits or costs for performing and documenting comparative analyses for NQTLs applicable to mental health and substance use disorder benefits and medical/surgical benefits, or making them available upon request, as these are already required by the provisions of the CAA, 2021 and are in the baseline.

¹⁷⁷ FAQs Part 45, Q6.

¹⁷⁸ *2022 MHPAEA Report to Congress*, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf>.

¹⁷⁹ *2023 MHPAEA Comparative Analysis Report to Congress*, www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

However, this regulatory impact analysis does take into account the expected impacts of these final rules on the preparation of plans' and issuers' comparative analyses, how these final rules will impact plans' and issuers' compliance and, in turn, access for participants, beneficiaries, and enrollees needing mental health and substance use disorder treatments, and whether plans and issuers need to change their policies and procedures to provide benefits in parity.

Some commenters stated that the proposal would require plans and issuers to substantially revise their comparative analyses, arguing the significance of those revisions makes the Departments' approach of conducting an incremental analysis of the additional requirements of this rulemaking inappropriate. In particular, one commenter stated that the imposition of the new "substantially all" test would require all comparative analyses to be redone, thereby imposing the full cost of performing these analyses under the proposed rules. In response, the Departments note that, as discussed earlier in this preamble, they are not finalizing the proposed mathematical tests for applying the substantially all and predominant tests, which would have based these determinations on the dollar amount of all plan payments for medical/surgical benefits expected to be paid. Instead, these final rules provide that an NQTL with respect to mental health or substance use disorder benefits is more restrictive, as written or in operation, than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification if the plan or issuer fails to satisfy the design and application requirements or the relevant data evaluation requirements. Additionally, the material differences standard in the relevant data evaluation requirements reflects an interpretation of the statutory terms "substantially all" and "predominant" in a manner that takes into account the multi-faceted nature of NQTLs, as well as the complexity of analyzing such NQTLs.

Because the CAA, 2021 requires that comparative analyses be performed and documented, the fact that plans and issuers were not adequately conducting the required analyses and documenting how they determined NQTLs were being applied in parity, is not a justification

for why these final rules should account for the full cost of those actions. Rather, these final rules consider as the baseline what plans and issuers should have done given the relevant statute and guidance irrespective of these final rules. Therefore, for this category of cost, the effect of these final rules is limited to those additional requirements included by the Departments in the final rules. Estimates are made based on the impact from the baseline on plans and issuers affected by these final rules, and assuming full compliance with the new requirements.

4. Summary of Impacts

These final rules define certain terms associated with MHPAEA's requirements for NQTLs and require that plans and issuers provide meaningful benefits for covered mental health conditions and substance use disorders in each classification in which meaningful medical/surgical benefits are provided. These final rules also provide that a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) may not impose any NQTL with respect to mental health or substance use disorder benefits in any classification that is more restrictive, as written and in operation, than the predominant NQTL that applies to substantially all medical/surgical benefits in the same classification. For this purpose, the plan and issuer must ensure that the NQTL satisfies both the design and application requirements and the relevant data evaluation requirements. Specifically, under these final rules, plans and issuers must continue to satisfy the design and application requirements from the 2013 final regulations, which require an analysis of the processes, strategies, evidentiary standards, and other factors used to design and apply NQTLs to mental health and substance use disorder benefits as compared to medical/surgical benefits. Plans and issuers have struggled with these requirements, as detailed in the Departments' 2022 MHPAEA Report to Congress¹⁸⁰ and the 2023 MHPAEA

¹⁸⁰ 2022 MHPAEA Report to Congress, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf>.

Comparative Analysis Report to Congress.¹⁸¹ Additionally, plans and issuers are not permitted to use any discriminatory factors or evidentiary standards to design or apply an NQTL, and they must satisfy new relevant data evaluation requirements as well as new requirements related to the elements and documentation of their comparative analyses.

In particular, to comply with the required content elements for a comparative analysis, plans and issuers must describe each NQTL and identify and define all the factors and evidentiary standards used to design or apply the NQTL. The plan or issuer must also describe how the factors identified are used in the design and application of the NQTL, and evaluate whether any processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, those with respect to medical/surgical benefits, both as written and in operation. Finally, plans and issuers must address the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the NQTLs within each classification, and the relative stringency of their application, both as written and in operation.

Accordingly, these final rules will increase plan and issuer compliance with the requirements for imposing NQTLs under MHPAEA and help ensure that NQTLs applicable to mental health and substance use disorder benefits are no more restrictive than the predominant NQTLs applicable to substantially all medical/surgical benefits in the same classification. The Departments acknowledge that past parity implementation has lacked consistency and thus had varied results, particularly for laws limiting management of behavioral health benefits or NQTLs. A 2012 study on the implementation of Oregon's 2007 comprehensive parity law, which mandated benefits for substance use disorders and restricted the use of behavioral health

¹⁸¹ 2023 MHPAEA Comparative Analysis Report to Congress, www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

management for fully insured commercial group plans, compared their expenditures for treatments to those of self-funded plans not covered by Oregon’s law. The study found that while plan expenditures for alcohol treatment services increased, other substance use treatments were not associated with a statistically significant increase in expenditures and that overall, the impact of parity on spending was not significantly different from zero.¹⁸² However, a broader study conducted in 2013 looked at treatment counts at specialty substance use disorder facilities between 2000 and 2008 across the United States to assess the impact of State-level substance use disorder parity laws on State aggregate treatment rates. While the study was not able to control for the source of insurance and employment status of those receiving treatment, the study did find that the implementation of any State substance use disorder parity laws was associated with increased access to specialty substance use disorder treatments—by 9 percent in all specialty substance use disorder treatment facilities and 15 percent in facilities accepting private insurance.¹⁸³

The Departments are of the view that, by finalizing these rules and requiring better documentation related to how plans and issuers design and apply NQTLs, the Departments and applicable State authorities will be better able to enforce existing parity requirements. In doing so, access to in-network, medically necessary treatments will increase for a significant segment of individuals whose health coverage will be affected by these final rules, resulting in better health outcomes and lower out-of-pocket costs related to mental health and substance use disorder benefits for participants, beneficiaries, and enrollees.

Plans and issuers will incur costs to comply with the requirements in these final rules. However, the Departments have determined that the benefits of these final rules justify the costs.

¹⁸² K. John McConnell, M. Susan Ridgely, & Dennis McCarty, *What Oregon's Parity Law Can Tell Us About the Federal Mental Health Parity and Addiction Equity Act and Spending on Substance Abuse Treatment Services*, 124(3) *Drug and Alcohol Dependence* pp. 340-346 (2012).

¹⁸³ Hefei Wen, Janet R. Cummings, Jason M. Hockenberry, Laura M. Gaydos, & Benjamin G. Druss, *State Parity Laws and Access to Treatment for Substance Use Disorder in the United States: Implications for Federal Parity Legislation*, 70 (12) *JAMA Psychiatry* pp. 1355-1362 (2013).

In accordance with OMB Circular A-4, Table 1 depicts an accounting statement summarizing the Departments' assessment of the benefits, costs, and transfers associated with these regulatory actions. The Departments are unable to quantify all benefits, costs, and transfers of these final rules, but have sought, where possible, to describe these non-quantified impacts.

The effects in Table 1 reflect non-quantified impacts and estimated direct monetary costs resulting from the provisions of these final rules.

| Table 1: Accounting Statement | | | | |
|--|----------|-------------|---------------|----------------|
| Benefits: | | | | |
| <ul style="list-style-type: none"> • Improved understanding of and compliance with MHPAEA by plans and issuers, resulting in better frameworks for determining whether plans and issuers are complying with MHPAEA with respect to NQTLs applicable to mental health and substance use disorder benefits and medical/surgical benefits. • Greater access and utilization of mental health and substance use disorder services by reducing barriers to coverage of mental health and substance use disorder treatment, which will result in better health outcomes for those with mental health conditions or substance use disorders. • Reduction in the negative impacts on families, friends, caregivers, and coworkers of those with untreated or poorly managed mental health conditions or substance use disorders based on their improved access to treatment. | | | | |
| Costs: | | | | |
| <ul style="list-style-type: none"> • Increased costs to plans and issuers to implement changes associated with the revision of plan provisions, which would result in increased costs from expanded coverage of mental health and substance use disorder services. • Costs to plans and issuers from collecting and evaluating outcomes data and documenting NQTL comparative analyses consistent with the requirements of these final rules of approximately \$656.2 million in the first year and approximately \$131.2 million in subsequent years or between 0.07 percent and 0.01 percent of total health insurance premiums in the group and individual markets. • Costs to plans and issuers for preparing and mailing the comparative analyses upon request to participants, beneficiaries, and enrollees of approximately \$14.8 million annually. • Cost to plan and issuers for providing comparative analyses for audits is approximately \$23,800. • First-year regulatory review costs to plans and issuers for familiarizing themselves with these final rules of approximately \$10.8 million. • Cost to plan and issuers to maintain recordkeeping is approximately \$12.2 million. • Potential increase in cost-sharing requirements and/or treatment limitations for medical/surgical benefits for participants, beneficiaries, and enrollees, if plans and issuers try to achieve parity by imposing new restrictions on medical/surgical benefits, rather than by reducing restrictions on access to mental health or substance use disorder benefits. • Potential costs to self-funded non-Federal governmental plans that opted out of MHPAEA to come into compliance with requirements under MHPAEA. • Cost savings to self-funded non-Federal governmental plans of approximately \$11,783 annually in total from no longer sending opt-out notices regarding a plan's MHPAEA opt-out election. • Cost savings for the Federal Government of approximately \$5,200 annually from fewer opt-out notices being submitted by self-funded non-Federal governmental plans. | | | | |
| Costs | Estimate | Year dollar | Discount Rate | Period Covered |

| | | | | |
|---|----------|------|-----------|-----------|
| Annualized Monetized (\$million/Year) | \$217.35 | 2024 | 7 percent | 2024-2033 |
| | \$207.04 | 2024 | 3 percent | 2024-2033 |
| Transfers: | | | | |
| <ul style="list-style-type: none"> • Potential transfers from plans and issuers to participants, beneficiaries, and enrollees resulting in lower out-of-pocket spending on mental health and substance use disorder services. • Potential transfers from participants, beneficiaries, and enrollees to plans and issuers caused by higher premiums or contributions associated with increased utilization of mental health and substance use disorder services, provider network improvements, and increased provider reimbursement rates. • Potential transfers from primary care providers to mental health providers for the treatment of mental health conditions and substance use disorders as a result of an increased number of in-network mental health and substance use disorder providers and decisions by participants, beneficiaries, and enrollees to obtain treatment from those providers instead of a primary care provider. | | | | |

5. Affected Entities

The following table summarizes the number of plans, issuers,¹⁸⁴ TPAs, and multiple employer welfare arrangement (MEWAs) that would be affected by the final rules.¹⁸⁵ These estimates are discussed in greater detail later in this regulatory impact analysis.

Table 2. Affected Entities

| | Self-Funded Plan Count | Mixed Insured Plan Count | Total |
|---|------------------------|--------------------------|-------|
| Issuers (health insurance company/State combinations) | - | - | 1,467 |
| TPAs | - | - | 205 |
| Plan MEWAs that are not fully insured | - | - | 132 |
| Non-plan MEWAs that are not fully insured | - | - | 21 |

¹⁸⁴ For purposes of this regulatory impact analysis, *health insurance company* refers to a single entity that offers health insurance coverage in one or multiple States, which might own or be affiliated with one or multiple entities that are separately required to be licensed to engage in the business of insurance in each such State. *Health insurance issuer* or *issuer* means an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed to engage in the business of insurance in a State and that is subject to State law that regulates insurance. PHS Act section 2791(b)(2) and 45 CFR 144.103.

¹⁸⁵ The Departments note that the number of issuers may be underestimated, since some managed behavioral health organizations may not be included in the issuer count.

| | Self-Funded Plan Count | Mixed Insured Plan Count | Total |
|---|-----------------------------------|-------------------------------------|--------------|
| Plans (total) ^{186,187} | 46,080 | 4,501 | 50,581 |
| Under 100 participants | 25,150 | 176 | 25,326 |
| 100 to 199 participants | 5,209 | 402 | 5,611 |
| 200 to 499 participants | 6,861 | 755 | 7,616 |
| 500 to 999 participants | 3,812 | 671 | 4,483 |
| 1,000 to 2,499 participants | 2,880 | 948 | 3,828 |
| 2,500 to 4,999 participants | 1,119 | 561 | 1,680 |
| 5,000 and above participants | 1,049 | 988 | 2,037 |
| Plans with less than 500 participants that will seek assistance with the comparative analyses from TPAs, MEWAs, or service providers | 37,220 | 1,333 | 38,553 |
| Plans with more than 500 participants that will conduct the comparative analysis themselves | 709 | 253 | 962 |
| Plans with more than 500 participants that will receive generic comparative analyses from TPAs or service providers and will then customize it | 4,076 | 1,458 | 5,534 |
| Non-Federal governmental plans with less than 500 participants that will seek assistance with the comparative analyses from TPAs or service providers | 26,584 | - | 26,584 |
| Non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves | 505 | - | 505 |
| Non-Federal governmental plans with more than 500 participants that will initially receive generic comparative analyses from TPAs or service providers and will then customize it | 2,906 | - | 2,906 |

¹⁸⁶ The Departments note that the final rules will affect approximately 106,000 fully insured plans with 50 to 100 participants. (Note: The Departments estimate that there are 140,998 ERISA-covered group health plans with 50 to 100 participants based on the Medical Expenditure Panel Survey Insurance Component (MEPS-IC) and the 2020 County Business Patterns from the Census Bureau. The Departments also estimate that 75 percent of ERISA-covered group health plans with 50 to 100 participants are fully insured based on assumptions referencing these same data. Thus, the Departments have calculated the number of fully insured plans with 50 to 100 participants in the following manner: 140,998 ERISA-covered group health plans with 50 to 100 participants × 75 percent = 105,749.)

¹⁸⁷ The Departments also note that the final rules will affect approximately 1,719,000 fully insured, non-grandfathered plans with less than 50 participants. (Note: The Departments estimate that there are 2,465,483 ERISA-covered group health plans with less than 50 participants based on data from the 2022 MEPS-IC and the 2020 County Business Patterns from the Census Bureau. The Departments also estimate that 83 percent of group health plans with less than 50 participants are fully insured based on data from the 2022 MEPS-IC. The 2020 KFF Employer Health Benefits Survey reported that in 2020, 16 percent of firms offering health benefits offered at least one grandfathered health plan; therefore, the Departments assume the percent of firms offering at least one non-grandfathered health plan is 84 percent (100 percent – 16 percent). KFF, *2020 Employer Health Benefits Survey* (Oct. 8, 2020), <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf>. Thus, the Departments have calculated the number of fully insured, non-grandfathered plans with less than 50 participants in the following manner: 2,465,483 small ERISA-covered group health plans × 83 percent × 84 percent = 1,718,935.)

5.1. Issuers, TPAs, and MEWAs

Under the Departments' final rules, issuers are responsible for providing data and comparative analyses for individual market plans. For small and large group market fully insured, employer-sponsored plans, including non-Federal governmental plans, both employer-sponsored health plans and health insurance issuers are responsible for providing data and comparative analyses, though for those plans, underlying data and analyses will likely be provided by issuers that design and market the plans. Self-funded group health plans, while responsible for complying with these rules, will likely seek assistance from their TPAs, MEWA administrators, and other service providers for collecting and analyzing the data, and generating the comparative analyses.

The Departments estimate that the final rules will affect 479 health insurance companies nationwide that provide coverage, including mental health and substance use disorder benefits, in the group and individual health insurance markets, with 1,467 issuers (health insurance company/State combinations).¹⁸⁸ In addition, there are an estimated 205 TPAs that provide services to group health plans, particularly for self-funded plans where TPAs often establish provider networks and adjudicate claims, which would be impacted by these final rules.¹⁸⁹ The Departments estimate that the final rules will affect at least 40 managed behavioral health organizations providing mental health and substance use disorder benefits to group health plans.¹⁹⁰ Additionally, based on the Form M-1 filings, the Departments estimate that there are 687 plan MEWAs, of which 132 are not fully insured, and 50 non-plan MEWAs, of which 21 are

¹⁸⁸ The Departments' estimate of the number of health insurance issuers is based on medical loss ratio (MLR) reports submitted by issuers for the 2022 reporting year. CMS, *Medical Loss Ratio Data and System Resources (2022)*, <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr>.

¹⁸⁹ Non-issuer TPAs based on data derived from the 2016 benefit year reinsurance program contributions.

¹⁹⁰ The Departments' estimate of the number of managed behavioral health organizations is based on industry trade association membership, including the National Behavioral Consortium (<https://www.nbcgroup.org/member-directory/>) and ABHW (<https://abhw.org/about/>).

not fully insured.¹⁹¹ These MEWAs, similar to issuers, are likely to provide support to employers or plans.

Issuers, TPAs, and MEWAs provide key support for plan compliance with laws and regulations for group health plans, including MHPAEA. The Departments' understanding, based on discussions with the regulated community and numerous direct investigations of plans, including the review of comparative analyses, is that issuers of fully insured coverage provide a menu of benefit combinations from which interested parties select their coverage designs. These coverage designs may include different features, such as varying deductibles, copayments, and coverage for specific items and services, allowing interested parties to choose the plan that best suits their health care needs. While issuers of fully insured health plans are responsible for overseeing the compliance framework and ensuring that plans comply with legal and regulatory requirements, TPAs play a crucial role in facilitating compliance for self-funded plans by providing administrative support, including claims adjudication, member enrollment, and customer service.

TPAs and insurance companies providing administrative services only (ASO) to self-funded plans overwhelmingly design the plans, administer the networks, manage claims, provide plan services, maintain and hold the data relevant for the comparative analyses, and help ensure MHPAEA compliance.¹⁹² Self-funded plans rarely build independent provider networks and instead rely on those built by TPAs (including those that are also health insurance companies). According to the 2019 KFF Employer Health Benefits Survey, only 8 percent of large, self-funded plans with 200 or more employees reported that they directly contracted with hospitals and health systems, independent of the plan's TPA, to provide health care services separate from

¹⁹¹ EBSA, *2020 Form M-1 Bulletin*, Table 1,

<https://www.dol.gov/sites/dolgov/files/ebsa/researchers/statistics/health-and-welfare-bulletins/m-1/2020.pdf>.

¹⁹² 85 FR 72158 (Jan 11, 2021).

the provider networks included in the plan network.¹⁹³

While the requirement to comply with MHPAEA is directly applicable to group health plans and health insurance issuers, the Departments anticipate that issuers and TPAs are best situated to conduct comparative analyses as required under the CAA, 2021 and these final rules, and to provide the analyses in an efficient and cost-effective manner, helping to reduce the compliance burden. Self-funded plans may, however, incur some additional costs to complete the comparative analysis initially prepared by the issuer or TPA to address unique plan issues and include all the information necessary to perform comparative analyses.

One commenter stated they are not aware of any TPA that has assumed compliance obligations wholesale, though they acknowledged that TPAs had cooperated and provided data in response to a government audit. Another commenter reported that TPAs working on behalf of group health plan sponsors struggle to obtain needed information to perform and document comparative analyses, such as when claims expenditure data collected by TPAs is not compatible for testing purposes and, moreover, is not reported at the plan sponsor level. It should be noted that these reported challenges are not unique to TPAs, but are the same issues facing issuers and self-funded plans. However, TPAs are more likely than plan sponsors to have expertise to navigate the challenges.

Other commenters supported the Departments' assumptions that employer-sponsored plans rely on their services providers and TPAs to conduct their comparative analyses. One commenter noted that only the insurance carriers, TPAs, and service providers that play a role in designing plans, administering networks, managing claims, providing plan services, and maintaining and holding the data relevant for the comparative analyses have the expertise to comply with and fulfill all the requirements outlined in the proposed rules. Another commenter

¹⁹³ KFF, *2019 Employer Health Benefits Survey*, Table 14.15 (Sept. 25, 2019), <https://www.kff.org/report-section/ehbs-2019-section-14-employer-practices-and-health-plan-networks/>.

noted that self-funded plan sponsors rely on TPAs and/or the owners of provider networks to develop plan designs and develop and impose NQTLs, arguing that if the TPA or owner of the provider networks do not share claims data, then the TPA or owner of the provider networks should be required to conduct analyses for the plans.

While the Departments acknowledge these concerns, based on their own observations when reviewing comparative analyses, the Departments expect that issuers, TPAs, and service providers will continue to provide assistance to evaluate NQTLs and perform and document comparative analyses, including data required under these final rules, for their plan clients. The Departments emphasize that the requirement to perform and document comparative analyses of the design and application of NQTLs has been effective under the CAA, 2021 for more than 3 years (since February 10, 2021) and is an independent statutory obligation that is not dependent upon a request by the Secretaries or an applicable State authority. Issuers and plans, in conjunction with their TPAs for self-funded group health plans, have had ample time to develop the internal structures required for analyzing NQTLs to ensure that their plans and coverage comply with MHPAEA. Finally, while plans could be charged for the services of issuers, TPAs, and other service providers, this arrangement provides for economies of scale in compliance, as issuers evaluate NQTLs, produce or assist in producing the comparative analyses for their products and plan designs, and, in combination with TPAs and other service providers, provide support for other requirements.

5.2 Group Health Plans

Group health plans sponsored by employers with 50 or more employees that offer mental health and substance use disorder benefits are generally required to comply with MHPAEA. Although MHPAEA includes a small employer exemption, group health plans sponsored by employers with less than 50 employees who purchase non-grandfathered small group coverage are required to comply with MHPAEA under the EHB requirements of the ACA. In this analysis,

plan size is used as a proxy for employer size to determine if a plan is affected. Evidence suggests that most large group plans offer mental health and substance use disorder benefits and nearly all participants are covered.¹⁹⁴

The Departments estimate that approximately 1,719,000 fully insured, non-grandfathered ERISA-covered group health plans with less than 50 participants and approximately 411,000 ERISA-covered group health plans with 50 or more participants, of which approximately 246,000 are self-funded group health plans, will be affected by these final rules.¹⁹⁵ In addition, the Departments estimate that these final rules will affect approximately 90,900 non-Federal governmental plans,¹⁹⁶ of which approximately 12,700 are plans with 50 or more participants.¹⁹⁷ The Departments requested comments on these estimates in the proposal, but did not receive any.

The estimated compliance costs associated with these final rules are impacted by whether a plan is fully insured or self-funded. The Departments anticipate that fully insured plans will receive compliance support in the form of comparative analyses and data analyses prepared by the issuer. For these plans, the burden is estimated as a cost for the issuer to prepare the analyses

¹⁹⁴ DOL, *Selected Medical Benefits: A Report from the Department of Labor to the Department of Health and Human Services* (Apr. 15, 2011), <https://www.bls.gov/ebs/additional-resources/selected-medical-benefits-a-report-from-dol-to-hhs.pdf>.

¹⁹⁵ The Departments estimate that there are 2,465,483 ERISA-covered group health plans with less than 50 participants and that 83 percent of group health plans with less than 50 participants are fully insured based on data from the 2022 MEPS-IC and the 2020 County Business Patterns from the Census Bureau. The 2020 KFF Employer Health Benefits Survey reported that in 2020, 16 percent of firms offering health benefits offered at least one grandfathered health plan. KFF, *2020 Employer Health Benefits Survey* (Oct. 8, 2020), <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf>. Thus, the Departments have calculated the number of fully insured, non-grandfathered plans with less than 50 participants in the following manner: 2,465,483 small ERISA-covered group health plans \times 83 percent \times (100 percent $-$ 16 percent) = 1,718,935. Based on the 2022 MEPS-IC and the 2020 County Business Patterns from the Census Bureau, the Departments estimate 60 percent of ERISA-covered group health plans with 50 or more participants are self-funded. Thus, the Departments calculate the number of self-funded group health plans in the following manner: 410,581 ERISA-covered group health plans with 50 or more participants \times 60 percent = 246,349.

¹⁹⁶ Based on data from the 2022 Census of Governments (<https://www.census.gov/data/tables/2022/econ/gus/2022-governments.html>), there are 90,887 State and local entities. The Departments assume there is one plan per entity on average. Therefore, the Departments estimate that there are 90,887 non-Federal governmental plans.

¹⁹⁷ MHPAEA applies to non-Federal governmental plans. Using data from the 2022 MEPS-IC and the 2020 County Business Patterns from the Census Bureau, the Departments estimate that 14 percent of ERISA-covered group health plans have 50 or more participants. The Departments use the percent of ERISA-covered group plans with 50 or more participants as a proxy for the percent of non-Federal governmental plans with 50 or more participants. Therefore, the Departments estimate that there are 12,724 public, non-Federal governmental plans with 50 or more participants that offer mental health or substance use disorder benefits (90,887 non-Federal governmental plans \times 14 percent of plans with 50 or more employees = 12,724).

and analyze the data. Self-funded plans may rely on issuers or TPAs acting as service providers, receive some support from their service providers that they supplement themselves, or produce the required information themselves.

Most employer-sponsored health plans are exempt from filing a Form 5500 due to size and the absence of plan assets, the majority of which are fully insured. Large health plans are required to file a Form 5500, regardless of funding arrangement. For statistical year 2021, 81,800 health plans filed a Form 5500. Of these plans, 50,600 were self-funded or mixed-insured,¹⁹⁸ of which 38,600 had less than 500 participants.¹⁹⁹ Additionally, the Departments estimate that there are 26,600 self-funded non-Federal governmental plans with less than 500 participants.²⁰⁰ The Departments assume that self-funded plans with less than 500 participants will receive assistance with the comparative analyses and data requirements from TPAs or service providers involved with the plans.

The Departments assume that some of the largest plans will incur the full cost of preparing the comparative analysis and conducting the required data analyses. Commenters suggested that some large, self-funded plans would conduct the comparative analyses themselves. To account for these plans, the Departments estimate that 8 percent of self-funded plans with 500 or more participants, or 962 ERISA covered plans²⁰¹ and 505 non-Federal

¹⁹⁸ A mixed-insured plan is funded through a mixture of insurance and self-insurance. EBSA, *Self-Insured Health Benefit Plans 2024: Based on Filings through 2021* (Sept. 30, 2023), Table 2, <https://www.dol.gov/sites/dolgov/files/EBSA/researchers/statistics/retirement-bulletins/annual-report-on-self-insured-group-health-plans-2024-appendix-b.pdf>.

¹⁹⁹ Estimates based on the 2021 Form 5500 data.

²⁰⁰ Based on the 2022 Census of Governments, there are 90,887 non-Federal governmental plans. Based on the 2022 MEPS-IC, the Departments estimate that 36.2 percent of non-Federal governmental plans are self-funded. Thus, 90,887 plans × 36.2 percent = 32,901 self-funded non-Federal governmental plans. Based on the 2021 Form 5500 data, the Departments estimate that 80.8 percent of self-funded health plans with less than 500 participants have filed the Form 5500. The Departments use the percent of self-funded health plans with less than 500 participants that have filed a Form 5500 as a proxy for the percent of self-funded non-Federal governmental plans with less than 500 participants. Thus, 32,901 self-funded non-Federal governmental plans × 80.8 percent = 26,584 self-funded non-Federal governmental plans with less than 500 participants.

²⁰¹ Based on the 2021 Form 5500 data, there are 12,028 self-funded plans with 500 or more participants. According to the 2019 KFF Employer Health Benefits Survey, only 8 percent of large, self-funded plans with 200 or more employees reported that they directly contracted with hospitals and health systems, independent of the plan's TPA, in order to provide health care and services separate from the provider networks included in the plan network. KFF,

governmental plans,²⁰² will prepare the comparative analysis and conduct the required data analyses themselves. The Departments estimate that 50 percent of the remaining self-funded plans with 500 or more participants, or 5,535 self-funded plans,²⁰³ and 2,900 self-funded non-Federal governmental plans with 500 or more participants will receive a generic comparative analysis from the TPA,²⁰⁴ which they will subsequently customize to suit their specific needs. These plans will incur costs, but not at the same level other entities preparing the comparative analysis and data for themselves.

Finally, HHS estimates that 230 self-funded non-Federal governmental plans will be affected by the implementation of the CAA, 2023 provision that sunsets the MHPAEA opt-out election.²⁰⁵ HHS is aware of at least 14 plans with collective bargaining agreements whose sponsors' MHPAEA opt-out elections could be in effect beyond 2024. The MHPAEA opt-out election of these plans with collective bargaining agreements will remain in effect until the last of these plans' respective collective bargaining agreements expires, all of which are anticipated to expire by 2028. HHS does not have precise information about the number of participants and

2019 Employer Health Benefits Survey (Sept. 25, 2019), Table 14.15, <https://www.kff.org/report-section/ehbs-2019-section-14-employer-practices-and-health-plan-networks/>. Thus, 12,028 self-funded plans with 500 or more participants \times 8 percent = 962 self-funded plans with more than 500 participants.

²⁰² Based on the 2022 Census of Governments, there are 90,887 non-Federal governmental plans. Based on the 2022 MEPS-IC, the Departments estimate that 36.2 percent of non-Federal governmental plans are self-funded. Thus, 90,888 plans \times 36.2 percent = 32,901 self-funded non-Federal governmental plans. Based on the 2021 Form 5500 data, the Departments estimate that 19.2 percent of health plans with more than 500 participants have filed the Form 5500. The Departments use the percent of health plans with more than 500 participants that have filed a Form 5500 as a proxy for the percent of non-Federal governmental plans with more than 500 participants. According to the 2019 KFF Employer Health Benefits Survey, only 8 percent of large, self-funded plans with 200 or more employees reported that they directly contracted with hospitals and health systems, independent of the plan's TPA, in order to provide health care and services separate from the provider networks included in the plan network. KFF, *2019 Employer Health Benefits Survey* (Sept. 25, 2019), Table 14.15, <https://www.kff.org/report-section/ehbs-2019-section-14-employer-practices-and-health-plan-networks/>. Thus, 32,901 non-Federal governmental plans \times 19.2 percent \times 8 percent = 505 non-Federal governmental plans with more than 500 participants.

²⁰³ Based on the 2021 Form 5500 data, there are a total of 50,581 self-funded plans. Thus, (50,581 self-funded plans – 38,533 self-funded plans with less than 500 participants – 962 self-funded plans with more than 500 participants) \times 50 percent = 5,535 self-funded plans with more than 500 participants.

²⁰⁴ Based on the 2022 Census of Governments, there are 90,887 non-Federal governmental plans. Based on the 2022 MEPS-IC, the Departments estimate that 36.7 percent of non-Federal governmental plans are self-funded. Thus, 90,888 plans \times 36.2 percent = 32,901 self-funded non-Federal governmental plans. Thus, (32,901 non-federal governmental plans – 26,584 non-Federal governmental plans with less than 500 participants – 505 self-funded plans with more than 500 participants) \times 50 percent = 2,906 non-Federal governmental plans with more than 500 participants.

²⁰⁵ CMS, HIPAA Opt-Out Elections for Self-Funded Non-Federal Governmental Plans, as of January 6, 2023.

beneficiaries of the plans that have elected to opt out of requirements under MHPAEA, as those plans are not required to report this information to HHS. However, HHS estimates that there are approximately 261 participants, on average, in each self-funded non-Federal governmental plan.²⁰⁶ HHS also estimates that there is one beneficiary for each plan participant on average. Therefore, approximately 120,000 participants and beneficiaries will be affected by this final provision.²⁰⁷

HHS solicited comments on the estimated number of self-funded non-Federal governmental plans and the estimated number of plan participants and beneficiaries that would be affected by the implementation of the CAA, 2023 provision that sunsets the MHPAEA opt-out election. Although HHS did not receive comments on the estimated number of self-funded non-Federal governmental plans or the estimated number of plan participants and beneficiaries that would be affected by the implementation of this provision, many commenters indicated that hundreds of thousands of public employees and their family members have been denied the critical MHPAEA protections due to the election option for self-funded non-Federal governmental plans to opt out of requirements under MHPAEA. Another commenter indicated that the ability to opt out of requirements under MHPAEA has compromised the health and well-being of State and local government employees, such as teachers, firefighters, and civil servants across the country. HHS agrees that a significant number of individuals will be impacted by the CAA, 2023 provision that sunsets the MHPAEA opt-out election and that these regulatory

²⁰⁶ According to data from the 2022 MEPS-IC (<https://meps.ahrq.gov/mepsweb/>), there are 19,231,948 State and local government employees, and 67.1 percent of these employees (12,904,637) are enrolled in health coverage through their jobs. Of these employees, 66.5 percent (8,581,584 employees) are participants in self-funded plans. Based on data from the 2022 Census of Governments (<https://www.census.gov/data/tables/2022/econ/gus/2022-governments.html>), there are 90,887 State and local government entities, and according to the 2022 MEPS-IC, 36.2 percent, or 32,901, of State and local government entities self-fund at least one plan. Therefore, the average number of participants per self-funded non-Federal governmental plan is $(8,581,584 \div 32,901) = 260.8$. Since HHS also estimates that there is one beneficiary for each plan participant on average, the average number of participants and beneficiaries per self-funded non-Federal governmental plan is $(260.8 \times 2) = 521.7$.

²⁰⁷ This estimate is calculated as follows: 230 self-funded non-Federal governmental plans that have elected to opt out of the requirements under MHPAEA \times approximately 521.7 participants and beneficiaries for each self-funded non-Federal governmental plan on average = 119,991.

amendments will ultimately increase access to mental health and substance use disorder services by requiring self-funded non-Federal governmental plans that had previously opted out to come into compliance with the requirements under MHPAEA.

5.3 Participants, Beneficiaries, and Enrollees Receiving Mental Health and Substance Use Disorder Treatment

There are approximately 56,984,000 participants and 50,407,000 beneficiaries in ERISA-covered group health plans with 50 or more participants,²⁰⁸ approximately 17,483,000 participants and approximately 14,854,000 beneficiaries in non-Federal governmental plans with 50 or more participants,²⁰⁹ approximately 10,258,000 participants and 8,629,000 beneficiaries in ERISA covered, non-grandfathered, fully insured health plans with less than 50 participants,²¹⁰ and approximately 12,000,000 individual health insurance coverage policyholders (with approximately 16,000,000 total enrollees).²¹¹

Since the enactment of MHPAEA, participants have increasingly utilized behavioral health services through their health coverage. Between 2007 and 2017, private insurance claim lines for behavioral health diagnoses increased by 320 percent.²¹² Claims data show that between

²⁰⁸ The Departments have not identified what share of plans with 50 or more participants offer mental health or substance use disorder benefits and so has assumed that all of these plans offer them. The Departments estimate that there are 56,983,874 participants and 50,407,439 beneficiaries in ERISA-covered group health plans with 50 or more participants. Estimates are based on the Departments' tabulations of the March 2022 Current Population Survey (CPS) Auxiliary Data (<https://www.dol.gov/agencies/ebsa/researchers/data/auxiliary-data>).

²⁰⁹ The Departments have not identified what share of plans with 50 or more participants offer mental health or substance use disorder benefits and so has assumed that all of these plans offer them. The Departments estimate that there are 17,482,879 participants in non-Federal governmental plans with 50 or more participants. Estimates are based on the Departments' tabulations of the March 2022 CPS Auxiliary Data (<https://www.dol.gov/agencies/ebsa/researchers/data/auxiliary-data>).

²¹⁰ The Departments estimate that there are 12,212,484 participants and 10,272,985 beneficiaries in fully insured, private-sector health plans with less than 50 participants based on the Departments' tabulations of the March 2022 CPS Auxiliary Data (<https://www.dol.gov/agencies/ebsa/researchers/data/auxiliary-data>). Assuming, based on KFF assumptions that 84 percent of participant and beneficiaries are in non-grandfathered plans (KFF, *2020 Employer Health Benefits Survey* (Oct. 8, 2020), <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf>), this will translate into an estimated 10,258,487 participants and 8,629,307 beneficiaries in fully insured, private-sector, non-grandfathered plans with less than 50 participants.

²¹¹ Based on MLR reports submitted by issuers for the 2022 reporting year, the number of policyholders in individual health insurance coverage offered in the individual market is approximately 12 million and the number of enrollees was approximately 16,000,000. CMS, *Medical Loss Ratio Data and System Resources* (2022), <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr>.

²¹² Robin Gelburd, *The Mental Health Parity Act: 10 Years Later*, *American Journal of Managed Care* (Nov. 22, 2018), <https://www.ajmc.com/view/the-mental-health-parity-act-10-years-later>.

2013 and 2019, the percentage of the employment-based coverage population under the age of 65 diagnosed with major depressive disorder increased from 4.1 percent to 5.3 percent, and the percentage of the population diagnosed with anxiety increased from 4.8 percent to 8.1 percent.²¹³ In 2020, 41 million Americans who were enrolled in employment-based coverage, including 6 million children, received mental health support, which constituted nearly 25 percent of employment-based health plan participants and beneficiaries.²¹⁴ A 2022 survey by SAMHSA indicated that among adults aged 18 or older, 23.1 percent (or 59.3 million people) had any mental illness and 6.0 percent (or 15.4 million people) had serious mental illness in the past year. The same survey also indicated that among individuals aged 12 or older, 17.3 percent (or 48.7 million people) had a substance use disorder in the past year, and of those only 14.9 percent (7.3 million people) received treatment for substance use disorder in the past year.²¹⁵

The COVID-19 public health emergency (PHE) exacerbated the need for mental health and substance use disorder treatments. During the pandemic, many adults consistently reported anxiety and depressive disorders symptoms, with 4 in 10 adults reporting symptoms in February 2021. Two years later in 2023, even as the pandemic receded from its peak, approximately 3 in 10 adults were still reporting symptoms of anxiety and depression.²¹⁶ The pandemic likewise negatively impacted the mental health of children and adolescents, worsening reported rates of

²¹³ Paul Fronstin & Christopher Roebuck, *How Do High-Deductible Health Plans Affect Use of Health Care Services and Spending Among Enrollees with Mental Health Disorders?*, EBRI Issue No. 555 Figure 3 (Mar. 10, 2022), https://www.ebri.org/docs/default-source/ebri-issue-brief/ebri_ib_555_mentalhealth-10mar22.pdf?sfvrsn=aec3b2f_2.

²¹⁴ AHIP, *How Employer-Provided Coverage Improves Access to Mental Health Support* (May 2022), https://www.ahip.org/documents/202205-CaW_MentalHealth-v03.pdf.

²¹⁵ SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2022 National Survey on Drug Use and Health*, pp. 33, 51-52 (Nov. 2023), <https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf>.

²¹⁶ Nirmita Panchal, Heather Saunders, Robin Rudowitz, & Cynthia Cox, *The Implications of COVID-19 for Mental Health and Substance Use*, KFF Issue Brief (Mar. 20, 2023), <https://www.kff.org/coronavirus-covid-19/issue-brief/the-implications-of-covid-19-for-mental-health-and-substance-use/>.

anxiety or depression which, in the 5 years preceding the pandemic, had already increased by 29 percent and 27 percent, respectively.²¹⁷

The pandemic may have long-term effects on mental health and substance use disorders, suggesting that the number of individuals affected by expanding access through their health plans will only continue to grow. A 2022 study examined the chronic effects of the pandemic on the mental health of Veterans and found that COVID-19 survivors were associated with a higher risk of developing mental health disorders, including anxiety, stress, depression, substance use, and neurocognitive decline, compared to individuals who did not have COVID-19.²¹⁸ Another 2022 study examined the mental health outcomes of COVID-19 survivors during the 12 months following their infection and found that COVID-19 survivors reported a high prevalence of depression, anxiety, and post-traumatic stress disorder at both the 6- and 12-months follow-up, indicating that the pandemic has long-term adverse mental health impacts on COVID-19 survivors.²¹⁹ Finally, a 2023 study found that the pandemic resulted in a long-term increase in the number of psychiatric inpatient admissions, suggesting that there is a post-pandemic need to prioritize psychiatric care.²²⁰

6. Studies Examining the Impact of MHPAEA and State Parity Laws

²¹⁷ Kristen Figas, Theodoros V. Giannouchos, & Elizabeth Crouch, *Child and Adolescent Anxiety and Depression Prior to and During the COVID-19 Pandemic in the United States*, 24 *Child Psychiatry & Human Development* pp. 1-11 (2023).

²¹⁸ Yan Xie, Evan Xu, & Ziyad Al-Aly, *Risks of Mental Health Outcomes in People with Covid-19: Cohort Study*, 376 *The BMJ* (2022), <https://www.bmj.com/content/376/bmj-2021-068993>.

²¹⁹ Mario G. Mazza, Mariagrazia Palladini, Rebecca De Lorenzo, Beatrice Bravi, Sara Poletti, Roberto Furlan, Fabio Ciceri, Patrizia Rovere-Querini, & Francesco Benedetti, *One-Year Mental Health Outcomes in a Cohort of COVID-19 Survivors*, 145 *Journal of Psychiatric Research* pp. 118-124 (2022).

²²⁰ Sean Warwicker, Denise Sant, Adrian Richard, Jake Cutajar, Annalise Bellizzi, Gertrude Micallef, Daniel Refalo, Liberato Camilleri, & Anton Grech, *A Retrospective Longitudinal Analysis of Mental Health Admissions: Measuring the Fallout of the Pandemic*, 20(2) *International Journal of Environmental Research and Public Health* p. 1194 (2023).

6.1 Research Examining the Impact of State Parity Laws

6.1.1 Research Finding State Parity Laws Increase the Utilization of Mental Health and Substance Use Disorder Care

Research has found mixed evidence on the impact of State parity laws prior to the implementation of MHPAEA. While the specifics of the State-level programs might be different from MHPAEA, this research can nonetheless provide important context and suggestive evidence for how modifications to parity policies such as the MHPAEA program²²¹ might impact healthcare demand and quality. While some studies did not identify a significant change in costs or usage of behavioral health treatments following the passage of State parity laws, others found that State parity laws increased the utilization of mental health care and substance use disorder care among populations at risk.

For example, a 2006 study evaluated changes in mental health care utilization before and after States implemented parity laws, comparing them with States that did not enact such laws in the same year controlling for State and year fixed effects. Using data from the 2001, 2002, and 2003 NSDUH, the study categorized individuals with individual or employer-sponsored health insurance by their level of mental and emotional distress during their most challenging month in the past year and found that State parity laws increased the likelihood of using any mental health care in the past year by up to 1.2 percentage points for individuals with lower distress levels and up to 1.8 percentage points for those with moderate distress levels. However, it is important to note that the study did not find a statistically significant effect on the mental health care utilization for individuals with severe distress levels. The authors noted that this group had

²²¹ The “MHPAEA program” refers to the MHPAEA statute, as amended, implementing regulations, and subsequent guidance, as discussed in section IV.3.

already been more likely to use mental health care even before the State parity laws were implemented, suggesting they may have sought such care regardless of these laws.²²²

Similarly, a 2008 study examined whether State parity laws affect mental health care utilization differently among low-income individuals and those with poor mental health conditions. To examine these effects, the study used pooled cross-sectional data from the National Survey of America's Families conducted in 1997, 1999, and 2001 and found that employees of small firms were more likely to use mental health and substance use disorder care after the implementation of State parity laws. While the study found no effect of parity for low-income adults for all employers, when limiting the sample to small employers, the study found that parity was associated with a 5-percentage-point increase in the probability of low-income individuals using mental health services. The study also found a large increase among those with poor mental health conditions employed by small employers, although this finding is only significant at a 10-percent significance level. The study did not find an effect for individuals with poor mental health for medium or large employers. The authors attributed these inconclusive results to the small sample size; therefore, the findings in this study should be interpreted with caution.²²³

Additionally, a 2013 study examined the effect of State parity laws on substance use disorder treatment using national survey data from 2000 to 2008 using State and year fixed effects to compare non-parity States to parity States prior to the implementation of MHPAEA. The authors reported that the baseline substance use disorder treatment rate before State parity laws were enacted was 1.40 percentage points in all specialty substance use disorder treatment facilities and 1.10 percentage points in facilities accepting private insurance. Relative to these

²²² Katherine M. Harris, Christopher Carpenter, & Yuhua Bao, *The Effects of State Parity Laws on the Use of Mental Health Care*, 44(6) *Medical Care* pp. 499-505 (2006).

²²³ Susan H. Busch & Colleen L. Barry, *New Evidence on the Effects of State Mental Health Mandates*, *INQUIRY: The Journal of Health Care Organization*, 45(3) *Provision, and Financing* pp. 308-322 (2008).

baseline rates, this study found that the implementation of any parity law increased the treatment rate by 9 percent in all specialty substance use disorder treatment facilities and by 15 percent in all treatment facilities accepting private insurance. When controlling for the comprehensiveness of the State parity law, the study found that full parity²²⁴ and parity-if-offered²²⁵ increased the substance use disorder treatment rate in all facilities by 13 percent and 8 percent, and by 21 percent and 10 percent in those accepting private insurance, respectively; States with partial parity²²⁶ did not have a significant effect on the substance use disorder treatment rates. The study conducted sensitivity analyses for facilities not accepting private insurance and found no difference in the treatment rates attributable to parity, suggesting that the effect of parity on the treatment rate is primarily driven by the increased treatment rate among the target population.²²⁷

6.1.2 Research Finding State Parity Laws Have Other Positive Effects

Other studies have found that State parity laws have positive effects that extend beyond the use of mental health care. For example, a 2013 study comparing suicide rates in States with and without parity laws during two distinct periods: 1990 to 1997 and 1998 to 2004, the period when the majority of States (22 out of 29) had implemented parity laws. The study found that State parity laws were associated with a 5-percent decrease in suicide rates, even after subjecting the analysis to several robustness checks.²²⁸

Similarly, a 2022 study examined how State parity laws affected suicide rates and educational outcomes among college-level students. Utilizing survey and administrative data spanning from 1998 to 2008, the study employed a difference-in-differences model and found

²²⁴ The study defined “full parity” as “requiring SUD coverage to be offered and offered on par with the comparable medical/surgical coverage in all aspects of cost sharing and treatment limitations.”

²²⁵ The study defined “parity-if-offered” as “not requiring SUD coverage to be offered, but if offered, it should be on par with the comparable medical/surgical coverage in all aspects of cost sharing and treatment limitations.”

²²⁶ The study defined “partial parity” as “requiring SUD coverage to be offered, allows for discrepancies between SUD coverage and comparable medical/surgical coverage in some aspects of cost sharing and treatment limitations.”

²²⁷ Hefei Wen, Janet R. Cummings, Jason M. Hockenberry, Laura M. Gaydos, & Benjamin G. Druss, *State Parity Laws and Access to Treatment for Substance Use Disorder in the United States: Implications for Federal Parity Legislation*, 70(12) *JAMA Psychiatry* pp. 1355-1362 (2013).

²²⁸ Matthew Lang, *The Impact of Mental Health Insurance Laws on State Suicide Rates*, 22(1) *Health Economics* pp. 73-88 (2013).

that State parity laws reduced the suicide rates, increased college grade point averages, and reduced the likelihood of college-level students reporting any poor mental health days. However, the study did not find evidence that State parity laws affect the likelihood of disenrolling from college. These findings remain consistent even after subjecting the analysis to several robustness checks. The authors acknowledged some limitations in the study. Specifically, the reported number of poor mental health days reported is based on self-assessment, rather than on clinical measures. There is also a possibility of underreporting due to the stigma associated with mental health.²²⁹

Finally, a 2015 study examined the effect of State parity laws on individuals aged 25 to 64 with moderate levels of distress.²³⁰ Using individual-level data from the National Health Interview Survey (1997 to 2001) and the Medical Expenditure Panel Survey (1998 to 2003), the study employed a triple-difference model and found a statistically significant increase in employment, weekly wages, and the number of hours worked following the passage of parity. The authors noted that the results do not indicate a shift in the labor demand curve, but rather an increase in the productivity of workers with moderate levels of distress.²³¹

Although the previous three studies suggest mental health outcomes may improve following the initiation of State parity policies, it is not clear from this research the mechanism driving any outcome improvements. Given a lack of data in both studies, the authors cannot directly show that State parity laws increase mental healthcare utilization. The causal impact of these policies, including whether parity would increase mental healthcare utilization, which would in turn improve health outcomes such as the suicide rate, can therefore not be directly

²²⁹ Keisha T. Solomon & Kabir Dasgupta, *State Mental Health Insurance Parity Laws and College Educational Outcomes*, 86 *Journal of Health Economics* (2022).

²³⁰ The author defines “moderately distressed individuals” based on their reported levels of distress in the National Health Interview Survey. The authors categorized “distress” as follows: scores below 1 indicate no distress, 1 to 5 indicate low distress, 6 to 11 indicate moderate distress, and 12 or above indicate severe distress.

²³¹ Martin Andersen, *Heterogeneity and the Effect of Mental Health Parity Mandates on the Labor Market*, 43 *Journal of Health Economics* (2015).

ascertained. Absent any utilization increases, it is possible that parity policies could improve the quality of care itself without additional demand, but further research is needed to answer how specifically parity laws affect downstream health outcomes.

6.1.3 Research Finding State Parity Laws Have Statistically Insignificant Effects

In contrast, some studies have found that State parity laws did not significantly improve access to mental health and substance use disorder care. For instance, a 2000 study focused on patients with mental health needs examined the impact of State parity laws on their insurance coverage, with varying specifications which defined this as insurance status, insurance generosity, and perceived access to care. Using national survey data from 1996 to 1998, the study found no statistically significant impact on insurance coverage or access to care for patients with mental health needs following the passage of State parity laws. The authors attributed this finding to several limitations of the study, including a relatively small sample size which limited the narrowness of State parity laws in terms of impact types of insurance coverage, and the significant number of individuals with mental health or substance use disorders who do not have health insurance coverage. Most significantly, while the study examined the impact of parity laws on access to insurance and care, it was not limited to behavioral health care and so the impact on those interventions may not have been statistically significantly captured.²³²

Furthermore, a 2013 study examined how State parity laws affected access to mental health care services for privately insured children and youths aged three to 17 with ASD. Using national survey data from 2005 to 2006 and adjusting for potential selection bias of States that enacted parity legislation, the study did not find evidence that State parity laws increased the utilization of mental health services for children with ASD. The authors suggested that differences in the availability of services, therapies, and treatments across States could explain

²³² Roland Sturm, *State Parity Legislation and Changes in Health Insurance and Perceived Access to Care Among Individuals with Mental Illness: 1996–1998*, 3(4) *The Journal of Mental Health Policy and Economics* pp. 209-213 (2000).

this lack of impact, as these children may not benefit from the same protections and service access afforded to children with other mental health conditions under State parity laws.

Additionally, the authors acknowledged limitations in their analysis, noting that the study did not provide information on the implementation of State parity laws. They cautioned that measurement errors could arise due to the potential delayed effects associated with varying implementation timelines of the State parity laws.²³³

6.2 Research Examining the Impact of MHPAEA on Utilization

Several studies have investigated the effect MHPAEA had on utilization of treatment for mental health conditions or substance use disorders. In general, the studies have found either a small or no effect on utilization after the implementation of MHPAEA.

For instance, a 2014 study analyzed pooled data from seven Federal Employees Health Benefits (FEHB) plans, four of which contracted with carve-out plans²³⁴ before and after parity implementation, two implemented carve-out plans when parity took effect, and one was not a carve-out plan. The authors looked at annual utilization, including psychotherapy visits, medication management visits, inpatient mental health or substance use disorder days, and mental health or substance use disorder prescription fills, for three target diagnoses: bipolar disorder, major depression, and adjustment disorder. Using a difference in differences model, the authors found a 12-percent statistically significant decrease in annual psychotherapy utilization for individuals diagnosed with adjustment disorders, and a statistically significant decrease in out-of-pocket spending for enrollees across all three diagnostic categories (ranging from \$78 to \$86) following parity implementation, and found no significant change for all other metrics. The authors opine that the observed decline in psychotherapy utilization may be related to the Office

²³³ Lucy A. Bilaver & Neil Jordan, *Impact of State Mental Health Parity Laws on Access to Autism Services*, 64(10) *Psychiatric Services* pp. 967-973 (2013).

²³⁴ Carve-out plans are defined as plans that only administer behavioral health benefits. (See Sarah A. Friedman, Francisca Azocar, Haiyong Xu, & Susan L. Ettner, *The Mental Health Parity and Addiction Equity Act (MHPAEA) Evaluation Study: Did Parity Differentially Affect Substance Use Disorder and Mental Health Benefits Offered by Behavioral Healthcare Carve-Out and Carve-In Plans*, 190 *Drug and Alcohol Dependence* pp. 151-158 (2018).)

of Personnel Management’s encouragement that FEHB plans utilize benefit management techniques to control spending increases following parity implementation.²³⁵

Along the same lines, a 2016 study used an interrupted time series model to investigate the effect of MHPAEA on the probability of specialty behavioral health treatment, levels of utilization, and expenditures for enrollees aged 27 to 64 in group health plans between 2008 and 2013, with Optum carve-outs. The authors focused on the following outcomes: expenditures (insurer and patient), number of outpatient visits (assessment/diagnostic evaluation, individual psychotherapy, family psychotherapy, and medication management), and number of days of care (structure outpatient, day treatment, residential care, and acute inpatient care). In the post-parity period, 2011 to 2013, the effect of parity differed by type of care: the probability of using any assessment/diagnostic evaluation, medication management, of family psychotherapy visits decreased, while the probability of using structure outpatient care and inpatient care increased. Under multiple specifications and sensitivity tests, the authors found that parity had “modest to no effect on service use.” Though they did find modest evidence that costs shifted from patient to health plans.²³⁶

Similarly, a 2019 study looked at insurance claims of enrollees under age 65 with continuous enrollment in a large group, employer-sponsored fully insured health plan between January 2005 and September 2015 to analyze whether parity implementation was associated with utilization and spending changes in behavioral health services compared to medical/surgical services. Parity had a positive but small, statistically significant impact on the share of enrollees that used any outpatient substance use disorder services. Specifically, parity increased the

²³⁵ Alisa Busch, Frank Yoon, Colleen Barry, Banessa Azzone, Sharone-Lisa Normand, Howard Goldman, & Haiden Huskamp, *The Effects of Parity on Mental Health and Substance Use Disorder Spending and Utilization: Does Diagnosis Matter?* 172(2) *American Journal of Psychiatry* pp. 180-187 (Feb. 2013).

²³⁶ Susan Ettner, Jessica Harwood, Amber Thalmayer, Michael Ong, Haiyong Xu, Michael Bresolin, Kenneth Wells, Chi-Hong Tseng, & Francisca Azocar, *The Mental Health Parity and Addiction Equity Act Evaluation Study: Impact on Specialty Behavioral Health Utilization and Expenditures Among “Carve-Out” Enrollees*, 50 *Journal of Health Economics* pp. 131-143 (2016).

percentage of enrollees that used any outpatient substance use disorder services by 0.023 percentage points in the first year following the implementation of MHPAEA and 0.068 percentage points by the end of 2015 relative to pre-MHPAEA levels. The authors also found that parity led to an increase in the average frequency of monthly services per user for both mental health and substance use disorder services, at a rate of 0.05 services per user for mental health services and 0.054 services per user for substance use disorder services. This implies that people receiving services received more services, on average.²³⁷

6.3 Research Examining the Impact of MHPAEA on Spending

Research has found mixed evidence on the impact of MHPAEA on spending. Some studies did not identify a change in out-of-pocket spending following the passage of MHPAEA, whereas others found that MHPAEA increased out-of-pocket spending on substance use disorder care.

For instance, a 2017 study examined whether MHPAEA increased behavioral health expenditures and utilization among a population with substance use disorders. Using Optum's claims and eligibility data from 2008 to 2013, the authors compared the utilization and expenditures for adults with alcohol or drug use disorders across several periods: pre-parity (2008 to 2009), transition period (2010),²³⁸ and post-parity period (2011 to 2013). They found that for carve-out plans managed by Optum, MHPAEA was associated with modest increases in total spending, plan spending, and patient out-of-pocket spending, as well as outpatient and inpatient utilization. Although the increases were mostly small in magnitude, they were evident across different types of care, potentially indicating small improvements in the accessibility to

²³⁷ Noah Mulvaney-Day, Brent Gibbons, Shums Alikhan, & Mustafa Karakus, *Mental Health Parity and Addiction Equity Act and the Use of Outpatient Behavioral Health Services in the United States, 2005-2016*, 109(3) *American Journal of Public Health* pp. 190-196 (2019).

²³⁸ The study defined the "transition" period as "when good-faith efforts at compliance with respect to coinsurance, copayments, combined medical-behavioral health deductibles, and quantitative treatment limits went into effect for plans renewing on a calendar-year basis."

various substance use disorder treatments.²³⁹ The authors note that these results are similar to other studies, which used the same data when examining adults in carve-in plans and carve-out plans.²⁴⁰

Additionally, a 2015 study examined whether MHPAEA was associated with changes in the out-of-network services for substance use disorder services. Using a 2007 to 2012 longitudinal, commercial claims database and employing an interrupted time-series design to analyze these effects, the study found that MHPAEA was associated with an increased probability of using out-of-network services at a rate of 0.0024 service users per month, an increased number of out-of-network out-patient visits at a rate of 0.0016 service users per month, and an increased average total spending on out-of-network services by \$49.81 per user per month, though it was found to have no effect on out-of-pocket spending. This result would represent a shift in expenses borne by the insurer, which might or might not be passed through to the insured through higher premiums, but the study lacked the data to assess this possibility. The authors acknowledged that the study was not able to examine the adequacy of substance use disorder provider networks, which may have influenced enrollees pursuit of out-of-network care.²⁴¹

Finally, a 2014 study examined the impact of MHPAEA on the utilization and spending of substance use disorder treatments. Using 2009 to 2010 administrative claims data from Aetna

²³⁹ Sarah Friedman, Haiyong Xu, Jessica M. Harwood, Francisca Azocar, Brian Hurley & Susan L. Ettner, *The Mental Health Parity and Addiction Equity Act Evaluation Study: Impact on Specialty Behavioral Healthcare Utilization and Spending Among Enrollees with Substance Use Disorders*, 80 *Journal of Substance Abuse Treatment* pp. 67-78 (2017).

²⁴⁰ Harwood, Jessica M., Francisca Azocar, Amber Thalmayer, Haiyong Xu, Michael K. Ong, Chi-Hong Tseng, Kenneth B. Wells, Sarah Friedman, & Susan L. Ettner, *The Mental Health Parity and Addiction Equity Act Evaluation Study: Impact on Specialty Behavioral Health Care Utilization And Spending Among Carve-In Enrollees*, 55(2) *Medical Care* pp. 164-172 (2017); and Susan L. Ettner, Jessica M. Harwood, Amber Thalmayer, Michael K. Ong, Haiyong Xu, Michael J. Bresolin, Kenneth B. Wells, Chi-Hong Tseng, & Francisca Azocar, *The Mental Health Parity and Addiction Equity Act Evaluation Study: Impact on Specialty Behavioral Health Utilization and Expenditures Among Carve-Out Enrollees*, 50 *Journal of Health Economics* pp. 131-143 (2016).

²⁴¹ Emma E. McGinty, Susan H. Busch, Elizabeth A. Stuart, Haiden A. Huskamp, Teresa B. Gibson, Howard H. Goldman, & Colleen L. Barry, *Federal Parity Law Associated with Increased Probability of Using Out-Of-Network Substance Use Disorder Treatment Services*, 34(8) *Health Affairs* pp. 1331-1339 (2015).

insurance, the study compared changes in outcomes among health plan enrollees one year before (2009) and one year after (2010) the implementation of MHPAEA, compared to enrollees covered by State parity laws in place prior to MHPAEA. The study found the MHPAEA was associated with a modest increase in spending on substance use disorder treatments (\$9.99 per health plan enrollee), but did not find significant changes in treatment initiation,²⁴² treatment engagement,²⁴³ or out-of-pocket spending. The authors acknowledged that these findings may not be generalizable to other insurance or population contexts, since the study evaluated the effects of parity on individuals insured by a single health insurer in 10 States with pre-existing State parity laws. Moreover, the study examined only the first year following MHPAEA's effective date, which may not have fully captured its implementation.²⁴⁴ As discussed in section IV.2.2, the Departments have published regulations and extensive guidance to facilitate the implementation and enforcement of MHPAEA.

7. Benefits

The Departments expect that these final rules will improve the quality of the comparative analyses performed and documented by plans and issuers required by MHPAEA, as amended by the CAA, 2021; help plans and issuers better understand and fulfill their obligations under MHPAEA; and promote greater clarity regarding differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits. By specifying more details on how to perform and document NQTL comparative analyses, the Departments expect improvements in plan and issuer compliance with the requirements for imposing NQTLs under

²⁴² The study defined “treatment initiation” as the “share of enrollees with a new episode of SUD treatment who initiated treatment within 14 days of their initial diagnosis.”

²⁴³ The study defined “treatment engagement” as the “share of enrollees with a new episode of SUD treatment who receive at least two SUD services within 30 days of their initial diagnosis.”

²⁴⁴ Susan H. Busch, Andrew J. Epstein, Michael O. Harhay, David A. Fiellin, Hyong Un, Deane Leader Jr, & Colleen L. Barry, *The Effects of Federal Parity on Substance Use Disorder Treatment*, 20(1) *The American Journal of Managed Care* (2014).

MHPAEA, and by doing so, increased access for participants, beneficiaries and enrollees to mental health and substance use disorder services.

Thus, these final rules will generate the following economic and societal benefits for participants, beneficiaries, and enrollees:

- improved understanding of and compliance with MHPAEA by plans and issuers, resulting in better frameworks for regulators, plans, and issuers to determine whether plans and issuers are complying with MHPAEA with respect to NQTLs applicable to coverage of mental health and substance use disorder benefits,
- greater access and utilization of mental health and substance use disorder services in response to a reduction in barriers to mental health and substance use disorder coverage (the greater utilization being a cost of the rule), resulting in better health outcomes among those with mental health conditions or substance use disorders, and
- reduced adverse impacts on the families, friends, caregivers, and coworkers of people who suffer from untreated or under treated mental health conditions or substance use disorders based on their improved access to treatment.

This analysis provides a mainly qualitative discussion of the benefits associated with these final rules, as the Departments do not have the data necessary to quantify the likely benefits associated with the additional guidance and its impact on ensuring better compliance with the rules related to NQTLs and access to mental health and substance use disorder benefits. Where possible, however, the Departments have provided estimates to illustrate some of the benefits of these final rules. The illustrative calculations address overlapping phenomena and thus are not summed due to the noteworthy potential for double-counting (moreover, for only a subset of the illustrated benefits have the associated treatment costs been quantified).

In addition, the Departments have identified several transfers that will occur due to this rulemaking, such as decreases in out-of-pocket spending and increases in premiums. These transfers are discussed in section IV.9 of this regulatory impact analysis.

The Departments requested comments and data in the proposed rules related to how the Departments might quantify these benefits. While one commenter stated that the Departments had not quantified the benefits of the proposal, they did not provide any data or recommendations on how these benefits could be quantified. Another commenter suggested that the Congressional Budget Office's (CBO) cost estimate²⁴⁵ of the CAA, 2021 may help the Departments to quantify the benefits of the proposal. However, the CBO report primarily focuses on the program cost of CAA, 2021, rather than addressing the specific impact of the additional requirements for documenting comparative analyses, and therefore the Departments are not able to utilize it for quantifying the benefits of these final rules.

7.1 Improved Understanding of and Compliance with MHPAEA by Plans and Issuers

As noted earlier, the 2022 MHPAEA Report to Congress²⁴⁶ found that none of the comparative analyses reviewed by the Departments under the first year of the CAA, 2021, contained sufficient information and documentation from plans and issuers upon initial receipt and nearly all were similarly deficient for the 2023 MHPAEA Comparative Analysis Report to Congress.²⁴⁷ As a result, the Departments had to make numerous requests for additional information. This process is costly for plans, issuers, and the Departments, and undermines the effectiveness of MHPAEA.

²⁴⁵ See CBO, *Summary Estimate for Divisions M Through FF, H.R. 133, Consolidated Appropriations Act, 2021 (Public Law 116-260), as Enacted on December 27, 2020* (Jan. 14, 2021), https://www.cbo.gov/system/files/2021-01/PL_116-260_Summary.pdf.

²⁴⁶ *2022 MHPAEA Report to Congress*, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf>.

²⁴⁷ *2023 MHPAEA Comparative Analysis Report to Congress*, www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

These final rules will clarify and strengthen the obligations of plans and issuers under MHPAEA, thus promoting compliance, by:

- placing renewed focus on the elimination of more restrictive barriers to access to mental health and substance use disorder benefits as compared to medical/surgical benefits,
- standardizing the definitions associated with the parity analysis for NQTLs applicable to mental health and substance use disorder benefits and medical/surgical benefits,
- providing examples of the application of MHPAEA to NQTLs, and
- setting forth the content and data evaluation requirements of the NQTL comparative analyses.

These final rules will help parties better understand what plans and issuers need to do to comply with MHPAEA, reduce uncertainty about compliance status, and help plans and issuers better identify areas they need to improve upon as well as reduce the need to revise analyses upon the Departments identifying non-compliance. In the course of implementing these final rules, the Departments anticipate that parties will adjust their policies and procedures in order to come into compliance and offer better coverage of mental health and substance use benefits to participants, beneficiaries, and enrollees.

Many commenters supported modifying existing definitions and adding new ones to the MHPAEA regulations, particularly for terms such as “medical/surgical benefits,” “mental health benefits,” and “substance use disorder benefits.” Commenters stated that these definitions would significantly improve clarity for plans and issuers. One commenter stated the proposal would clearly specify how mental health and substance use disorder benefits must be defined for MHPAEA compliance purposes, minimize situations where contradictions with State guidelines limit protections under MHPAEA, and ensure that plans appropriately classify mental health and

substance use disorder benefits and medical/surgical benefits. The Departments acknowledge the supportive comments and agree that modifying and adding definitions, particularly for key terms like “medical/surgical benefits,” “mental health benefits,” and “substance use disorder benefits,” will enhance clarity and ensure consistent application of the MHPAEA requirements across plans and issuers, and have done so in these final rules.

Commenters also expressed support for clarifying the application of MHPAEA’s requirements to NQTLs. One commenter stated that the proposal provides more specificity for plans and issuers to assess their NQTLs applicable to mental health or substance use disorder benefits, and the information that must be included in a comparative analysis of NQTLs applicable to mental health and substance use disorder benefits and medical/surgical benefits. The commenter further stated the proposal reduces uncertainty for all parties, while providing greater clarity for consumers and other stakeholders to assess whether an NQTL is compliant with MHPAEA. Additionally, the commenter stated that the proposal provides greater clarity for insurers and patients and helps State insurance regulators better enforce existing regulations. The Departments acknowledge the supportive comments and agree that the final rules provide clarity to the statutory requirements for the regulated community and other interested parties.

However, some commenters expressed concern regarding whether certain policies and procedures would now be prohibited under MHPAEA, as interpreted through the proposed rules, if finalized. One commenter, in objecting to the proposed mathematical substantially all and predominant tests, stated that the most significant cost is not in conducting the comparative analysis, but rather in the additional expenses incurred should plans and issuers no longer be able to utilize common medical management techniques that improve cost and quality outcomes, such as prior authorization and concurrent review.

As stated earlier in this preamble, the Departments are not finalizing the proposed mathematical test for applying the substantially all and predominant tests in these final rules.

These final rules also do not eliminate the use of prior authorization or other medical management NQTLs applicable to both mental health and substance use disorder benefits and medical/surgical benefits. However, NQTLs applicable to mental health and substance use disorder benefits and medical/surgical benefits must be designed and applied in compliance with MHPAEA's parity requirements. Moreover, as discussed earlier in this preamble, the Departments anticipate that these final rules will promote changes in network composition and medical management techniques that result in more robust mental health and substance use disorder provider networks, as well as fewer and less restrictive prior authorization requirements for individuals seeking mental health and substance use disorder treatment. While this could increase costs in some cases, there are potential offsetting benefits in other cases for the reduction in the use of medical management techniques.

7.2 Greater Access to Mental Health and Substance Use Disorder Treatments

By improving plan and issuer understanding of the requirements under MHPAEA and clarifying how comparative analyses must be performed and documented, these final rules will improve compliance. Specifically, this will ensure compliance with the design and application requirements and the relevant data evaluation requirements so that NQTLs applied to mental health and substance use disorder benefits are no more restrictive than the predominant limitation applicable to substantially all medical/surgical benefits. The Departments are of the view that this will, in turn, expand access to and utilization of mental health and substance use disorder services. These final rules will have the greatest direct benefits for individuals who currently forego treatments or cannot access specialized care for a mental health condition or substance use disorder because their plan or coverage imposes barriers to accessing benefits for coverage of these services that are greater than the barriers for accessing medical/surgical services.

The Departments do not have sufficient data to estimate how many participants, beneficiaries, and enrollees will receive treatment, or more appropriate treatment, as a result of

these final rules. However, research has demonstrated that participants, beneficiaries, and enrollees experienced increased access to mental health and substance use disorder treatments following the implementation of MHPAEA. Drawing on these studies, the Departments expect that this rulemaking, in further improving compliance with MHPAEA, will result in significant improvements in access to mental health and substance use disorder care.

For example, a 2018 study examined how MHPAEA affected the coverage of commercial health plans in the United States. The study found that between 2010²⁴⁸ and 2014, 68 percent of insurance products had expanded behavioral health coverage, and among plans that expanded services, 96 percent reported it was in part because of parity requirements.²⁴⁹ Further, a 2017 study examined the prevalence of behavioral health quantitative treatment limitations in large group health plans that utilized carve-out and carve-in services of a single service provider. While prior to implementation of MHPAEA, quantitative treatment limitations existed, following its implementation virtually all of those plans had eliminated quantitative treatment limitations.²⁵⁰ A 2019 study of claims data from both a pre-parity (January 2005 through December 2010) and post-parity period (January 2011 through September 2015), found that while MHPAEA did not appreciably increase the share of participants utilizing any outpatient mental health services, it did increase the frequency of use and total utilization of outpatient mental health and substance use disorder services of participants already receiving these services.²⁵¹ Moreover, a 2020 study of MHPAEA, using 2007 and 2011 to 2012 data from the National Survey of Children's Health, found that among children and adolescents with family

²⁴⁸ The effective date for MHPAEA for calendar year plans is January 1, 2010. See CMS, *The Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA)* (2010).

²⁴⁹ Dominic Hodgkin, Constance M. Horgan, Maureen T. Stewart, Amity E. Quinn, Timothy B. Creedon, Sharon Reif, & Deborah W. Garnick, *Federal Parity and Access to Behavioral Health Care in Private Health Plans*, 69(4) *Psychiatric Services* pp. 396-402 (2018).

²⁵⁰ Thalmayer, Amber Gayle, Sarah A. Friedman, Francisca Azocar, Jessica M. Harwood, & Susan L. Ettner, *The Mental Health Parity and Addiction Equity Act (MHPAEA) Evaluation Study: Impact on Quantitative Treatment Limits*, 68(5) *Psychiatric Services* pp. 435-442 (2017).

²⁵¹ Norah Mulvaney-Day, Brent J. Gibbons, Shums Alikhan, & Mustafa Karakus, *Mental Health Parity and Addiction Equity Act and the Use of Outpatient Behavioral Health Services in the United States, 2005–2016*, 109(S3) *American Journal of Public Health* pp. S190-S196 (2019).

income between 150 and 400 percent of the Federal poverty level in States without prior parity laws, the enactment of MHPAEA resulted in a 2.8-percentage-point increase in mental health care utilization.²⁵²

These final rules will directly benefit individuals who are currently enrolled in a plan with narrower networks, with regard to mental health and substance use disorder benefits compared to the networks for medical/surgical benefits, which prevent participants, beneficiaries, and enrollees from being able to access care from in-network providers and receive the benefits they need. A 2017 study of ACA Marketplace provider networks found that mental health networks were significantly narrower on average than primary care networks, providing less than half the share of providers practicing within a State-level market.²⁵³ A 2023 secret shopper study conducted by the Senate Committee on Finance contacted 10 providers from directories of 12 plans, making a total of 120 calls. The study found that more than 80 percent of mental health providers contacted were either unreachable, not in-network, or not accepting new patients.²⁵⁴

Ghost or phantom networks – collections of providers and facilities that are listed as being within a plan’s or issuer’s network but, in fact, are not available to participants, beneficiaries, and enrollees for treatment on an in-network basis – make it difficult for participants to find in-network providers.²⁵⁵ One 2020 national survey of privately insured individuals that received mental health treatment found that more than half of those patients that used a provider directory encountered inaccuracies which made them more likely to be treated by

²⁵² Xiaoxue Li & Jie Ma, *Does Mental Health Parity Encourage Mental Health Utilization Among Children and Adolescents? Evidence From the 2008 Mental Health Parity and Addiction Equity Act (MHPAEA)*, 47(1) *The Journal of Behavioral Health Services & Research* pp. 38-53 (2020).

²⁵³ Jane M. Zhu, Yuehan Zhang, & Daniel Polsky, *Networks in ACA Marketplaces are Narrower for Mental Health Care than for Primary Care*, 36(9) *Health Affairs* pp. 1624-1631 (Sept. 2017).

²⁵⁴ Senate Committee on Finance Majority, *Majority Study Findings: Medicare Advantage Plan Directories Haunted by Ghost Networks* (2023),

<https://www.finance.senate.gov/imo/media/doc/050323%20Ghost%20Network%20Hearing%20-%20Secret%20Shopper%20Study%20Report.pdf>.

²⁵⁵ GAO, *Mental Health Care: Access Challenges for Covered Consumers and Relevant Federal Efforts*, GAO-22-104597 (Mar. 2022), <https://www.gao.gov/assets/gao-22-104597.pdf>.

an out-of-network provider, and four times as likely to receive a surprise, out-of-network bill.²⁵⁶

In response to the Departments' proposal, numerous commenters stated that they believed the proposed rules would benefit patients, specifically by improving access to mental health and substance use disorder treatments. Several commenters stated the proposed rules would ensure more equitable access to care by addressing burdensome administrative practices, such as NQTLs and other utilization management techniques, which negatively impact patient access to mental health and substance use disorder benefits. Additionally, many other commenters suggested that the enhanced clarity and transparency provided by the proposed rules would alleviate administrative burdens and, as such, help to streamline access to behavioral health care. The Departments acknowledge these supportive comments and agree that the final rules will increase access to mental health and substance use disorder treatments.

Given those concerns highlighted by commenters regarding challenges related to accessing mental health substance use disorder benefits, the final rules particularly highlight parity in NQTLs related to network composition as an area that requires improvement. By requiring plans and issuers to collect and evaluate relevant data on provider networks, including for network composition NQTLs, the final rules will help to ensure that individuals have more equitable access to in-network providers that are available to provide care for mental health conditions and substance use disorders. Additionally, by ensuring that plans and issuers collect and evaluate data related to NQTLs for network composition for mental health and substance use disorder benefits and medical/surgical benefits, and as necessary address material differences in access between these benefits, the Departments expect that the final rules will improve the ability of participants, beneficiaries, and enrollees to access available in-network mental health and substance use disorder providers. Thus, the final rules will reduce barriers to accessing mental

²⁵⁶ Susan H. Busch & Kelly A. Kyanko, *Incorrect Provider Directories Associated with Out-of-Network Mental Health Care and Outpatient Surprise Bills*, 39(6) Health Affairs pp. 975-983 (June 2020).

health and substance use disorder care.

This discussion focuses on the benefits for participants, beneficiaries, and enrollees who were previously prevented from receiving mental health or substance use disorder treatment. For a discussion of the effects on participants, beneficiaries, and enrollees who were previously paying out-of-pocket for treatment, refer to section IV.9.1 of this regulatory impact analysis pertaining to transfers.

The implementation of the CAA, 2023 provision that sunsets the MHPAEA opt-out election is expected to reduce financial and non-financial barriers to accessing mental health and substance use disorder treatment for participants and beneficiaries of self-funded non-Federal governmental plans that elected to opt out of requirements under MHPAEA. This is expected to result in increased access to mental health and substance use disorder care and, as discussed in more detail in the section IV.7.3, lead to better health outcomes for plan participants and beneficiaries who need mental health or substance use disorder services.

7.3 Better Health Outcomes Among Those with Mental Health Conditions and Substance Use Disorders

The Departments are of the view that by ensuring parity in medical management techniques and other NQTLs imposed by plans and issuers, the final rules will reduce barriers for participants, beneficiaries, and enrollees seeking mental health and substance use disorder care. As discussed later in this regulatory impact analysis, the removal of barriers preventing individuals from accessing mental health and substance use disorder treatment on par with medical/surgical treatment will in turn produce better patient outcomes, including potentially lives saved.

Research has demonstrated that MHPAEA has already had a positive effect on improving access to treatment. A 2016 study examining the initial effects of MHPAEA found that following implementation, prior authorization requirements were less common for behavioral health care

services than in previous years.²⁵⁷ Further, removal of treatment limitations has had significant beneficial impacts in the mental health and substance use disorder space. A 2013 study, which analyzed changes in suicide rates by age groups before and after State parity laws were enacted, found that, controlling for State-specific time trends, enactment of parity laws was associated with a 5-percent decrease in suicides.²⁵⁸ It is worth noting, however, that State parity laws do not apply to most self-funded employer-sponsored health coverage, which comprise a large portion of the population in States affected by these final rules. As such, the impact of the laws in that study may have been somewhat dampened. For a more detailed description of this study, see section IV.6.1.

If, as the Departments expect, these final rules similarly increase access to mental health and substance use disorder care, the potential benefits could be significant. Using the suicide fatality rate for adults in 2021 from the Centers for Disease Control and Prevention (CDC) of approximately 14.1 per 100,000 persons²⁵⁹ and the 2020 Agency for Healthcare Research and Quality youth suicide fatality rate of approximately 6.3 per 100,000,²⁶⁰ and applying these rates to the numbers of individuals 12 years old and older with private health insurance,²⁶¹ suggests approximately 22,200 suicide deaths annually for adults²⁶² and 979 suicide deaths annually for children 12-17 years old.²⁶³ For illustrative purposes, the Departments assume that these final

²⁵⁷ Constance M. Horgan, Dominic Hodgkin, Maureen T. Stewart, Amity Quinn, Elizabeth L. Merrick, Sharon Reif, Deborah W. Garnick, & Timothy B. Creedon, *Health Plans' Early Response to Federal Parity Legislation for Mental Health and Addiction Services*, 67(2) *Psychiatric Services* pp. 162-168 (2016).

²⁵⁸ Matthew Lang, *The Impact of Mental Health Insurance Laws on State Suicide Rates*, 22(1) *Health Economics*, pp. 73-88 (2013).

²⁵⁹ CDC, National Center for Health Statistics, *Provisional Estimates of Suicide by Demographic Characteristics: United States, 2022*, Report No. 34 (Nov. 2023), <https://www.cdc.gov/nchs/data/vsrr/vsrr034.pdf>.

²⁶⁰ Agency for Healthcare Research and Quality, *2022 National Healthcare Quality and Disparities Report, Child and Adolescent Mental Health* (Oct. 2022), <https://www.ncbi.nlm.nih.gov/books/NBK587174/>.

²⁶¹ Based on the Departments' tabulations of adults with non-Federal employer-sponsored insurance (ESI) and/or private health insurance (157.4 million) and the number of children 12-17 with non-Federal ESI and/or private health insurance (15.5 million) off the March 2022 CPS Auxiliary Data (<https://www.dol.gov/agencies/ebsa/researchers/data/auxiliary-data>).

²⁶² The estimate is calculated as follows: 157,443,601 participants with commercial health insurance × 0.014-percent adult suicide fatality = 22,200 adult suicide fatalities.

²⁶³ The estimate is calculated as follows: 15,541,261 children aged 12-17 with private health insurance × 0.0063-percent suicide fatalities = 979 fatalities.

rules would have roughly 40 percent of the impact of the Lang study, or a 2-percent reduction of fatalities.²⁶⁴ As such, the Departments estimate that the final rules could help prevent 444 adult²⁶⁵ and 20 youth²⁶⁶ fatalities from suicide annually. Using the 2023 estimate of the value of a statistical life (VSL) developed by the U.S. Department of Transportation (DOT), \$13.2 million,^{267,268} this would translate into benefits of \$6.11 billion annually.^{269,270} The Departments recognize the uncertainty in the production of VSL benefit estimates. This uncertainty arises from a variety of assumptions that are key to the VSL estimate, such as the underlying demographic characteristics of the affected population or the differential willingness-to-pay for statistically equivalent but qualitatively different risks.²⁷¹ To account for potential sensitivity arising from such uncertainty, the Departments have conducted a sensitivity analysis of these benefits and, following guidance on VSL sensitivity analysis,²⁷² produced a lower and upper estimate of the VSL of approximately \$5.3 million and \$18.5 million, respectively.²⁷³ Utilizing

²⁶⁴ This estimate of a 2-percent reduction is based on the estimate of 5 percent previously cited, revised downward by 60 percent to account for the indirect impact of the final rule on access, compared to the initial introduction of mental health parity laws. See Matthew Lang, *The Impact of Mental Health Insurance Laws on State Suicide Rates*, 22(1) Health Economics, pp. 73-88 (2013).

²⁶⁵ The estimate is calculated as follows: 22,200 fatalities from suicide × 2-percent reduction in suicides = 444 fatalities prevented.

²⁶⁶ The estimate is calculated as follows: 979 fatalities from suicide × 2-percent reduction in suicides = 20 fatalities prevented.

²⁶⁷ DOT, *Departmental Guidance on Valuation of a Statistical Life in Economic Analysis*, effective May 7, 2024, <https://www.transportation.gov/office-policy/transportation-policy/revised-departmental-guidance-on-valuation-of-a-statistical-life-in-economic-analysis>.

²⁶⁸ The VSL utilized by the Departments in this analysis is one of several VSLs estimated by Federal agencies, all of which vary slightly in their estimated VSL. The HHS VSL in 2024 is \$13.1 million. More information on the HHS VSL can be found in *HHS Standard Values for Regulatory Analysis, 2024* (Jan. 25, 2024) at

<https://aspe.hhs.gov/sites/default/files/documents/cd2a1348ea0777b1aa918089e4965b8c/standard-ria-values.pdf>.

²⁶⁹ This estimate is calculated as follows: 444 adult fatalities prevented + 20 youth fatalities prevented × \$13,200,000 VSL = \$6,124,800,000.

²⁷⁰ Some methodological approaches to the VSL apply a distinct, and often higher, value to children. While the Departments do not utilize such an approach here, they recognize this estimate may undervalue the true benefits as the final rules' effects include a risk reduction of fatality to minor children.

²⁷¹ Individuals express a different willingness to pay to reduce the fatality risk of some deaths (those with a perceived associated morbidity, such as cancer) more than others (such as car accidents), though the risks may be equivalent. DOT guidance on the VSL suggests utilizing a single, nationwide value that does not adjust the VSL based on the nature of the risk or the underlying characteristics of the affected population but encourages a sensitivity analysis to reflect such uncertainty.

²⁷² For more information on the VSL guidance utilized, see the DOT's *Revised Departmental Guidance on Valuation of a Statistical Life in Economic Analysis*, <https://www.transportation.gov/office-policy/transportation-policy/revised-departmental-guidance-on-valuation-of-a-statistical-life-in-economic-analysis>.

²⁷³ The lower and upper bounds are estimated as 40 percent below and above the central estimate of \$13,200,000, per DOT guidance on conducting a sensitivity analysis for a VSL estimate.

this range of estimates, the Departments accordingly estimate the value of the benefits of reduced mortality arising from increased mental health treatment utilization at between \$2.5 billion and \$8.6 billion annually.²⁷⁴

These benefits further illustrate the value of receiving treatment earlier and the harms of delaying treatment. While 75 percent of mental illness onsets before age 25, individuals between age 18 and 25 have a considerably higher prevalence of serious mental illness²⁷⁵ than any other age group but the lowest rate of mental health treatment.^{276,277} Moreover, research suggesting that early symptom onset is associated with elevated risk for comorbid mental health disorders, as well as worsening health outcomes, illustrates the critical need for early mental health interventions and treatment access.^{278,279} However, the majority of adolescents with a mental health condition do not receive treatment.²⁸⁰ One review of recent changes in mental health treatment noted that “young people typically demonstrate a need for care prior to reaching the

²⁷⁴ These estimates are calculated as: The lower VSL estimate of \$5,280,000 × 464 fatalities prevented = \$2,447,665,113. The lower VSL estimate of \$18,480,000 × 464 fatalities prevented = \$8,566,827,999.

²⁷⁵ Serious mental illness is defined as a “mental, behavioral, or emotional disorder resulting in serious functional impairment, which substantially interferes with or limits one or more major life activities.” (See National Institute of Health, *Mental Illness*, <https://www.nimh.nih.gov/health/statistics/mental-illness>)

²⁷⁶ Peter J. Uhlhaas, Christopher G. Davey, Urvakhsh Meherwan Mehta, Jai Shah, John Torous, Nicholas B. Allen, Shelli Avenevoli, Tolulope Bella-Awusah, Andrew Chanen, Eric Y. H. Chen, Christoph U. Correll, Kim Q. Do, Helen L. Fisher, Sophia Frangou, Ian B. Hickie, Matcheri S. Keshavan, Kerstin Konrad, Francis S. Lee, Cindy H. Liu, Beatriz Luna, Patrick D. McGorry, Andreas Meyer-Lindenberg, Merete Nordentoft, Dost Öngür, George C. Patton, Tomáš Paus, Ulrich Reininghaus, Akira Sawa, Michael Schoenbaum, Gunter Schumann, Vinod H. Srihari, Ezra Susser, Swapna K. Verma, T. Wilson Woo, Lawrence H. Yang, Alison R. Yung & Stephen J. Wood, *Towards a Youth Mental Health Paradigm: A Perspective and Roadmap*, *Molecular Psychiatry* 28, 3171-3181 (2023).

²⁷⁷ SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2022 National Survey on Drug Use and Health* (2023), <https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf>.

²⁷⁸ Ronald C. Kessler, Patricia Berglund, Olga Demler, Robert Jin, Kathleen R. Merikangas, & Ellen E. Walters, *Lifetime Prevalence and Age-of-Onset Distributions of DSM-IV Disorders in the National Comorbidity Survey Replication*, 62(6) *Arch Gen Psychiatry* pp. 593–602 (2005).

²⁷⁹ Peter J. Uhlhaas, Christopher G. Davey, Urvakhsh Meherwan Mehta, Jai Shah, John Torous, Nicholas B. Allen, Shelli Avenevoli, Tolulope Bella-Awusah, Andrew Chanen, Eric Y. H. Chen, Christoph U. Correll, Kim Q. Do, Helen L. Fisher, Sophia Frangou, Ian B. Hickie, Matcheri S. Keshavan, Kerstin Konrad, Francis S. Lee, Cindy H. Liu, Beatriz Luna, Patrick D. McGorry, Andreas Meyer-Lindenberg, Merete Nordentoft, Dost Öngür, George C. Patton, Tomáš Paus, Ulrich Reininghaus, Akira Sawa, Michael Schoenbaum, Gunter Schumann, Vinod H. Srihari, Ezra Susser, Swapna K. Verma, T. Wilson Woo, Lawrence H. Yang, Alison R. Yung & Stephen J. Wood, *Towards a Youth Mental Health Paradigm: A Perspective and Roadmap*, *Molecular Psychiatry* 28, 3171-3181 (2023).

²⁸⁰ Kathleen Ries Merikangas, Jian-ping He, Marcy E. Burstein, Joel Swendsen, Shelli Avenevoli, Brady Case, Katholiki Georgiades, Leanne Heaton, Sonja Swanson, & Mark Olfson, *Service Utilization for Lifetime Mental Disorders in U.S. Adolescents: Results of the National Comorbidity Survey Adolescent Supplement*, 50(1) *Journal of the American Academy of Child Adolescent Psychiatry*, pp. 32-45 (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4408275>.

threshold for a traditional major psychiatric diagnosis where distress, functional impairment and warning signs . . . of mental illness are present, making early intervention at this time point crucial to preventing or reducing the severity of a full-threshold disorder.”²⁸¹ Further, this review noted that early intervention is key for reducing “premature death, social isolation, poor functioning and reduced educational and vocational productivity.” In recent years, research has driven an increased interest in early intervention services for younger individuals.²⁸²

Mental health research often evaluates the benefits of mental health care in terms of a quality-adjusted life year (QALY), an assessment metric that evaluates the changes to a person’s quality of life arising from an intervention. According to the National Institute for Health and Care Excellence, one QALY “is equal to 1 year of life in perfect health.”²⁸³ In 2015 New York City launched a program called ThriveNYC, which included 54 initiatives to improve mental health, including additional screening and collaborative care. The study found that, on average, a 20-year-old who received these interventions would see an increase of 0.38 QALYs (representing a change in quality of life, with no estimation in this study of changes to length of life) relative to those who did not receive these interventions.²⁸⁴

Another study compared the cost effectiveness of early intervention to standard care for the treatment of first-episode psychosis, finding that from a societal perspective (that is, quality of life, educational attainment, and gainful employment), early intervention resulted in higher discounted QALYs and lower costs than standard care. While acknowledging that earlier interventions result in higher lifetime costs than the standard care perspective, the authors still

²⁸¹ Patrick D. McGorry & Christina Mei, *Early Intervention in Youth Mental Health: Progress and Future Directions*, 21(4) Evidence Based Mental Health pp. 182-184 (2018).

²⁸² *Ibid.*

²⁸³ National Institute of Health and Care Excellence, *Glossary*, <https://www.nice.org.uk/glossary>.

²⁸⁴ Boshen Jiao, Zohn Rosen, Martine Bellanger, Gary Belkin, & Peter Muennig, *The Cost-Effectiveness of PHQ Screening and Collaborative Care for Depression in New York City*, PLoS One 12(8):e0184210 (Aug. 31, 2017), <https://pubmed.ncbi.nlm.nih.gov/28859154/>.

found early intervention to be cost effective.²⁸⁵

The Departments do not anticipate the benefits to be exclusive to prevented suicides. The final rules are also expected to increase access to and utilization of behavioral health services and substance use disorder services.²⁸⁶ The 2022 NSDUH from SAMHSA indicates that 1.4 percent of adults with private health insurance reported having an OUD in the past year, while only 29 percent of those individuals indicated receiving treatment for OUD in the same year.²⁸⁷ A 2017 study utilizing claims and eligibility data from nearly 6 million enrollees found that parity resulted in a 17 percent increase in use of OUD treatment services, which illustrates a strong, positive relationship between parity and the utilization of behavioral health services.²⁸⁸ As discussed in section IV.6.1.3, there have been findings of positive or no impact of MHPAEA on the utilization of mental health and substance use disorder services. For illustrative purposes, the Departments assume that these final rules would have roughly 40 percent of the impact of the 2017 study, or an approximately 7 percent increase in OUD treatment service utilization.²⁸⁹ This would result in approximately 43,000 additional individuals receiving OUD treatment each year.²⁹⁰ Considerable research has demonstrated the efficacy of treatment for

²⁸⁵ Saadia Sediqzadah, Allison Portnoy, Jane J. Kim, Matcheri Keshavan, & Ankur Pandya, *Cost-Effectiveness of Early Intervention in Psychosis: A Modeling Study*, 73(9) *Psychiatric Services* pp. 961-1080 (2022).

²⁸⁶ Constance M. Horgan, Dominic Hodgkin, Maureen T. Stewart, Amity Quinn, Elizabeth L. Merrick, Sharon Reif, Deborah W. Garnick, & Timothy B. Creedon, *Health Plans Early Response to Federal Parity Legislation for Mental Health and Addiction Services*, 62(2) *Psychiatric Services* pp. 162-168 (2016).

²⁸⁷ SAMHSA, Center for Behavioral Health Statistics and Quality, *National Survey on Drug Use and Health, 2021 and 2022*, <https://www.samhsa.gov/data/data-we-collect/nsduh-national-survey-drug-use-and-health>.

²⁸⁸ Sarah Friedman, Haiyong Xu, Jessica M. Harwood, Francisca Azocar, Brian Hurley, & Susan L. Ettner, *The Mental Health Parity and Addiction Equity Act Evaluation Study: Impact on Specialty Behavioral Healthcare Utilization and Spending Among Enrollees with Substance Use Disorders*, 80 *Journal of Substance Abuse Treatment* pp. 67-78 (2017).

²⁸⁹ This estimate of a 7 percent reduction is based on the estimate of 17 percent previously cited, revised downward by 60 percent to account for the indirect impact of expanded parity associated with these final rules. See Sarah Friedman, Haiyong Xu, Jessica M. Harwood, Francisca Azocar, Brian Hurley, & Susan L. Ettner, *The Mental Health Parity and Addiction Equity Act Evaluation Study: Impact on Specialty Behavioral Healthcare Utilization and Spending Among Enrollees with Substance Use Disorders*, 80 *Journal of Substance Abuse Treatment* pp. 67-78 (2017).

²⁹⁰ This estimate is calculated as follows: 157,443,601 adult participants with private health insurance × 1.4 percent indicate OUD in past year = 2,125,489 adults with private health insurance and OUD. Then, 2,125,489 × 29 percent receiving treatment = 616,817 adults with OUD and private health insurance receiving treatment annually. Lastly, 616,817 × 6.98 percent increase in adults with private health insurance receiving treatment = 43,054 additional adults receiving treatment for OUD annually.

OD, ^{291,292,293,294,295,296,297} including several recent studies that have observed the reduction of both fatal and non-fatal overdoses for people diagnosed with OD after receiving treatment. For example, an 18-month observational study of multiple cohorts of people receiving OD treatments across the United States between 2017 and 2021 found that following outpatient treatment for OD, the number of patient overdoses, arrests, and drug-related hospitalizations were all reduced by over 50 percent.²⁹⁸ Similarly, a 2024 retrospective study of opioid overdose fatalities found that individuals who recently received treatment for OD experienced approximately 34 percent to 38 percent fewer overdose deaths compared to those who did not receive treatment.²⁹⁹ A 2021 study funded by the National Institute on Drug Abuse (NIDA) found that, across a nationally representative cohort of individuals with OD, common treatments for OD were associated with a reduction in the number of overdoses by 11 to 21

²⁹¹ SAMHSA, *Medications for Opioid Use Disorder: For Healthcare and Addiction Professionals, Policymakers, Patients, and Families* (2021), <https://store.samhsa.gov/sites/default/files/pep21-02-01-002.pdf>.

²⁹² National Academies of Sciences, Engineering, and Medicine, *Medications for Opioid Use Disorder Save Lives* (2019), Washington, DC: The National Academies Press.

²⁹³ Nisha Nataraj, S. Michaela Rikard, Kun Zhang, Xinyi Jiang, Gery P. Guy Jr, Ketra Rice, Christine L. Mattson, R. Matthew Gladden, Desiree M. Mustaquim, Zachary N. Illg, Puja Seth, Rita K. Noonan, & Jan L. Losby, *Public Health Interventions and Overdose-Related Outcomes Among Persons with Opioid Use Disorder*, 7(4) JAMA Network Open (2024).

²⁹⁴ Nora D. Volkow, Thomas R. Frieden, Pamela S. Hyde, & Stephen S. Cha, *Medication-Assisted Therapies — Tackling the Opioid Overdose Epidemic*, 370(22) New England Journal of Medicine (2014), <https://www.nejm.org/doi/full/10.1056/NEJMp1402780>.

²⁹⁵ Robert P. Schwartz, Jan Gryczynski, Kevin E. O’Grady, Joshua M. Sharfstein, Gregory Warren, Yngvild Olsen, Shannon G. Mitchell, & Jerome H. Jaffe, *Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995-2009*, 103(5) American Journal of Public Health pp. 917-922 (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3670653>.

²⁹⁶ SAMHSA, *TIPS 63: Medications for Opioid Use Disorder* (2021), <https://store.samhsa.gov/sites/default/files/pep21-02-01-002.pdf>.

²⁹⁷ National Academies of Sciences, Engineering, and Medicine, *Medications for Opioid Use Disorder Save Lives*, Washington, DC: The National Academies Press (2019), <https://doi.org/10.17226/25310>.

²⁹⁸ Jill A. Dever, Marci F. Hertz, Laura J. Dunlap, John S. Richardson, Sara Beth Wolicki, Bradley B. Biggers, Mark J. Edlund, Michele K. Bohm, Didier Turcios, Xinyi Jiang, Hong Zhou, Mary E. Evans, Gery P. Guy, Jr., *The Medications for Opioid Use Disorder Study: Methods and Initial Outcomes from an 18-Month Study of Patients in Treatment for Opioid Use Disorder*, Public Health Reports pp. 1-10 (2024), <https://pubmed.ncbi.nlm.nih.gov/38268479/>.

²⁹⁹ Robert Heimer, Anne C. Black, Hsiuju Lin, Laretta E. Grau, David A. Fiellin, Benjamin A. Howell, Kathryn Hawk, Gail D’Onofrio, & William C. Becker, *Receipt of Opioid Use Disorder Treatment Prior to Fatal Overdoses and Comparison to No Treatment in Connecticut, 2016-2017*, Drug and Alcohol Dependence (2024), <https://pubmed.ncbi.nlm.nih.gov/38043226/>.

percent, with an average reduction of 16 percent across all treatment types.³⁰⁰ This study assessed the effects of all three FDA-approved medications for OUD in various combinations with and without the most common treatments (psychotherapy, contingency management, and overdose education and naloxone distribution).³⁰¹ Utilizing life tables, clinical data, and relevant literature on treatment outcomes, the study produced a dynamic compartmental model to analyze the effects of medications and treatments on overdoses and mortality. While it is limited by the scope and availability of relevant secondary data, the model employs parameters, robustness checks, and sensitivity analysis that sufficiently validate the empirical model.

To illustrate the potential impact of these final rules, the Departments employ this lower estimate of a 16 percent reduction in overdoses following treatment, and estimate that increased treatment for expanded OUD access and utilization could result in the prevention of approximately 730 non-fatal overdoses each year.^{302,303} Utilizing data from the CDC estimating

³⁰⁰ The Departments averaged the reduction in overdoses arising from four treatment outcomes against the baseline of no treatment: Medicated-Assisted Treatment (MAT) only, MAT in addition to Contingency Management (CM), MAT in addition to Psychotherapy (PT), as well as MAT in addition to both CM and PT. (See Michael Fairley, Keith Humphreys, Vilija R. Joyce, Mark Bounthavong, Jodie Trafton, Ann Combs, Elizabeth M. Oliva, Jeremy D. Goldhaber-Fiebert, Steven M. Asch, Margaret L. Brandeau, & Douglas K. Owens, *Cost-Effectiveness of Treatments for Opioid Use Disorder*, 78(7) JAMA Psychiatry pp. 767-777 (2021), <https://pubmed.ncbi.nlm.nih.gov/33787832/>.)

³⁰¹ Outcomes related to overdose education and naloxone distribution were not used in estimating the impacts of OUD treatment in the final rule, as naloxone is a common over-the-counter product not intended to treat OUD, but rather reverse an opioid overdose. While it may help to reduce overdoses and OUD-related fatalities, it is not a “treatment” per se and as such, is not considered when estimating the benefits of treatment.

³⁰² This estimate is calculated as follows: 43,054 additional adults receiving treatment for OUD × (10,860 per 100,000 non-fatal overdose rate for those with OUD) = 4,676 non-fatal overdoses. 4,676 non-fatal overdoses × 15.6 percent reduction = 730 non-fatal overdoses prevented.

³⁰³ The Departments utilized the nonfatal overdose rate calculated for 2023 to produce these estimates. Specifically, this calculation was derived from the data supplement, eTable 9, as $(1,927,706 \text{ non-fatal overdoses in 2023} \div (16,072,360 \text{ individuals with OUD in 2023} + 1,677,988 \text{ individuals receiving medication for OUD})) \times 100,000 = 10,860$ per 100,000 non-fatal overdose rate for those with OUD. (See Nisha S. Nataraj, Michaela Rikard, Kun Zhang, Xinyi Jiang, Gery P. Guy, Ketra Rice, Christine L. Mattson, Matthew Gladden, Desiree M. Mustaquim, Zachary N. Illg, Puja Seth, Rita K. Noonan, & Jan L. Losby, *Public Health Interventions and Overdose-Related Outcomes Among Persons with Opioid Use Disorder*, Supplement 1, eTable 9, 7(4) Substance Use and Addiction (2024).)

the average medical and non-medical cost of non-fatal overdoses,³⁰⁴ the Departments estimate the benefits of these reduced non-fatal overdoses at \$16.4 million annually.^{305,306,307}

The benefits of individuals diagnosed with an OUD receiving treatment may go beyond the benefit of reduced harms from overdoses. Mortality data of individuals diagnosed with an OUD indicate overdoses comprise approximately half of fatalities for such individuals, who are increasingly at risk of death from infectious disease, common co-morbid conditions such as liver or heart disease, accidental deaths, suicide, and other physical traumas.³⁰⁸ Research indicates that individuals with an OUD that are receiving treatment, while still at increased risk from all-cause mortality compared to the general population, may experience a reduced risk of mortality after receiving treatment for their OUD condition.^{309,310} One study found that mortality rates were 35 percent lower for individuals that received treatment for OUD than for those who did not receive

³⁰⁴ Non-medical costs of non-fatal overdoses are derived from work loss costs and monetized quality-adjusted life loss per injury. Medical costs of non-fatal overdoses are derived from healthcare provider payments that include inpatient, outpatient, and outpatient drug costs.

³⁰⁵ Cora Peterson, Ketra L. Rice, Dionne D. Williams, & Robert Thomas, *WISQARS Cost of Injury for Public Health Research and Practice*, 29(2) Injury Prevention (Nov. 2022).

³⁰⁶ The average cost of non-fatal overdose requiring hospitalization = \$19,256 average associated QALY non-medical cost per hospitalization + \$33,026 average associated medical cost per hospitalization = \$52,282 per non-fatal overdose hospitalization. The average cost of non-fatal overdose requiring only treatment and release = \$3,254 average associated QALY non-medical cost per treatment and release + \$9,614 associated medical cost per treatment and release = \$12,868 per non-fatal overdose requiring only treatment and release. (See Cora Peterson, Ketra L. Rice, Dionne D. Williams, & Robert Thomas, *WISQARS Cost of Injury for Public Health Research and Practice*, 29(2) Injury Prevention (Nov. 2022).

³⁰⁷ The estimate is calculated as follows: 730 non-fatal overdoses prevented × 24.36 percent overdose hospitalization rate = 178 non-fatal overdose hospitalizations prevented. \$52,282 per non-fatal overdose hospitalization × 178 non-fatal overdose hospitalizations prevented = \$9,304,598. Additionally, 730 non-fatal overdoses × 75.64 percent overdose treatment and release rate = 552 non-fatal overdose treatment and releases prevented. \$12,868 per non-fatal overdose requiring treatment and release × 552 non-fatal overdoses requiring treatment and release = \$7,109,073. As such, the total benefit estimate related to non-fatal overdoses is calculated as: \$9,304,598 + \$7,109,073 = \$16,413,761.

³⁰⁸ Elizabeth Evans, Libo Li, Jeong Min, David Huang, Darren Urada, Lei Liu, Yih-Ing Hser, & Bohdan Nosyk, *Mortality Among Individuals Accessing Pharmacological Treatment for Opioid Dependence in California, 2006 – 2010*, *Addiction* 110(6): 996-1005 (June 2015).

³⁰⁹ Marc Larochelle, Dana Bernson, Thomas Land, Thomas Stopka, Na Wang, Ziming Xuan, Sarah Bagley, Jane Liebschutz, Alexander Walley, *Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association with Mortality: A Cohort Study*, *Ann Intern Med* 169(3): 137-145 (2018), <https://pubmed.ncbi.nlm.nih.gov/29913516/>.

³¹⁰ Yih-Ing Hser, Larissa J. Mooney, Andrew J. Saxon, Karen Miotto, Douglas S. Bell, Yuhui Zhu, Di Liang, and David Huang, *High Mortality among Patients with Opioid Use Disorder in a Large Healthcare System*, *J Addict Med* 11(4): 315-319 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5930020/>.

treatment.^{311,312} This retrospective cohort study used expansive, linked public health, medical, and vital statistics data from a single State to establish a robust population cohort of individuals with OUD for which mortality was the observed outcome over approximately 45,000 person-years following an initial detox episode. While a potential limitation of observational studies is the presence of confounding variables distorting measured outcomes, the breadth of the data being utilized, which included data from insurance claims and extensive medical histories, limit this concern. The findings of the study, indicating a high all-cause and overdose-related mortality rate for individuals with OUD and resultant decline following treatment, are consistent with other research findings and, as an observational cohort study, represent a high level of evidence.^{313,314}

Employing this estimate of an approximately 35 percent reduction in fatalities following treatment to illustrate the potential impact of these final rules, the Departments estimate that increased treatment for expanded OUD access and utilization could result in the prevention of approximately 702 fatalities from all causes in persons receiving treatment for OUD each year.³¹⁵ The Departments have utilized the VSL, as with their estimate of the value of prevented suicides, to estimate the benefits of reduced mortality arising from increased OUD treatment utilization at

³¹¹ The reduction in all-cause mortality was calculated as the change in the crude mortality rate per 100 person-years from 1.94 (for those not receiving any treatment) to 1.27 (for those receiving either MOUD treatment, inpatient treatment, or both). Thus, the percentage change in the rates from 1.94 per 100 person-years to 1.27 per 100 person-years is approximately 35 percent.

³¹² Alexander Walley, Sara Lodi, Yijing Li, Dana Bernson, Hermik Babakhanlou-Chase, Thomas Land, & Marc R. Larochele, *Association Between Mortality Rates and Medication and Residential Treatment After Inpatient Medically Managed Opioid Withdrawal: A Cohort Analysis*, 115(8) *Addiction* pp. 1496-1508 (Aug. 2020).

³¹³ Marc Larochele, Dana Bernson, Thomas Land, Thomas Stopka, Na Wang, Ziming Xuan, Sarah Bagley, Jane Liebschutz, Alexander Walley, *Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association with Mortality: A Cohort Study*, *Ann Intern Med* 169(3): 137-145 (2018), <https://pubmed.ncbi.nlm.nih.gov/29913516/>.

³¹⁴ Yih-Ing Hser, Larissa J. Mooney, Andrew J. Saxon, Karen Miotto, Douglas S. Bell, Yuhui Zhu, Di Liang, and David Huang, *High Mortality among Patients with Opioid Use Disorder in a Large Healthcare System*, *J Addict Med* 11(4): 315-319 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5930020/>.

³¹⁵ This estimate is calculated as: 43,054 additional beneficiaries receiving treatment for OUD × 4.70 crude mortality rate per 100 person-years for OUD = 2,024 expected fatalities in the absence of treatment. Adjusting the crude mortality rate downward 34.7 percent to 3.07 following treatment for this group, the expected fatalities would be estimated as 43,054 additional beneficiaries receiving treatment for OUD × 3.07 crude mortality rate per 100 person-years for OUD = 1,322 expected fatalities following treatment. As such, the Departments estimate the prevented fatalities from all causes arising from OUD treatment to be: 2,024 – 1,322 = 702 prevented fatalities.

\$9.3 billion annually.³¹⁶ As discussed earlier in this section, the Departments recognize some uncertainty in the production of VSL benefit estimates.³¹⁷ To account for potential sensitivity arising from such uncertainty, the Departments have conducted a sensitivity analysis of these benefits and, following guidance on VSL sensitivity analysis,³¹⁸ produced a lower and upper estimate of the VSL of approximately \$5.3 million and \$18.5 million, respectively.³¹⁹ Utilizing this range of estimates, the Departments accordingly estimate the value of the benefits of reduced mortality arising from increased OUD treatment utilization at between \$3.7 billion and \$13.0 billion annually.³²⁰

Mental health and substance use disorders do not always occur in isolation, but are commonly co-occurring conditions, as individuals with substance use disorders are more likely to experience a mental health condition than the general population and nearly half of adults with serious mental illness also have a substance use disorder.³²¹ Such co-occurring conditions can significantly exacerbate the severity of symptoms as well as negative health outcomes related to these conditions.³²² Additionally, individuals with mental health conditions and substance use disorders are known to commonly experience physical co-morbidities that can significantly impact overall health and quality of life. A 2011 study indicated that over 68 percent of adults

³¹⁶ This estimate is calculated as: the value of a statistical life of \$13,200,000 × 702 prevented fatalities = \$9,269,545,489.

³¹⁷ Individuals express a different willingness to pay to reduce the fatality risk of some deaths (those with a perceived associated morbidity, such as cancer) more than others (such as car accidents), though the risks may be equivalent. DOT guidance on the VSL suggests utilizing a single, nationwide value that does not adjust the VSL based on the nature of the risk or the underlying characteristics of the affected population but encourages a sensitivity analysis to reflect such uncertainty.

³¹⁸ For more information on the VSL guidance utilized, see The DOT's *Revised Departmental Guidance on Valuation of a Statistical Life in Economic Analysis*, <https://www.transportation.gov/office-policy/transportation-policy/revised-departmental-guidance-on-valuation-of-a-statistical-life-in-economic-analysis>.

³¹⁹ The lower and upper bounds are estimated as 40 percent below and above the central estimate of \$13,200,000, per DOT guidance on conducting a sensitivity analysis for a VSL estimate.

³²⁰ These estimates are calculated as: The lower VSL estimate of \$5,280,000 × 702 fatalities prevented = \$3,707,818,196. The lower VSL estimate of \$18,480,000 × 702 fatalities prevented = \$12,977,363,685.

³²¹ SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2022 National Survey on Drug Use and Health* (Nov. 2023), <https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf>.

³²² Beth Han, Wilson Compton, Carlos Blanco, & Lisa Colpe, *Prevalence, Treatment, and Unmet Treatment Needs of US Adults with Mental Health and Substance Use Disorders*, 36(10) *Health Affairs* pp. 1739-1747 (2017), <https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2017.0584>.

with a mental health disorder reported a comorbid medical disorder while 29 percent indicated they had another comorbid mental health condition.³²³ Human immunodeficiency virus (HIV), hepatitis, and diabetes are all more prevalent among those with substance use disorders or mental health conditions than the general population, while such physical or other mental comorbid conditions are more likely to be adversely impacted by poor disease management and treatment adherence when co-occurring with a mental health condition or substance use disorder.^{324,325,326,327,328,329} A 2022 study observing the presence of comorbid conditions for inpatient hospitalizations found that 81 percent of hospitalizations for a mental health condition or substance use disorder had a co-morbid condition.³³⁰ The study also found that co-morbid conditions were associated with a longer hospitalization period, a higher cost per hospitalization, as well as increased mortality during hospitalization.³³¹

As mental health conditions and substance use disorders can make preventing, managing, and treating physical comorbidities difficult, improvements in mental health and substance use disorder outcomes may also improve overall physical health outcomes and lower healthcare costs

³²³ Benjamin Druss & Elizabeth Walker, *Mental Disorders and Medical Comorbidity*, Research Synthesis Report No. 21, Robert Wood Johnson Foundation (Feb. 2011), <https://up2riverside.org/wp-content/uploads/2024/04/medicalcomorbidity.pdf>.

³²⁴ Elizabeth C. Verna, Aaron Schluger, & Robert S. Brown Jr., *Opioid Epidemic and Liver Disease*, 1(3) JHEP Report pp. 240-255 (Sept. 2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7001546/pdf/main.pdf>.

³²⁵ T. Jake Liang & John W. Ward, *Hepatitis C in Injection-Drug Users – A Hidden Danger of the Opioid Epidemic*, 378(13) *New England Journal of Medicine* pp. 1169-1171 (Mar. 2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5993680/pdf/nihms972424.pdf>.

³²⁶ Alain K. Koyama, A. Hora, Kai McKeever Bullard, Stephen R. Benoit, Shichao Tang, & Pyone Cho, *State-Specific Prevalence of Depression Among Adults With and Without Diabetes – United States, 2011–2019*, 20(70) *Preventing Chronic Disease* (Aug. 2023), https://www.cdc.gov/pcd/issues/2023/pdf/22_0407.pdf.

³²⁷ United Nations Office on Drugs and Crime, *Comorbidities in Drug Use Disorders* (Mar. 2022), https://www.unodc.org/documents/drug-prevention-and-treatment/UNODC_Comorbidities_in_drug_use_disorders.pdf.

³²⁸ National Institute on Drug Abuse, *Common Comorbidities with Substance Use Disorders Research Report* (Apr. 2020), <https://www.ncbi.nlm.nih.gov/books/NBK571451/>.

³²⁹ Stephen Magura, Andrew Rosenblum, & Chunki Fong, *Factors Associated with medication Adherence among Psychiatric Outpatients at Substance Abuse Risk*, *Open Addict J.* (4), 58-64 (Nov. 2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3526017/>.

³³⁰ Pamela Owens, Lan Liang, Marguerite Barrett, and Kathryn Fingar, *Comorbidities Associated with Adult Inpatient Stays, 2019*. Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project, Statistical Brief #303 (Dec. 2022).

³³¹ Pamela Owens, Lan Liang, Marguerite Barrett, and Kathryn Fingar, *Comorbidities Associated with Adult Inpatient Stays, 2019*. Agency for Healthcare Research and Quality, Healthcare Cost and Utilization Project, Statistical Brief #303 (Dec. 2022).

for participants.^{332,333} Data from Evernorth Health Services, a subsidiary of Cigna, indicates that accessing mental health and substance use disorder services can result in considerable cost savings for patients diagnosed with a mental health condition and substance use disorder concern, producing a reported cost savings of between \$1,134 to \$3,321 per person over the first 27 months following diagnosis.³³⁴ Similarly, a 2012 study of patients with a mental health condition and comorbid physical health condition found that treating the underlying mental health condition yielded significant improvements in the comorbid physical conditions, resulting in increased positive health outcomes and lower long-term healthcare costs.³³⁵ The Departments, in evaluating the impacts of these final rules, anticipate that, by prohibiting inequitable barriers to coverage, the estimated improvements in mental health conditions and substance use disorders will help reduce the severity of comorbid conditions, improve related health outcomes for participants, beneficiaries, and enrollees, and as such, represent a substantial, but potentially unquantified, benefit.

7.4 Reduced Adverse Impacts on the Families, Friends, Caregivers, and Coworkers of People Who Suffer from Untreated or Poorly Managed Mental Health Conditions and Substance Use Disorders

These final rules will help employees, caregivers and their families meet their mental health and substance use disorder care needs, and thus, may improve the productivity and resulting earnings of workers dealing with mental health conditions and substance use disorder.

³³² United Nations Office on Drugs and Crime, *Comorbidities in Drug Use Disorders* (Mar. 2022), https://www.unodc.org/documents/drug-prevention-and-treatment/UNODC_Comorbidities_in_drug_use_disorders.pdf.

³³³ Wayne Katon, Joan Russo, Elizabeth H. B. Lin, Julie Schmittdiel, Paul Ciechanowski, Evette Ludman, Do Peterson, Bessie Young, & Michael Von Korff, *Cost-Effectiveness of a Multi-Condition Collaborative Care Intervention: A Randomized Controlled Trial*, 69(5) *Archives of General Psychiatry* (May 2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3840955/pdf/nihms521136.pdf>.

³³⁴ Evernorth Health Services, *Behavioral Health Care Significantly Lowers Medical Care Costs* (Jan. 2023), <https://www.evernorth.com/behavioral-health-study>.

³³⁵ Wayne Katon, Joan Russo, Elizabeth H. B. Lin, Julie Schmittdiel, Paul Ciechanowski, Evette Ludman, Do Peterson, Bessie Young, & Michael Von Korff, *Cost-Effectiveness of a Multi-Condition Collaborative Care Intervention: A Randomized Controlled Trial*, 69(5) *Archives of General Psychiatry* (May 2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3840955/pdf/nihms521136.pdf>.

Among adults with any mental health condition in 2022, only 50.6 percent received treatment.³³⁶ Moreover, while 19.4 percent of NSDUH respondents 12 and older were classified as needing substance use disorder treatment in 2022, only 4.6 percent of respondents 12 and older indicated that they received treatment that year.³³⁷ One survey found that more than 85 percent of individuals that did not receive their needed mental health or substance use care reported negative impacts, including personal relationship issues, job issues and performing poorly or dropping out of school.³³⁸

The economic impact of untreated mental health conditions and substance use disorders can be significant. A 2021 study of claims data for large, self-funded health plans looked at the economic burden attributable to major depressive disorder, including the direct costs associated with treatment, suicide-related costs, and workplace costs, between 2010 and 2018. During that period, overall economic burden of adults with a major depressive disorder increased 37.9 percent (from \$236.6 billion to \$326.2 billion). While part of the cost increase can be attributed to a 12.9 percent increase in the number of adults with major depressive disorders, direct costs became a smaller share of the total costs, with workplaces costs, defined as missed work (due to injury/illness, discretionary time off and disability) and lower productivity while at work, constituting 61 percent of the costs in 2018 and increasing from \$48.3 billion in 2010 to \$70.8 billion in 2018.³³⁹ A 2015 study examined the impact of State parity laws on individuals with moderate levels of mental distress and found that State parity laws were associated with an increase in overall employment, weekly wages, and the number of hours worked per week, and

³³⁶ SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2022 National Survey on Drug Use and Health*, Figure 62, p. 61 (Nov. 2023), <https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf>.

³³⁷ SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2022 National Survey on Drug Use and Health*, Figures 54 and 55, pp. 50-51 (Nov. 2023), <https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf>.

³³⁸ National Council for Mental Wellbeing, *2022 Access to Care Survey Results* (May 11, 2022), <https://www.thenationalcouncil.org/wp-content/uploads/2022/05/2022-Access-To-Care-Survey-Results.pdf>.

³³⁹ Paul E. Greenberg, Andree-Anne Fournier, Tammy Sisitsky, Mark Simes, Richard Berman, Sarah H. Koenigsberg, & Ronald C. Kessler, *The Economic Burden of Adults with Major Depressive Disorder in the United States (2010 and 2018)*, 39(6) *Pharmacoeconomics* pp. 653-665 (2021).

attributed these changes to the increased productivity of these workers.³⁴⁰ A 2023 study critically reviewed 38 studies on the relationship between mental health and lost productivity, and found that poor mental health was associated with increased presenteeism³⁴¹ and absenteeism.³⁴²

These final rules will also have significant indirect impacts on families, friends, caregivers, and coworkers with untreated or poorly managed mental health conditions and substance use disorders, as well as society at large. By prohibiting inequitable barriers to coverage and thereby increasing access to mental health and substance use disorder services, these final rules will lead to more people receiving treatment, reducing the burden on family members and other support systems. For example, this includes untreated maternal mental health conditions, which can lead to a reduced ability to work, increased risk of suicide, increased use of public services, and worse maternal and child health. A 2022 study of the cost of maternal mental health conditions to Texas women and their children projected costs for the 2019 birth cohort from the time of conception through 5 years postpartum to total \$2.2 billion.³⁴³ Untreated maternal mental health conditions include untreated perinatal mood and anxiety disorders, which have been found to account for approximately \$48 million in societal costs in Vermont for the average annual birth cohort from conception through 5 years postpartum, including \$12.5 million in productivity loss and \$9.4 million in non-obstetric health expenditures.³⁴⁴

The cost in missed productivity for workers with fair or poor mental health due to

³⁴⁰ Martin Andersen, *Heterogeneity and the Effect of Mental Health Parity Mandates on the Labor Market*, 43 *Journal of Health Economics* (2015).

³⁴¹ The study defined “presenteeism” as “decreased productivity at work.”

³⁴² Claire de Oliveira, Makeila Saka, Lauren Bone, & Rowena Jacobs, *The Role of Mental Health on Workplace Productivity: A Critical Review of the Literature*, 21(2) *Applied Health Economics and Health Policy* pp. 167-193 (2023).

³⁴³ Caroline Margiotta, Jessica Gao, So O’Neil, Divya Vohra, & Kara Zivin, *The Economic Impact of Untreated Maternal Mental Health Conditions in Texas*, 22(700) *BMC Pregnancy Childbirth* (2022).

³⁴⁴ Isabel Platt, Emma Pendl-Robinson, Eric Dehus, So O’Neil, Divya Vohra, Kara Zivin, Michael Kenny & Laura Pentenrieder, *Estimating the Costs of Untreated Perinatal Mood and Anxiety Disorders in Vermont*, *Mathematica* (May 2023), <https://www.mathematica.org/publications/societal-costs-of-perinatal-mood-and-anxiety-disorders-in-vermont>.

unplanned absences was estimated as \$47.6 billion annually in 2022.³⁴⁵ A 2022 study found that households with a family member diagnosed with a mental health disorder had lower health status scores compared to households without a mental illness diagnosis, suggesting evidence of family spillover effects on mental illness.³⁴⁶ Finally, a 2021 study estimated that the societal costs of untreated OUD was approximately \$1.02 trillion in 2017, which includes \$35 billion in health care costs and \$92 billion in lost productivity.³⁴⁷

These final rules are expected to improve access to and utilization of mental health and substance use disorder services by removing barriers to access to mental health and substance use disorder benefits caused by NQTLs. By enhancing treatment for these conditions and disorders, these final rules will likely result in reduced productivity loss or missed workdays for individuals suffering from mental health conditions or substance use disorders. Furthermore, the improved management and treatment of these conditions and disorders will potentially lead to reduced adverse impacts on the families, friends, and coworkers of those affected, as untreated or poorly managed mental health conditions and substance use disorders can have significant spillover effects on an individual's personal and professional lives.

8. Costs

These final rules aim to promote access to mental health and substance use disorder benefits by clarifying how plans and issuers must ensure that their plans and coverage are designed, as written and in operation, to comply with MHPAEA's parity requirements for mental health and substance use disorder benefits and medical/surgical benefits, and allowing them to more easily identify changes needed to bring their plans and coverage into compliance. The

³⁴⁵ Dan Witters & Sangeeta Agrawal, *The Economic Cost of Poor Employee Mental Health*, Gallup Workplace (Dec. 13, 2022), <https://www.gallup.com/workplace/404174/economic-cost-poor-employee-mental-health.aspx?version=print>.

³⁴⁶ Donghoon Lee, Yeonil Kim, & Beth Devine, *Spillover Effects of Mental Health Disorders on Family Members' Health-related Quality of Life: Evidence from a US Sample*, 42(1) *Medical Decision Making* pp. 80-93 (2022).

³⁴⁷ Curtis Florence, Feijun Luo, & Ketra Rice, *The Economic Burden of Opioid Use Disorder and Fatal Opioid Overdose in the United States, 2017*, 218 *Drug and Alcohol Dependence* (2021).

Departments acknowledge that plans and issuers, in revising their approach to performing and documenting their already required comparative analyses, will incur additional costs. Moreover, by removing some of the barriers to access to mental health and substance use disorder treatments caused by existing NQTLs, the Departments expect increased utilization of mental health and substance use disorder services, which will also increase costs. This collection of costs would appropriately be included in any comparison with the benefits described, and in some cases illustratively quantified, elsewhere in this regulatory impact analysis.

It is notable that the Departments are clarifying existing requirements, and only the cost burden limited to those additional content elements outlined in these final rules is a key topic discussed in the following sections.

8.1 Comment Summary

In response to the proposal, many commenters expressed concern that the Departments underestimated the burden of collecting the required data, the burden required in conducting the proposed mathematical substantially all and predominant tests, the number of NQTLs that would need to be analyzed for each plan and issuer, and the amount of time that it would take to conduct those analyses. Commenters stated that in order to comply with the proposed rules, plans and issuers would need to purchase new data systems and hire additional staff or contractors. One commenter further stated that existing systems to provide mental health and substance use disorder benefits, such as carve out plans, would be eliminated under the proposed rule, as vendors would not be able to build networks of mental health and substance use disorder providers in alignment with networks of medical/surgical providers, as required under the proposed special rule for network composition.

Several commenters questioned the Departments' assumptions related to the number of NQTLs for which plans and issuers would need to produce comparative analyses. While the Departments assumed that issuers would impose twice as many NQTLs as plans, several

commenters did not think the number of NQTLs would vary between plans and issuers.

Commenters also argued that the number of NQTLs that plans and issuers would need to analyze would be roughly twice the Departments' proposed assumption for issuers, 16 NQTLs rather than 8, based on the Departments' descriptions of types of NQTLs listed in the proposed rule. Consistent with the explanation earlier in this preamble, the Departments note that they do not intend to provide an exhaustive list of NQTLs. Plans and issuers may be analyzing a fewer or greater number of NQTLs than the number of NQTLs listed in the illustrative, non-exhaustive list in these final rules.

Commenters also questioned the amount of time that it would take to conduct the NQTL comparative analyses under the proposal. While the Departments assumed that the plans and issuers preparing their own comparative analyses would incur an incremental burden of 10 hours per NQTL in the first year and 4 hours per NQTL in subsequent years, several commenters thought this was an underestimate. For instance, one commenter stated that it currently takes a team of subject matter experts, compliance officials, a project manager, and attorneys or consultants 60 hours in the first year and 12 hours in subsequent years to produce NQTL comparative analyses as required under the CAA, 2021 and current guidance. The commenter suggested that the added requirements for the comparative analysis under these final rules could require at least an additional 60 hours per NQTL.

Another commenter estimated that the cost to issuers of fully insured plans to conduct the comparative analyses for all NQTLs is approximately between \$200,000 and \$300,000 (200 to 300 external attorney or consultant hours in addition to several hundred in-house staff hours). The commenter also reported that for large, self-funded plans, while issuers and TPAs prepare and distribute baseline comparative analysis, plans would still need to customize the comparative analysis. The commenter estimated that the cost for large self-funded plans to customize the comparative analysis and request additional information and data for all NQTLs is approximately

between \$50,000 and \$150,000 (100 to 200 external attorney or consultant hours in addition to in-house staff work). The Departments are not clear whether these suggested costs represent current expenditures or projections of the added requirements for the comparative analyses. The commenter further stated that time and cost estimates for plans with behavioral carve-out vendors should be higher.

In preparing these final rules, the Departments have considered these comments and have clarified the requirements and reevaluated their estimates as appropriate. The specific adjustments to the estimates are discussed in section IV.8.4 of this regulatory impact analysis.

8.2 Commenters' Cost Estimates

As discussed earlier in this regulatory impact analysis, commenters questioned the Departments' assumptions related to the number of NQTLs imposed by plans and issuers on mental health and substance use disorder benefits and medical/surgical benefits, and the amount of time that it would take to conduct the additional requirements for producing comparative analyses and analyzing data, beyond what was required in CAA, 2021. The Departments have reviewed these comments, which include estimates made by those commenters, on the expected additional costs to prepare NQTL comparative analyses under the proposed rules. While these comments are helpful to understand the cost implications of the final rules and how they differ from the proposal, the Departments disagree with some of the inputs and underlying assumptions of these cost estimates and use different assumptions in section IV.8.4 of this regulatory impact analysis. The commenters' cost estimates do, however, demonstrate a possible upper bound on the costs associated with these final rules.

8.2.1 Association for Behavioral Health and Wellness

The Departments considered estimates and assumptions regarding the costs to prepare the NQTL comparative analyses under the proposed rules made by the Association for Behavioral Health and Wellness (ABHW). ABHW reports that the amendments would require plans and

issuers to analyze 15 NQTLs on average. They also reported that it currently takes a team of subject matter experts, compliance officials, a project manager, and attorneys or consultants 60 hours to prepare each comparative analysis for a typical NQTL as required under the CAA, 2021 and current guidance. Thus, ABHW estimates that a comparable burden (60 hours per NQTL) is needed to review and revise the analyses under the updated requirements in the first year. In addition, they also estimate it would require 12 hours in each subsequent year to produce the comparative analyses. For the purpose of this calculation, the Departments have estimated a composite wage rate of \$167.48, which consist of attorneys, actuaries, and data analysts.³⁴⁸ Based on these assumptions, and the Departments’ estimates of affected entities, this would result in a cost burden of \$984.8 million in the first year and \$197 million in subsequent years, resulting in a 3-year average cost burden of \$459.6 million. See Table 3 for more details.

ABHW also suggested that issuers and plans would need to hire at least three full-time equivalent new staff members to help with the proposed relevant data evaluation requirements. This additional cost was not included in their cost estimates.

Table 3. Incremental Cost to Prepare the Comparative Analyses based on the Association for Behavioral Health and Wellness’s Assumptions

| | Number of Entities | Number of NQTLs per Entity | Number of Hours per NQTL | Total Hour Burden | Hourly Wage | Cost |
|---|--------------------|----------------------------|--------------------------|-------------------|-------------|-----------------|
| | (A) | (B) | (C) | (A × B × C) | (D) | (A × B × C × D) |
| <i>First Year</i> | | | | | | |
| Issuers (health insurance company/State combinations) | 1,467 | 15 | 60 | 1,320,300 | \$167.48 | \$221,123,844 |
| TPAs | 205 | 15 | 60 | 184,500 | \$167.48 | \$30,900,060 |

³⁴⁸ The wage rate of an attorney, actuary, and data analyst is, respectively, \$165.71, \$177.11, and \$159.61. (Internal DOL calculation based on 2024 labor cost data. For a description of DOL’s methodology for calculating wage rates, see EBSA, *Labor Cost Inputs Used in the Employee Benefits Security Administration, Office of Policy and Research’s Regulatory Impact Analyses and Paperwork Reduction Act Burden Calculations* (June 2019), <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf>.) The composite wage rate is estimated in the following manner: [$\$165.71 \times (1 \div 3) + \$159.61 \times (1 \div 3) + \$177.61 \times (1 \div 3) = \167.48].

| | | | | | | |
|--|---------------|-----------|----------|------------------|----------|----------------------|
| Self-funded plans with more than 500 participants that will conduct a comparative analysis themselves | 709 | 15 | 60 | 638,100 | \$167.48 | \$106,868,988 |
| Self-funded plans with more than 500 participants that will receive a generic comparative analysis from TPA or service providers, and will then customize it | 4,076 | 15 | 30 | 1,834,200 | \$167.48 | \$307,191,816 |
| Self-funded non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves | 505 | 15 | 60 | 454,500 | \$167.48 | \$76,119,660 |
| Self-funded non-Federal governmental plans with more than 500 participants that will initially receive generic comparative analyses from TPAs or service providers, and will then customize it | 2,906 | 15 | 30 | 1,307,700 | \$167.48 | \$219,013,596 |
| Plan MEWAs that are not fully insured | 132 | 15 | 60 | 118,800 | \$167.48 | \$19,896,624 |
| Non-plan MEWAs that are not fully insured | 21 | 15 | 60 | 18,900 | \$167.48 | \$3,165,372 |
| <i>First-year Total</i> | 10,021 | 15 | - | 5,877,000 | - | \$984,279,960 |
| <i>Subsequent Years</i> | | | | | | |
| Issuers (health insurance company/State combinations) | 1,467 | 15 | 12 | 264,060 | \$167.48 | \$44,224,769 |
| TPAs | 205 | 15 | 12 | 36,900 | \$167.48 | \$6,180,012 |
| Self-funded plans with more than 500 participants that will conduct the comparative analysis themselves | 709 | 15 | 12 | 127,620 | \$167.48 | \$21,373,798 |
| Self-funded plans with more than 500 participants that will receive a generic comparative analysis from TPAs or service providers, and will then customize it | 4,076 | 15 | 6 | 366,840 | \$167.48 | \$61,438,363 |
| Self-funded non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves | 505 | 15 | 12 | 90,900 | \$167.48 | \$15,223,932 |
| Self-funded non-Federal governmental plans with more than 500 participants that will initially receive generic comparative analyses from TPAs or service providers, and will then customize it | 2,906 | 15 | 6 | 261,540 | \$167.48 | \$43,802,719 |
| Plan MEWAs that are not fully insured | 132 | 15 | 12 | 23,760 | \$167.48 | \$3,979,325 |
| Non-plan MEWAs that are not fully insured | 21 | 15 | 12 | 3,780 | \$167.48 | \$633,074 |
| <i>Subsequent Years Total</i> | 10,021 | 15 | - | 1,175,400 | - | \$196,855,992 |
| Total (3-year average) | 10,021 | 15 | - | 2,742,600 | - | \$459,330,648 |

The Departments conducted a sensitivity analysis of the assumption that 50 percent of self-funded plans and another 50 percent of self-funded non-Federal governmental plans with more than 500 participants will receive a generic comparative analysis from TPAs or service providers, which they will then need to customize. For every 10-percentage-point increase or decrease in the number of self-funded plans and self-funded non-Federal governmental plans with more than 500 participants that need to customize documentation received from TPAs or service providers, the cost would increase or decrease by \$24.6 million.³⁴⁹

8.2.2 Blue Cross Blue Shield Association

The Blue Cross Blue Shield Association (BCBSA) asked the Departments to specifically quantify the costs of preparing additional comparative analysis beyond the four priority NQTLs outlined in FAQs Part 45. BCBSA stated that based on the number of NQTLs identified in the regulation, and the additional NQTLs identified in the preamble, the proposed rules would require plans and issuers to prepare comparative analyses for at least 17 NQTLs (7 from the preamble, and 10 from the regulation, counting those related to network composition as 3 separate NQTLs), all with the associated documentation and outcomes data.

BCBSA estimated that the cost of issuers of fully insured plans to conduct the comparative analyses for all NQTLs would range between \$200,000 and \$300,000. BCBSA also estimated the cost for large self-funded plans that receive a generic comparative analysis from the issuer, which they then need to customize and request additional information and data for all NQTLs referenced in the proposal, is between \$50,000 and \$150,000. BCBSA did not explain if these cost estimates were for all years or were applicable to just the first year. Based on BCBSA's assumptions, and the Departments' estimates of affected entities, this will result in a

³⁴⁹ The Departments estimate the 10-percentage-point incremental cost by adding the total cost of self-funded plans and self-funded non-Federal governmental plans that will receive a generic comparative analysis from issuers, TPAs, or service providers and will then customize it (found in Table 3) in the first year and subsequent years, creating a 3-year average cost, and then multiplying the 3-year average cost by 10 percent.

lower bound cost of \$957.4 million and an upper bound cost of \$2 billion. See Table 4 for more details.

Table 4. Annual Costs to Conduct the Comparative Analyses for all NQTLs based on Blue Cross Blue Shield Association’s Assumptions

| | Number of Entities | Lower Bound Cost per Entity | Total Lower Bound Cost | Upper Bound Cost per Entity | Total Upper Bound Cost |
|--|---------------------------|------------------------------------|-------------------------------|------------------------------------|-------------------------------|
| | (A) | (B) | (A × B) | (C) | (A × C) |
| Issuers (health insurance company/State combinations) | 1,467 | \$200,000 | \$293,400,000 | \$300,000 | \$440,100,000 |
| TPAs | 205 | \$200,000 | \$41,000,000 | \$300,000 | \$61,500,000 |
| Self-funded plans with more than 500 participants that will conduct the comparative analysis themselves | 709 | \$200,000 | \$141,800,000 | \$300,000 | \$212,700,000 |
| Self-funded plans with more than 500 participants that will receive a generic comparative analysis from TPAs or service providers, and will then customize it | 4,076 | \$50,000 | \$203,800,000 | \$150,000 | \$611,400,000 |
| Self-funded non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves | 505 | \$200,000 | \$101,000,000 | \$300,000 | \$151,500,000 |
| Self-funded non-Federal governmental plans with more than 500 participants that will initially receive generic comparative analyses from TPAs or service providers, and will then customize it | 2,906 | \$50,000 | \$145,300,000 | \$150,000 | \$435,900,000 |
| Plan MEWAs that are not fully insured | 132 | \$200,000 | \$26,400,000 | \$300,000 | \$39,600,000 |
| Non-plan MEWAs that are not fully insured | 21 | \$200,000 | \$4,200,000 | \$300,000 | \$6,300,000 |
| Total | 10,021 | - | \$956,900,000 | - | \$1,959,000,000 |

The Departments conducted a sensitivity analysis of the assumption that 50 percent of self-funded plans and another 50 percent of self-funded non-Federal governmental plans with more than 500 participants will receive a generic comparative analysis from the issuer, and will

then customize it. For every 10-percentage-point increase or decrease in the number of self-funded plans and self-funded non-Federal governmental plans with more than 500 participants that need to customize documentation received from TPAs or service providers, the cost would increase or decrease by \$34.9 million in the total lower bound cost³⁵⁰ and \$104.7 million in the total upper bound cost.³⁵¹

8.3 Final Amendments to the Existing MHPAEA Regulations (26 CFR 54.9812-1, 29 CFR 2590.712, and 45 CFR 146.136)

As part of these final rules, the Departments have added new definitions, amended existing definitions, and clarified and added new requirements for NQTLs imposed with respect to mental health or substance use disorder benefits. For example, as discussed earlier in this preamble, the final rules clarify that any condition or disorder defined by the plan or coverage as being or as not being a mental health condition or a substance use disorder must be defined consistent with generally recognized independent standards of current medical practice. To be consistent with those generally recognized independent standards of current medical practice, these final rules state that the plan's or coverage's definition of "mental health benefits" must include all conditions covered under the plan or coverage, except for substance use disorders, that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed in the most current version of the DSM. Similarly, the definition of "substance use disorder benefits" must include all disorders covered under the plan or coverage that fall under any of the diagnostic categories listed as a mental or behavioral disorder due to

³⁵⁰ The Departments estimate the 10-percentage-point incremental cost in the lower bound by adding the total lower bound cost of self-funded plans and self-funded non-Federal governmental plans that will initially receive a generic comparative analysis from issuers, TPAs, or service providers and will then customize it (found in Table 4) and then multiplying the sum by 10 percent.

³⁵¹ The Departments estimate the 10-percentage-point incremental cost in the upper bound adding the total upper bound cost of self-funded plans and self-funded non-Federal governmental plans that will initially receive a generic comparative analysis from issuers, TPAs, or service providers and will then customize it (found in Table 4) and then multiplying the sum by 10 percent.

psychoactive substance use (or equivalent category) in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed as a Substance-Related and Addictive Disorder (or equivalent category) in the most current version of the DSM.

Under these final rules, plans and issuers are required to collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits. In addition, these final rules require plans and issuers to determine whether the relevant data reflect material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits and take reasonable action, as necessary to address such differences to ensure compliance, in operation, with 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4). Relevant data for all NQTLs could include, as appropriate, but are not limited to, the number and percentage of claims denials and any other data relevant to the NQTL required by State law or private accreditation standards. Additionally, for NQTLs related to network composition, relevant data could include, as appropriate, but are not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (for comparable services and as benchmarked to a reference standard).

The proposed rules would have required plans and issuers to apply the proposed mathematical substantially all and predominant tests to each NQTL applicable to mental health or substance use disorder benefits and medical/surgical benefits. As discussed earlier in this preamble, the Departments decline to finalize the proposed mathematical tests for applying the substantially all and predominant tests in these final rules. However, plans and issuers are required to collect and evaluate relevant data for NQTLs applicable to mental health and

substance use disorder benefits and medical/surgical benefits under these final rules. For NQTLs related to network composition, plans and issuers must collect and evaluate relevant data in a manner reasonably designed to assess the aggregate impact of all such NQTLs on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits. Under these final rules, the Departments may specify the type, form, and manner for the relevant data evaluation requirement in future guidance, but for some plans and issuers already subject to existing data requirements under MHPAEA, Federal transparency rules,³⁵² and State law and private accreditation standards, some of the additional data burden associated with this rulemaking will be mitigated.

These final rules could cause plans and issuers to revise their policies and procedures to remove or modify NQTLs in response to the Departments' clarifications and examples. Requirements such as covering meaningful benefits for mental health conditions and substance use disorders (determined in comparison to the benefits provided for medical conditions and surgical procedures); assessing whether the relevant data evaluated suggest that the NQTL contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits; and not using or taking the steps necessary to correct, cure, or supplement the information, evidence, sources, or standards used to inform a factor or evidentiary standard that would have been biased or not objective in the absence of such steps could also cause plans and issuers to revise their policies and procedures.

For example, a 2016 study examined how private health plans responded to the 2010 interim final rules implementing MHPAEA and found that the majority of plans had eliminated quantitative treatment limitations referred to as "special annual limits" related to behavioral health treatments. The percentage of health insurance products with such limits on mental health treatments decreased from 28 percent in 2009 to 4 percent in 2010, and a similar decrease was

³⁵² 85 FR 72158 (Nov. 12, 2020).

observed for health insurance products with such limits on substance use disorder treatments (from 26 percent in 2009 to 3 percent in 2010).³⁵³ A 2019 study of claims data from both a pre-parity (January 2005 through December 2010) and post-parity period (January 2011 through September 2015), found that while MHPAEA did not appreciably increase the share of participants utilizing any outpatient mental health services, it did increase the frequency of use and total utilization of outpatient mental health and substance use disorder services of participants already receiving these services.³⁵⁴

Plans and issuers could incur costs to implement changes associated with revising coverage and plan provisions to ensure that they comply with the requirements of these final rules or ceasing the imposition of an NQTL as directed by the Departments or an applicable State authority after a final determination of noncompliance under Code section 9812(a)(8), ERISA section 712(a)(8), or PHS Act section 2726(a)(8), or 26 CFR 54.9812-2, 29 CFR 2590.712-1, or 45 CFR 146.137, which might result in increased costs from expanded utilization of mental health and substance use disorder services. Recent data suggests that mental health and substance use disorder services account for a small portion of total health care expenditures, representing just 8.4 percent of all expenses in 2021 for individuals with private insurance.³⁵⁵ The Departments face uncertainty in quantifying these costs and did not receive public comments containing data or information to inform these estimates. As such, the Departments cannot estimate the potential increase in utilization and which services might see the largest increase in utilization.

³⁵³ Constance M. Horgan, Dominic Hodgkin, Maureen T. Stewart, Amity Quinn, Elizabeth L. Merrick, Sharon Reif, Deborah W. Garnick, & Timothy B. Creedon, *Health Plans' Early Response to Federal Parity Legislation for Mental Health and Addiction Services*, 67(2) *Psychiatric Services* pp. 162-168 (2016).

³⁵⁴ Norah Mulvaney-Day, Brent J. Gibbons, Shums Alikhan, & Mustafa Karakus, *Mental Health Parity and Addiction Equity Act and the Use of Outpatient Behavioral Health Services in the United States, 2005-2016*, 109(S3) *Am J Public Health* pp. S190-S196 (2019).

³⁵⁵ Agency for Healthcare Research and Quality, *Medical Expenditure Panel Survey, Total Expenditures (\$) in Millions by Condition, United States, 2016 to 2021*, <https://datatools.ahrq.gov/meps-hc?tab=medical-conditions&dash=17>.

8.3.1 Mitigation in Utilization Costs from Telehealth Expansion

As discussed in section 2 of this regulatory impact analysis, individuals seeking mental health or substance use disorder treatment often face barriers preventing them from accessing care, such as inadequate networks. Telehealth is one method of care that has the potential to improve access to treatment for mental health conditions or substance use disorders, particularly as research has documented that it can be as effective as in-person treatment,³⁵⁶ particularly when the treatment is provided through video instead of audio-only.³⁵⁷ These final rules require plans and issuers to collect and evaluate relevant data and, where the relevant data suggest that the NQTL contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, to take reasonable action, as necessary, to address the material differences to ensure compliance, in operation, with 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4). One potential reasonable action a plan or issuer could take to address material differences in access with respect to relevant data for NQTLs related to network composition may include expanding the availability of telehealth arrangements to mitigate any overall mental health and substance use

³⁵⁶ For example, the following studies found that telehealth treatment was as effective as in-person treatment: David Turgoose, Rachel Ashwick, & Dominic Murphy, *Systematic Review of Lessons Learned from Delivering Tele-therapy to Veterans with Post-traumatic Stress Disorder*, 24(9) *Journal of Telemedicine and Telecare* pp. 575-585 (2018); Nyssa Z. Bulkes, Kaley Davis, Brian Kay, & Bradley C. Riemann, *Comparing Efficacy of Telehealth to In-Person Mental Health Care in Intensive-Treatment-Seeking Adults*, 145 *Journal of Psychiatric Research* pp. 347-352 (2022); Jaime Moreno-Chaparro, Eliana I. Parra Esquivel, Angy Lucia Santos Quintero, Laura Paez, Sandra Martinez Quinto, Bayron Esteven Rojas Barrios, Juan Felipe Samudio, & Karol Madeline Romero Villareal, *Telehealth Interventions Aimed at Parents and Caregivers of Children Living in Rural Settings: A Systematic Review*, *Child Care in Practice* pp. 1-24 (2022); Lori Uscher-Pines, Lauren E. Riedel, Ateev Mehrotra, Sherri Rose, Alisa B. Busch, & Haiden A. Huskamp, *Many Clinicians Implement Digital Equity Strategies to Treat Opioid Use Disorder: Study Examines Clinicians' Use of Telehealth and Digital Equity Strategies to Treat Opioid Use Disorder*, 42(2) *Health Affairs* pp. 182-186 (2023).

³⁵⁷ Some studies have found that a majority of clinicians and patients do not prefer audio-only telehealth to in-person care, implying that many of the benefits tied to telehealth are specifically for telehealth with video. For example: Lori Uscher-Pines, Lauren E. Riedel, Ateev Mehrotra, Sherri Rose, Alisa B. Busch, & Haiden A. Huskamp, *Many Clinicians Implement Digital Equity Strategies to Treat Opioid Use Disorder: Study Examines Clinicians' Use of Telehealth and Digital Equity Strategies to Treat Opioid Use Disorder*, 42(2) *Health Affairs* pp. 182-186 (2023); Gillian K. SteelFisher, Caitlin L. McMurtry, Hannah Caporello, Keri M. Lubell, Lisa M. Koonin, Antonio J. Neri, Eran N. Ben-Porath, Ateev Mehrotra, Ericka McGowan, Laura C. Espino, & Michael L. Barnett, *Video Telemedicine Experiences in COVID-19 Were Positive, but Physicians and Patients Prefer In-Person Care for The Future: Study Examines Patient and Physician Opinion of Telemedicine Experiences During COVID-19*, 42(4) *Health Affairs* pp. 575-584 (2023).

disorder provider shortages in a geographic area.

The COVID-19 pandemic sparked increased demand for health care services, including behavioral health services delivered remotely. While in February 2020 telehealth claims accounted for only around 1 percent of claims pertaining to mental health or substance use disorder benefits, by April 2020 they accounted for over 50 percent of the claims and still accounted for approximately 40 percent of claims at the end of 2021.³⁵⁸ The expansion was significantly aided by the Departments issuing guidance providing time-limited Federal flexibilities for private health plans to expand access to telehealth, which specifically included coverage of treatment for mental health conditions and substance use disorders. These Federal flexibilities included “allowing midyear plan design changes to increase telehealth coverage,” “allowing certain employers to offer coverage only for services provided via telehealth and other remote care services,” and “allowing telehealth coverage pre-deductible” for catastrophic plans and for health savings account-qualified high deductible health plans.³⁵⁹

While the COVID-19 PHE ended on May 11, 2023,³⁶⁰ many of the telehealth flexibilities it allowed were extended under the CAA, 2023 through December 31, 2024.³⁶¹ Additionally, Medicare has permanently adopted policies allowing patients to receive behavioral and mental care through telehealth within their homes,³⁶² and a survey of States indicated that, for Medicaid, “all or most expansions of behavior health providers and/or services allowed for telehealth would

³⁵⁸ Norah Mulvaney-Day, David Dean, Jr., Kay Miller, & Jessica Camacho-Cook, *Trends in Use of Telehealth for Behavioral Health Care During the COVID-19 Pandemic: Considerations for Payers and Employers*, 36(7) *American Journal of Health Promotion* pp. 1237-1241 (2022).

³⁵⁹ Congressional Research Service, *Federal Telehealth Flexibilities in Private Health Insurance During the COVID-19 Public Health Emergency: In Brief* (2023), <https://crsreports.congress.gov/product/pdf/R/R47424>.

³⁶⁰ Executive Office of the President, *Statement of Administration Policy* (Jan. 30, 2023), <https://www.whitehouse.gov/wp-content/uploads/2023/01/SAP-H.R.-382-H.J.-Res.-7.pdf>.

³⁶¹ Pub. L. 117–328 (Dec. 29, 2022).

³⁶² HHS, *Telehealth Policy Changes After the COVID-19 Public Health Emergency* (Dec. 19, 2023), <https://telehealth.hhs.gov/providers/telehealth-policy/policy-changes-after-the-covid-19-public-health-emergency#temporary-medicare-changes-through-december-31,-2024>.

be maintained after the public emergency.”³⁶³ For private plans, access to telehealth for mental health and substance use disorder care will depend on plan design.

By nature, telehealth makes accessing treatment for mental health conditions and substance use disorders more convenient for many patients, particularly for those who do not have the ability, time, or means to travel to an appointment or who need care from a provider that specializes in a particular treatment that is not available in their geographic area. Despite observing similar levels of mental illness and psychiatric disorders in urban residents, one research paper remarked that rural residents face “challenges accessing care systems due to geographic isolation, reduced access to and engagement with appropriate providers, lower socioeconomic status, generally lower levels of educational attainment, as well as reluctance to seek help due to discrimination and stigma.”³⁶⁴ An analysis of 2021 outpatient visits reported that 55 percent of patients in rural areas relied on telehealth for outpatient mental health and substance use services compared to 35 percent in urban areas.³⁶⁵ Given that 73.3 million people in the United States live in a geographic area designated as a mental health professional shortage area, of which 24.4 million resided in a rural area, telehealth is likely to continue to be a necessary means to offset provider network limitations in these areas.³⁶⁶

As with rural populations, many underserved racial, ethnic, cultural minorities, and individuals with disabilities face barriers to receiving treatment for mental health conditions and substance use disorders. These barriers may include language, stigma, or finding a therapist that

³⁶³ Madeline Guth, *Telehealth Delivery of Behavioral Health Care in Medicaid: Findings from a Survey of State Medicaid Programs*, KFF (Jan. 2023), <https://www.kff.org/mental-health/issue-brief/telehealth-delivery-of-behavioral-health-care-in-medicare-findings-from-a-survey-of-state-medicare-programs/>.

³⁶⁴ Dawn A. Morales, Crystal L. Barksdale, & Andrea C. Beckel-Mitchener, *A Call to Action to Address Rural Mental Health Disparities*, 4 *Journal of Clinical and Translational Science* pp. 463-467 (2020).

³⁶⁵ Justin Lo, Matthew Rae, Krutika Amin, Cynthia Cox, Nirmita Panchal, & Benjamin F. Miller, *Telehealth Has Played an Outsized Role Meeting Mental Health Needs During the COVID-19 Pandemic*, KFF Issue Brief (Mar. 15, 2022), <https://www.kff.org/mental-health/issue-brief/telehealth-has-played-an-outsized-role-meeting-mental-health-needs-during-the-covid-19-pandemic/>.

³⁶⁶ HHS, Health Resources and Services Administration, Bureau of Health Workforce, *Designated Health Professional Shortage Areas: Second Quarter of Fiscal year 2024 Designated HPSA Quarterly Summary* (Mar. 2024), <https://data.hrsa.gov/Default/GenerateHPSAQuarterlyReport>.

understands their situation. While important in many areas of health care, many underserved populations prefer to receive treatment for mental health conditions and substance use disorders specifically from a provider with an understanding of their cultural background. A 2022 study found that there was an overall increase in the use and willingness to use video telehealth during the pandemic, with the highest levels of increase being seen among Black adults and adults with lower educational attainment. Certain communities became more willing to use telehealth, since many patients had their first telehealth experience with their trusted health care provider during the pandemic and their positive experiences eliminated their concerns with telehealth, such as concerns related to privacy or to the level of engagement of a provider through telehealth.³⁶⁷

In addition to expanding access, telehealth has also been found to improve the retention of patients receiving mental health and substance use disorder care. A 2023 retrospective cohort study of treatment-seeking patients enrolled in a substance use disorder treatment program in Ohio found that “[p]atients who received services through telehealth with video in the initial 14 days of diagnosis had a lower hazard of dropout, compared to patients receiving solely in-person services.” Moreover, when compared to in-person care, patients receiving services through either video or telephone were more likely to have higher treatment engagement, which was defined as “initiating treatment and completing at least two treatment visits within 34 days of the initiation visit.”³⁶⁸

Research has demonstrated that telehealth for medical appointments saves patients time and money.³⁶⁹ A 2021 study focused specifically on the travel cost savings associated with using

³⁶⁷ Shira H. Fischer, Zachary Predmore, Elizabeth Roth, Lori Uscher-Pines, Matthew Baird, & Joshua Breslau, *Use of and Willingness to Use Video Telehealth Through the COVID-19 Pandemic: Study Examines the Use of and the Willingness to Use Video Telehealth During the COVID-19 Pandemic*, 41(11) *Health Affairs* pp. 1645-1651 (2022).

³⁶⁸ Danielle M. Gainer, Celeste Wong, Jared A. Embree, Nina Sardesh, Amna Amin, & Natalie Lester, *Effects of Telehealth on Dropout and Retention in Care Among Treatment-Seeking Individuals with Substance Use Disorder: A Retrospective Cohort Study*, 58(4) *Substance Use & Misuse* pp. 481-490 (2023).

³⁶⁹ Studies finding that telehealth has decreased travel expenses include: Josephine C. Jacobs, Jiaqi Hu, Cindie Slightam, Amy Gregory, & Donna M. Zulman, *Virtual Savings: Patient-Reported Time and Money Savings from a VA National Telehealth Tablet Initiative*, 26(8) *Telemedicine and e-Health* 1178-1183 (2020); Navjit W. Dullet,

tele-mental health services in a pediatric outpatient psychology clinic. The study found that patients experienced a median of 132 miles saved by not travelling to an in-person session, which translated to a median 3.5 hours saved not travelling to an in-person session and a median cost savings of \$22 per session over the course of the telehealth treatment.³⁷⁰ The benefits of telehealth are particularly relevant for mental health and substance use disorder treatment because treatment often requires frequent sessions or appointments.

It is important to note that, while telehealth may improve access, it is not a perfect solution. For instance, it has limitations in certain segments of the population, such as individuals with limited English proficiency³⁷¹ or without access to computers or the internet.³⁷² Additionally, many individuals may prefer in-person care over telehealth. A survey published in 2023 showed that while patients have differing preferences for in-person care or telehealth, many are not able to find care that fits their preferences. Of the respondents receiving therapy, less than half were able to select whether they received in-person care or telehealth.³⁷³ Further, interviews conducted with respondents found that while many patients appreciate the convenience of telehealth, others expressed concern about the rapport between the patient and provider during telehealth. The authors cautioned that while telehealth is an attractive way to expand access to mental health care for much of the population, telehealth may not alone be sufficient for all

Estella M. Geraghty, Taylor Kaufman, Jamie L. Kisse, Jesse King, Madan Dharmar, Anthony C. Smith, & James P. Marci, *Impact of a University-Based Outpatient Telemedicine Program on Time Savings, Travel Costs, and Environmental Pollutants*, 20(4) *Value in Health* pp. 542-546 (2017).

³⁷⁰ William S. Frye, Lauren Gardner, & Jazmine S. Mateus, *Utilising Telemental Health in a Paediatric Outpatient Psychology Clinic: Therapeutic Alliance and Outcomes*, 22(2) *Counselling and Psychotherapy Research* pp. 322-330 (2022).

³⁷¹ Jorge A. Rodriguez, Altaf Saadi, Lee H. Schwamm, David W. Bates, & Lipika Sama, *Disparities in Telehealth Use Among California Patients with Limited English Proficiency*, 40(3) *Health Affairs* pp. 487-495 (2021).

³⁷² United States Census Bureau, *Computer and Internet Use in the United States: 2018* (2021), <https://www.census.gov/newsroom/press-releases/2021/computer-internet-use.html>.

³⁷³ The survey found that 30.6 percent of respondents were working with providers who only offered in-person care or telehealth, while 24.4 percent of respondents were working with providers who offered both modalities but chose for the patient.

individuals or conditions.³⁷⁴ Therefore, while telehealth may contribute significantly to the alleviation of mental health and substance use disorder provider shortages, it may not be a viable alternative for everyone.

8.4 New Regulations (26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137 and 146.180)

These final rules set forth content requirements for comparative analyses required by the CAA, 2021 and outline the timeframes and processes for plans and issuers to provide their comparative analyses to the Departments and applicable State authorities upon request. Under these final rules, the Departments outlined the elements that a comparative analysis must include for each NQTL (in addition to the requirements to include a written list of all NQTLs imposed under the plan or coverage). They include, as described in more detail earlier in this preamble:

- A description of the NQTL,
- Identification and definition of the factors used to design or apply the NQTL,
- A description of how factors are used in the design and application of the NQTL,
- A demonstration of comparability and stringency, as written,
- A demonstration of comparability and stringency, in operation, and
- Findings and conclusions.

However, because these elements are already required under the CAA, 2021, the cost of these final rules is more limited than the full cost of generating a comparative analysis. For instance, plans and issuers are already required under the CAA, 2021 to provide a description of the specific plan or coverage terms or other relevant terms regarding the NQTLs that applies to such plan or coverage, and a description of all the mental health and substance use disorder benefits and medical or surgical benefits to which each such term applies in each respective

³⁷⁴ Jessica Sousa, Andrew Smith, Jessica Richard, Maya Rabinowitz, Pushpa Raja, Ateev Mehrotra, Alisa B. Busch, Haiden A. Huskamp, & Lori Uscher-Pines, *Choosing or Losing in Behavioral Health: A Study of Patients' Experiences Selecting Telehealth Versus In-Person Care*, 42(9) Health Affairs pp 1275-1282 (2023).

benefit classification.³⁷⁵ Similarly, plans and issuers are already required to identify the factors used to determine that the NQTLs will apply to mental health or substance use disorder benefits and medical or surgical benefits,³⁷⁶ and the evidentiary standards used for the factors identified, when applicable, provided that every factor shall be defined, and any other source or evidence relied upon to design and apply the NQTLs to mental health or substance use disorder benefits and medical or surgical benefits.³⁷⁷ Moreover, the CAA, 2021 requires that the comparative analyses demonstrate that the processes, strategies, evidentiary standards, and other factors used to apply NQTLs to mental health and substance use disorder benefits, as written and in operation, are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used to apply the NQTLs to medical or surgical benefits in the benefits classification,³⁷⁸ as well as the specific findings and conclusions reached by the plan or issuer, including any results of the analyses that indicate that the plan or coverage is or is not in compliance with MHPAEA.³⁷⁹

In their comparative analyses, plans and issuers must describe each NQTL and identify and define all the factors and evidentiary standards used to design or apply the NQTL. The plan or issuer also must describe how the factors identified are used in the design and application of the NQTL, and evaluate whether any processes, strategies, evidentiary standards, or other factors used in designing and applying the NQTL to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, those with respect to medical/surgical benefits, both as written and in operation. The explanation of how the plan or issuer evaluates compliance, in operation, with MHPAEA must identify the relevant data collected and evaluated, and document the outcomes that resulted from the application of the NQTL to mental health or

³⁷⁵ Code section 9812(a)(8)(A)(i), ERISA section 712(a)(8)(A)(i), and PHS Act section 2726(a)(8)(A)(i).

³⁷⁶ Code section 9812(a)(8)(A)(ii), ERISA section 712(a)(8)(A)(ii), and PHS Act section 2726(a)(8)(A)(ii).

³⁷⁷ Code section 9812(a)(8)(A)(iii), ERISA section 712(a)(8)(A)(iii), and PHS Act section 2726(a)(8)(A)(iii).

³⁷⁸ Code section 9812(a)(8)(A)(iv), ERISA section 712(a)(8)(A)(iv), and PHS Act section 2726(a)(8)(A)(iv).

³⁷⁹ Code section 9812(a)(8)(A)(v), ERISA section 712(a)(8)(A)(v), and PHS Act section 2726(a)(8)(A)(v).

substance use disorder benefits and medical/surgical benefits. In limited circumstances where relevant data is temporarily unavailable for a newly imposed NQTL, the comparative analysis must include a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed. Additionally, in rare instances where no data exists that can reasonably assess any relevant impact of an NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, the plan or issuer must provide a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the NQTL's impact, an explanation of why the nature of the NQTL prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure that the NQTL complies with MHPAEA. In the instances where there is a temporary data lag for a newly imposed NQTL or no data exists that can reasonably assess any relevant impact of an NQTL, providing this justification for the temporary data lag is likely to be less expensive than the estimated burden for doing an analysis when there is data. However, as explained earlier in this preamble, the Departments are of the view that nearly all NQTLs will have some relevant data to collect and evaluate; therefore, the Departments estimate the burden as if every plan and issuer performs the data analysis.

These final rules require additional specificity with regard to the findings and conclusion of the comparative analysis. While these final rules provide specificity for how a plan or issuer must comply with the comparative analysis requirements, they are primarily providing additional clarification and requirements with respect to the statutory content elements of a comparative analysis outlined in the CAA, 2021, so that plans and issuers can perform and document sufficient comparative analyses.

Additionally, for ERISA plans, these final rules also require the comparative analysis to

include a certification by one or more named fiduciaries that they have engaged in a prudent process to select one or more qualified service providers to perform and document a comparative analysis in connection with the imposition of any NQTLs that apply to mental health and substance use disorder benefits under the plan in accordance with applicable law and regulations, and have satisfied their duty to monitor those service providers as required under part 4 of ERISA with respect to the performance and documentation of such comparative analysis. The cost to provide the certification is included in the cost estimates to prepare the comparative analysis.

In the proposed rules, the Departments estimated that, on average, plans would need to analyze four separate NQTLs and issuers would need to analyze eight NQTLs to satisfy the comparative analysis requirements.³⁸⁰ The Departments further estimated that plans and issuers preparing their own comparative analyses would incur an incremental burden of 10 hours per NQTL in the first year, with 2 hours for a general or operations manager to review the requirements and outline the changes needed for the comparative analyses and 8 hours for a business operations specialist to prepare the comparative analyses. Once the comparative analyses are performed and documented, the Departments noted that plans and issuers would need to update the analyses when making changes to the terms of the plan or coverage, including changes to the way NQTLs are applied to mental health and substance use disorder benefits, as well as medical/surgical benefits. In subsequent years, the Departments estimated that plans and issuers would incur an incremental burden of 4 hours annually per NQTL to update the analyses,

³⁸⁰ The Departments generally identify a unique NQTL based on whether a specific plan or issuer has defined the NQTL using different factors or evidentiary standards than other NQTLs. For example, if a plan applies an identical prior authorization requirement NQTL to four different benefit classifications, or to four different benefit package options in the same plan, the Departments would consider the NQTL as just one “unique” NQTL, even though it is technically four separate NQTLs. When a comparative analysis request is sent to an issuer with identical NQTLs that apply to many fully insured plans, the Departments similarly count the NQTL as one unique NQTL, even though there are technically many separate NQTLs for the different plans. The Departments acknowledge that if they instead counted each NQTL separately by benefit classification, plan, and product, irrespective of whether the NQTLs are administered in the same way in these different contexts, then the number of NQTLs would be substantially larger. This distinction may explain why the Departments’ estimate of NQTLs was lower than that of commenters.

with 1 hour for a general or operations manager and 3 hours for a business operations specialist.

In response to commenters' concerns that the Departments underestimated the number of NQTLs that each plan or issuer would need to provide comparative analyses for, and that plans and issuers would on average have the same number of NQTLs, the Department have revised their assumptions to 10 NQTLs for both plans and issuers. While one commenter suggested the average number of NQTLs should be more than 15 at a minimum, and another commenter noted that the proposal and guidance referenced at least 17 NQTLs, the Departments note that the number of NQTLs vary by issuer and plans and that most will not incorporate every NQTL listed in the proposal and the guidance (while some plans and issuers might incorporate others not listed). Taking into account the Departments' experience and comments received, the Departments assume 10 NQTLs but present a sensitivity analysis using 15 NQTLs.

The Departments assume that the incremental costs to collect the data and review and revise the comparative analyses will require 60 hours per NQTL in the first year and 12 hours per NQTL in subsequent years. For plan sponsors that receive a generic comparative analysis from a TPA that will require customizing to suit the plan's specific needs, the Departments assume that it will take 30 hours per NQTL in the first year and 6 hours per NQTL in subsequent years. While plans and issuers can use other professionals to fulfill their requirements, for purposes of developing the wage estimate, the Departments assume that it will take a team of data analysts, actuaries, and attorneys to collect the data and prepare the comparative analyses, and have estimated a composite wage rate of \$167.48.³⁸¹ See Table 5 for calculations and burden totals.

³⁸¹ The wage rate of an attorney, actuary, and data analyst is, respectively, \$165.71, \$177.11, and \$159.61. (Internal DOL calculation based on 2024 labor cost data. For a description of DOL's methodology for calculating wage rates, see EBSA, *Labor Cost Inputs Used in the Employee Benefits Security Administration, Office of Policy and Research's Regulatory Impact Analyses and Paperwork Reduction Act Burden Calculations* (June 2019), <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf>.) The composite wage rate is estimated in the following manner: $[\$165.71 \times (1 \div 3) + \$159.61 \times (1 \div 3) \times \$177.61 \times (1 \div 3) = \$167.48]$.

The Departments conducted a sensitivity analysis of the assumption that plans and issuers would each analyze 10 NQTLs. If the Departments assume that plans and issuers analyze 15 NQTLs, the cost burden would increase by \$328.1 million in the first year and \$65.6 million in the subsequent years, resulting in a 3-year average cost increase of \$153.1 million.

Table 5. Incremental Cost to Fulfill the Data Requirements and Prepare the Comparative Analyses

| | Number of Entities | Number of NQTLs per Entity | Number of Hours per NQTL for Data and Comparative Analysis | Total Hour Burden | Hourly Wage | Cost |
|--|--------------------|----------------------------|--|-------------------|-------------|-----------------|
| | (A) | (B) | (C) | (A × B × C) | (D) | (A × B × C × D) |
| <i>First Year</i> | | | | | | |
| Issuers (health insurance company/State combinations) | 1,467 | 10 | 60 | 880,200 | \$167.48 | \$147,415,896 |
| TPAs | 205 | 10 | 60 | 123,000 | \$167.48 | \$20,600,040 |
| Self-funded plans with more than 500 participants that will conduct the comparative analysis themselves | 709 | 10 | 60 | 425,400 | \$167.48 | \$71,245,992 |
| Self-funded plans with more than 500 participants that will receive generic comparative analyses from TPAs or service providers, and will then customize it | 4,076 | 10 | 30 | 1,222,800 | \$167.48 | \$204,794,544 |
| Self-funded non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves | 505 | 10 | 60 | 303,000 | \$167.48 | \$50,746,440 |
| Self-funded non-Federal governmental plans with more than 500 participants that will initially receive generic comparative analyses from TPAs or service providers, and will then customize it | 2,906 | 10 | 30 | 871,800 | \$167.48 | \$146,009,064 |

| | Number of Entities | Number of NQTLs per Entity | Number of Hours per NQTL for Data and Comparative Analysis | Total Hour Burden | Hourly Wage | Cost |
|--|--------------------|----------------------------|--|-------------------|-------------|----------------------|
| | (A) | (B) | (C) | (A × B × C) | (D) | (A × B × C × D) |
| Plan MEWAs that are not fully insured | 132 | 10 | 60 | 79,200 | \$167.48 | \$13,264,416 |
| Non-plan MEWAs that are not fully insured | 21 | 10 | 60 | 12,600 | \$167.48 | \$2,110,248 |
| First-year Total | 10,021 | - | - | 3,918,000 | - | \$656,186,640 |
| <i>Subsequent Years</i> | | | | | | |
| Issuers (health insurance company/State combinations) | 1,467 | 10 | 12 | 176,040 | \$167.48 | \$29,483,179 |
| TPAs | 205 | 10 | 12 | 24,600 | \$167.48 | \$4,120,008 |
| Self-funded plans with more than 500 participants that will conduct the comparative analysis themselves | 709 | 10 | 12 | 85,080 | \$167.48 | \$14,249,198 |
| Self-funded plans with more than 500 participants that will receive generic comparative analyses from TPAs or service providers, and will then customize it | 4,076 | 10 | 6 | 244,560 | \$167.48 | \$40,958,909 |
| Self-funded non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves | 505 | 10 | 12 | 60,600 | \$167.48 | \$10,149,288 |
| Self-funded non-Federal governmental plans with more than 500 participants that will initially receive generic comparative analyses from TPAs or service providers, and will then customize it | 2,906 | 10 | 6 | 174,360 | \$167.48 | \$29,201,813 |
| Plan MEWAs that are not fully insured | 132 | 10 | 12 | 15,840 | \$167.48 | \$2,652,883 |
| Non-plan MEWAs that are not fully insured | 21 | 10 | 6 | 2,520 | \$167.48 | \$422,050 |

| | Number of Entities | Number of NQTLs per Entity | Number of Hours per NQTL for Data and Comparative Analysis | Total Hour Burden | Hourly Wage | Cost |
|-------------------------------|---------------------------|-----------------------------------|---|--------------------------|--------------------|------------------------|
| | (A) | (B) | (C) | (A × B × C) | (D) | (A × B × C × D) |
| Subsequent Years Total | 10,021 | - | - | 783,600 | - | \$131,237,328 |
| Total (3-year average) | 10,021 | - | - | 1,828,400 | | \$306,220,432 |

Additionally, plans and issuers must make the comparative analyses and other applicable information required by the CAA, 2021 available upon request to participants, beneficiaries, and enrollees in all non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage (including a provider or other person acting as a participant’s, beneficiary’s, or enrollee’s authorized representative) in connection with an adverse benefit determination, as well as to participants and beneficiaries in plans subject to ERISA. The Departments estimate that on average each plan or issuer will receive one request annually and that plans and issuers will annually incur a burden of 5 minutes for a clerical worker to prepare and send the comparative analyses to each requesting participant or beneficiary. The Departments received comments suggesting that this underestimated the demand for these analyses as well as the cost to produce them. However, after reviewing data on the number of appealed mental health or substance use disorder claims per year, which serves as a proxy for when participants or beneficiaries would request an analysis, the Departments are of the view that this estimate is appropriate. Moreover, because plans and issuers are already responsible for preparing these analyses, the only cost associated with providing them are the clerical ones outlined earlier in this preamble. See Table 6 for calculations and burdens totaling the cost to

prepare the analysis.³⁸²

Table 6. Costs to Prepare the Comparative Analysis Upon Participant Request

| | Number of Entities | Number of NQTLs per Entity | Number of Hours per NQTL | Total Hour Burden | Hourly Wage | Cost |
|---|--------------------|----------------------------|--------------------------|-------------------|-------------|---------------------|
| | (A) | (B) | (C) | (A × B × C) | (C) | (A × B × C × D) |
| Issuers (health insurance company/State combinations) | 1,467 | 1 | 0.0833 | 122 | \$65.99 | \$8,051 |
| ERISA-covered group health plans | 2,129,516 | 1 | 0.0833 | 177,460 | \$65.99 | \$11,710,585 |
| Non-Federal governmental plans | 90,887 | 1 | 0.0833 | 7,574 | \$65.99 | \$499,808 |
| Plan MEWAs that are not fully insured | 132 | 1 | 0.0833 | 11 | \$65.99 | \$726 |
| Non-plan MEWAs that are not fully insured | 21 | 1 | 0.0833 | 2 | \$65.99 | \$132 |
| Annual Total | 2,222,023 | - | - | 185,169 | - | \$12,219,302 |

The Departments further assume that 58.3 percent of requests will be delivered electronically, resulting in a de minimis cost.³⁸³ The remaining 41.7 percent of requests will be mailed, at a cost of \$2.79 each.³⁸⁴ See Table 7 for calculations and burden totaling the cost to distribute the analysis.

Table 7. Costs to Distribute the Comparative Analysis upon Participant or Beneficiary Request

³⁸² In Table 6, the number of ERISA-covered group health plans is calculated in the following manner: 410,581 ERISA-covered group health plans with 50 or more participants + 1,718,935 ERISA-covered fully insured, non-grandfathered plans with less than 50 participants = 2,129,516.

³⁸³ According to data from the National Telecommunications and Information Agency (NTIA), 37.4 percent of individuals age 25 and over have access to the internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out of electronic disclosure that are automatically enrolled (for a total of 31.4 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 44.1 percent of individuals age 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61.0 percent of internet users use online banking, which is used as the proxy for the number of internet users who will affirmatively consent to receiving electronic disclosures (for a total of 26.9 percent receiving electronic disclosure outside of work). Combining the 31.4 percent who will receive electronic disclosure at work with the 26.9 percent who will receive electronic disclosure outside of work produces a total of 58.3 percent who will receive electronic disclosure overall. See Quantria Strategies, *Improving Outcomes with Electronic Delivery of Retirement Plan Documents* (June 2015), https://www.sparkinstitute.org/content-files/improving_outcomes_with_electronic_delivery_of_retirement_plan_documents.pdf. See also Pew Research Center, *51% of U.S. Adults Bank Online* (Aug. 2013), https://www.pewresearch.org/internet/wp-content/uploads/sites/9/media/Files/Reports/2013/PIP_OnlineBanking.pdf. See also NTIA, *NTIA Data Explorer* (June 2024), <https://www.ntia.gov/data/explorer>.

³⁸⁴ The postage for a first-class mail large envelope is \$2.04 and the material cost is \$0.05 per page. Thus, \$2.04 + (\$0.05 × 15 pages) = \$2.79.

| | Number of Entities | Estimated Page Length | Paper and Printing Cost (per page) | Mailing Cost | Cost |
|---|--------------------|-----------------------|------------------------------------|--------------|--|
| | (A) | (B) | (C) | (D) | $[(A \times B \times C) + (A \times D)] \times 41.7 \text{ percent}$ |
| Issuers (health insurance company/State combinations) | 1,467 | 15 | \$0.05 | \$2.04 | \$1,603 |
| ERISA-covered Group Health Plans | 2,129,516 | 15 | \$0.05 | \$2.04 | \$2,326,581 |
| Non-Federal Governmental Plans | 90,887 | 15 | \$0.05 | \$2.04 | \$105,741 |
| Plan MEWAs that are not fully insured | 132 | 15 | \$0.05 | \$2.04 | \$144 |
| Non-plan MEWAs that are not fully insured | 21 | 15 | \$0.05 | \$2.04 | \$23 |
| Annual Total | 2,222,023 | - | - | - | \$2,585,169 |

Finally, these final rules require that group health plans and health insurance issuers offering group or individual health insurance coverage must make comparative analyses available upon request to the Departments or an applicable State authority. The CAA, 2021 requires the Departments to collect no fewer than 20 comparative analyses per year, but it also provides that the Departments shall request that a group health plan or issuer submit the comparative analyses for plans that involve potential MHPAEA violations or complaints regarding noncompliance with MHPAEA that concern NQTLs, and any other instances in which the Departments determine appropriate. Based on prior experience and current funding, DOL and HHS expect to each request 20 comparative analyses each year. To provide the Departments with their comparative analyses and associated documentation, the Departments estimate, based on internal discussion, that it will take a total of 5 hours for plans, with 1 hour for a general or operations manager and 4 hours for a business operations specialist. See Table 8 for calculations and burden totals.

Table 8. Costs of Providing Comparative Analyses for Audits

| | Number of Entities | Hour Burden per Entity | Total Hour Burden | Hourly Wage | Cost |
|---|--------------------|------------------------|-------------------|-------------|-----------------|
| | (A) | (B) | (A × B) | (C) | (A × B × C) |
| General Operations Manager (Requested by HHS) | 20 | 1 | 20 | \$137.67 | \$2,753 |
| Business Operations Specialist (Requested by HHS) | 20 | 4 | 80 | \$114.36 | \$9,149 |
| General Operations Manager (Requested by DOL) | 20 | 1 | 20 | \$137.67 | \$2,753 |
| Business Operations Specialist (Requested by DOL) | 20 | 4 | 80 | \$114.36 | \$9,149 |
| Total | 40 | - | 200 | - | \$23,804 |

In the first year, group health plans and issuers will need time to familiarize themselves with these final rules to ensure that their comparative analyses comply with all applicable requirements. The Departments assume that on average it will require 6.5 hours for an attorney to review these final rules.³⁸⁵ See Table 9 for calculations and burden totals.

Table 9. Costs for Rule Familiarization

| | Number of Entities | Number of NQTLs per Entity | Hour Burden per Entity | Total Hour Burden | Hourly Wage | Cost |
|---|--------------------|----------------------------|------------------------|-------------------|-------------|-----------------|
| | (A) | (B) | (C) | (A × B × C) | (D) | (A × B × C × D) |
| <i>First Year</i> | | | | | | |
| Issuers (health insurance company/State combinations) | 1,467 | 1 | 6.5 | 9,536 | \$165.71 | \$1,580,211 |
| TPAs | 205 | 1 | 6.5 | 1,333 | \$165.71 | \$220,891 |
| Self-funded plans with more than 500 participants that will conduct the comparative analysis themselves | 709 | 1 | 6.5 | 4,609 | \$165.71 | \$763,757 |
| Self-funded plans with more than 500 participants that will receive generic comparative analyses from TPAs or service providers, and will then customize it | 4,076 | 1 | 6.5 | 26,494 | \$165.71 | \$4,390,321 |

³⁸⁵ The reading time is calculated based on an average 250 words per minute reading rate.

| | Number of Entities | Number of NQTLs per Entity | Hour Burden per Entity | Total Hour Burden | Hourly Wage | Cost |
|--|--------------------|----------------------------|------------------------|-------------------|-------------|---------------------|
| | (A) | (B) | (C) | (A × B × C) | (D) | (A × B × C × D) |
| Self-funded non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves | 505 | 1 | 6.5 | 3,283 | \$165.71 | \$544,026 |
| Self-funded non-Federal governmental plans with more than 500 participants that will initially receive generic comparative analyses from TPAs or service providers, and will then customize it | 2,906 | 1 | 6.5 | 18,889 | \$165.71 | \$3,130,096 |
| Plan MEWAs that are not fully insured | 132 | 1 | 6.5 | 858 | \$165.71 | \$142,179 |
| Non-plan MEWAs that are not fully insured | 21 | 1 | 6.5 | 137 | \$165.71 | \$22,702 |
| First-year Total | 10,021 | - | - | 65,139 | - | \$10,794,184 |

According to the 2022 National Health Expenditure Data, the total contribution of private employers to health insurance premiums is \$592.2 billion. The total contribution of State and local employers to health insurance premiums is \$194.5 billion.³⁸⁶ The total health expenditure on the individual market is \$93.9 billion.³⁸⁷ In the first year, the cost to comply with these final rules is estimated to be approximately \$681.8 million,³⁸⁸ which represents 0.08 percent of total premiums in these markets. In subsequent years, the cost to comply with these final rules is estimated to be approximately \$146.1 million,³⁸⁹ which represents 0.02 percent of total

³⁸⁶ CMS, *National Health Expenditure Data*, NHE Tables - Table 24, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/nationalhealthaccountshistorical>.

³⁸⁷ CMS, *National Health Expenditure Data*, NHE Tables - Table 21, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/nationalhealthaccountshistorical>.

³⁸⁸ The cost is estimated as follows: \$656.2 million for collecting the data and preparing the comparative analyses + \$10.8 million for reviewing the final rules and amendments + \$12.2 million to prepare the comparative analyses upon request of participants and beneficiaries + \$2.6 million to distribute the comparative analyses to participants and beneficiaries + \$0.02 million for audit of comparative analyses = \$681.8 million.

³⁸⁹ The cost is estimated as follows: \$131.2 million for collecting the data and preparing the comparative analyses + \$12.2 million for preparing the comparative analyses upon request of participants and beneficiaries + \$2.6 million to

premiums in these markets.

In the proposed rules, HHS assumed that most of the self-funded non-Federal governmental plans that would be affected by the implementation of the CAA, 2023 provision that sunsets the MHPAEA opt-out election offered mental health and substance use disorder benefits, but that many of these plans might not be complying with MHPAEA. HHS assumed that plans would incur costs to come into compliance and noted that, in particular, some plans might remove limits on or offer more generous mental health and substance use disorder benefits, which would likely increase utilization of mental health and substance use disorder services, increasing the number of claims submitted, and the overall costs incurred by these plans. HHS also noted that plans that have opted out of requirements under MHPAEA would also need to conduct NQTL comparative analyses if they were not already doing so. HHS solicited comments on the potential costs to these plans to come into compliance with MHPAEA. Although the Departments received comments on the potential underestimation of costs related to NQTL comparative analysis requirements (refer to section IV.8.1 of this regulatory impact analysis for further discussion), HHS did not receive any comments specific to the costs associated with coming into compliance for self-funded non-Federal governmental plans. As such, HHS is unable to estimate the costs to these plans because the extent to which these plans are currently out of compliance is unknown, and costs associated with coming into compliance are expected to vary from plan to plan.

HHS estimates that the regulatory amendments to implement a provision of the CAA, 2023 that sunsets the election option for sponsors of self-funded non-Federal governmental plans to opt out of requirements under MHPAEA eliminates the need for sponsors to submit a notice to the Federal Government regarding their plan's opt-out election, as long as the sponsors do not

distribute the comparative analyses to participants and beneficiaries + \$0.02 million for audit of comparative analyses = \$146.1 million.

elect to permissibly opt out of other requirements. HHS estimates that sponsors of 185 plans will no longer submit a notice to the Federal Government regarding their plan's opt-out election. This is estimated to generate a total cost savings of approximately \$11,783 for plans (as discussed later in section V.2.5 of the PRA analysis for HHS), and cost savings of approximately \$5,200 for the Federal Government as HHS will no longer have to process the opt-out notices previously submitted by these plans.

8.5 Illustration of Cost Increases for Plans and Issuers

As discussed in the benefits section, the Departments estimate that the final rules will increase access and subsequently the utilization or frequency of use of behavioral health services. The Departments also recognize that increased service utilization will likely increase costs for plans. These costs will likely differ significantly by the type of condition and the type of treatment. The analysis that follows provides an illustration of potential increases in costs for plans associated with depression and substance use disorder treatments.

Increasing access to mental health services is estimated to result in a significant reduction in suicides, as enumerated in section IV.7.2. While many mental health conditions and substance use disorders may increase the risk of suicide, suicide itself is an outcome that may or may not be tied directly to mental health conditions or substance use disorders. As such, it is difficult to directly tie the decrease in suicides discussed in section IV.7.2 to increased costs.

However, the most common mental health condition among those who attempt suicide, as well as one of the most highly prevalent mental health conditions in the United States, is depressive disorder.^{390,391} Research indicates that individuals with major depressive disorder are at an elevated risk of suicide and that approximately two-thirds have contemplated suicide.³⁹²

³⁹⁰ Jan Fawcett, *The Neurological Basis of Suicide* (2012).

³⁹¹ Ronald C. Kessler, Patricia Berglund, Olga Demler, Robert Jin, Kathleen R. Merikangas, & Ellen E. Walters, *Lifetime Prevalence and Age-of-Onset Distributions of DSM-IV Disorders in the National Comorbidity Survey Replication*, 62(6) *Arch Gen Psychiatry* pp. 593–602 (2005).

³⁹² Navneet Bains & Sara Abdijadid, *Major Depressive Disorder* (2023).

Furthermore, major depressive disorder was the most common comorbid condition in a study of U.S. suicides, followed by substance use disorder.³⁹³ Individuals with major depressive disorder and another comorbid condition (such as a substance use disorder or anxiety disorder) are at even greater risk of suicide.³⁹⁴ Data from the 2022 NSDUH indicates that approximately 8 percent of individuals who have private health insurance experienced a major depressive episode in the past year, of whom 64 percent received treatment for depression.³⁹⁵

Table 10. Number of People Diagnosed with a Major Depressive Episode in the Past Year

| | 2021 | 2022 |
|---|------------|------------|
| Total | | |
| All Ages | 21,553,000 | 22,475,000 |
| With Private Health Insurance | 11,750,000 | 12,551,000 |
| Receiving Treatment for Depression | | |
| All Ages | 12,932,000 | 14,088,000 |
| With Private Health Insurance | 7,540,000 | 8,240,000 |
| Not Receiving Treatment for Depression | | |
| All Ages | 8,621,000 | 8,387,000 |
| With Private Health Insurance | 4,210,000 | 4,311,000 |
| SAMHSA, <i>2022 National Survey on Drug Use and Health</i> (Nov. 2023), https://www.samhsa.gov/data/report/2022-nsduh-detailed-tables . | | |

As discussed in Section 6.1.3, MHPAEA has been found to have mixed effects on the utilization of mental health services. A 2019 study found that, outside of substance use disorder, MHPAEA was not associated with an increase in new utilization of behavioral healthcare. However, the authors did find an increase in the average frequency of monthly outpatient services per user.³⁹⁶ Critically, increased frequency of mental health and OUD treatment

³⁹³ Ian Rockett, Rockett, Ian RH, Shuhui Wang, Yinjuan Lian, & Steven Stack, *Suicide-Associated Comorbidity Among US Males and Females: A Multiple Cause-of-Death Analysis*, 13(5) *Injury Prevention* pp. 311-315 (2007).

³⁹⁴ Navneet Bains & Sara Abdijadid, *Major Depressive Disorder* (2023).

³⁹⁵ SAMHSA, *2022 National Survey on Drug Use and Health* (Nov. 2023), <https://www.samhsa.gov/data/report/2022-nsduh-detailed-tables>.

³⁹⁶ Noah Mulvaney-Day, Brent Gibbons, Shums Alikhan, & Mustafa Karakus, *Mental Health Parity and Addiction Equity Act and the Use of Outpatient Behavioral Health Services in the United States, 2005-2016*, 109(3) *American Journal of Public Health* pp. 190-196 (2019).

utilization have both been associated with decreasing risks of mortality from suicide and OUD.^{397,398}

The 2019 study also found that the average insurer cost for members receiving treatment increased following the passage of MHPAEA. According to the study, in September 2015, the last month of data considered, MHPAEA was associated with an average insurer cost increase of \$16.17 for each member receiving treatment for mental health per month.³⁹⁹

For the purposes of this analysis, it is helpful to consider this measurement in terms of the increased cost per member with depression, regardless of treatment status. To estimate a per-member cost, regardless of treatment status, the Departments scaled the estimate by the proportion of individuals who had a major depressive episode in 2015, with private insurance, and who received treatment for depression. Applying these assumptions, the Departments estimate that in 2015, MHPAEA was associated with a \$11.15 increase in average monthly insurer spending per member with depression.⁴⁰⁰

The Departments do not have data on per-member per-month costs associated with a major depressive illness alone. Based on a 2018 Milliman report, the Departments estimate that

³⁹⁷ Brian K. Ahmedani, Joslyn Westphal, Kirsti Autio, Farah Elsis, Edward L. Peterson, Arne Beck, Beth E. Waitzfelder, Rebecca C. Rossom, Ashli A. Owen-Smith, Frances Lynch, Christine Y. Lu, Cathrine Frank, Deepak Prabhakar, Jordan M. Braciszewski, Lisa R. Miller-Matero, Hsueh-Han Yeh, Yong Hu, Riddhi Doshi, Stephen C. Waring, & Gregory E. Simon, *Variation in Patterns of Health Care Before Suicide: A Population Case-Control Study*, 127 *Prev Med.* (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6744956/>.

³⁹⁸ Elizabeth Evans, Libo Li, Jeong Min, David Huang, Darren Urada, Lei Liu, Yih-Ing Hser, & Bohdan Nosyk, *Mortality Among Individuals Accessing Pharmacological Treatment for Opioid Dependence in California, 2006 – 2010*, 110(6) *Addiction* pp. 996-1005 (2015), <https://pubmed.ncbi.nlm.nih.gov/25644938/>.

³⁹⁹ This is calculated by applying the coefficient estimates found in Table 2 of the study that denote the average monthly insurer spending per service user. The study includes 129 months of data, of which 57 are in the post-period. For month 57, the cost is estimated to be \$86.64 absent MHPAEA and \$102.81 with the implementation of MHPAEA. The study estimates that insurer spending per service user will continue to increase over time. However, this linear trend was established within the sample. The Department hesitates to extrapolate the linear trend outside of the sample. Additionally, the study does not include overall significant or joint significant tests of this regression. (See Noah Mulvaney-Day, Brent Gibbons, Shums Alikhan, & Mustafa Karakus, *Mental Health Parity and Addiction Equity Act and the Use of Outpatient Behavioral Health Services in the United States, 2005-2016*, 109(3) *American Journal of Public Health* pp. 190-196 (2019).)

⁴⁰⁰ In 2015, 9,257,000 individuals with private insurance had a major depressive episode, of which 6,381,000 received treatment for depression. (See SAMHSA, Results from the 2015 National Survey on Drug use and Health: Detailed Tables (Sept. 2016), <https://www.samhsa.gov/data/sites/default/files/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015/NSDUH-DetTabs-2015.pdf>.) This represents approximately 69 percent. As such, the Departments estimate the per-member cost increase as: \$16.17 per member receiving treatment × 69 percent of members with depression receiving treatment = \$11.15 per member with depression (regardless of treatment status).

the 2015 per-member per-month behavioral healthcare cost⁴⁰¹—including behavioral inpatient, outpatient, professional, and prescription drug costs—was \$225.10 for someone with a serious and persistent mental illness and \$116.59 on average for someone with any mental illness.⁴⁰² Milliman defines a serious and persistent mental illness as someone treated for bipolar disorder, major depression, paranoid and other psychotic disorder, or schizoaffective disorder. As costs to treat bipolar disorder, psychotic disorder, and schizoaffective disorder are likely higher than costs to treat major depression, on average, the Departments are of the view that the per-member per-month costs represent an overestimate for costs to treat major depression. Similarly, the Departments expect that the per-member per-month costs to treatment someone with any mental illness likely represent an underestimate due to factors such as underdiagnosis, comorbidities, and delayed treatments. Additionally, the per-member per-month costs may not fully capture indirect costs or the cost of out-of-network care, further suggesting that the total costs of adequately treating mental illness are likely higher. As such, the Departments are of the view that these two measures create a reasonable range with regard to major depression.

Based on this analysis, the estimated \$11.15 increase in monthly insurer spending per-member with depression accounts for 5.0 percent of the per-member per-month costs for someone with a serious and persistent mental illness or 9.6 percent of the average cost for someone with any mental illness. In 2021, total expenditures for private insurance were \$981.2

⁴⁰¹ This cost estimate is calculated from costs incurred by both the participant and the insurer, similar to expenditures used elsewhere in this analysis, such as the Medical Expenditure Panel Survey Household Component (MEPS-HC).

⁴⁰² Melek (2018) uses 2015 claims data and apply annual cost trends to estimate 2017 values. The report states that they use an annual cost trend of 10 percent to behavioral health care and 12 percent to behavioral prescription costs. For someone with a serious and persistent mental illness, the report estimates that the per-member per-month cost was \$119.00 for behavioral health care (i.e. behavioral inpatient, outpatient, professional care) and \$159.00 for behavioral prescriptions, resulting in a total cost of \$178.00. The weighted average per-member per-month cost of having any mental illness, the report estimates a cost of \$55.08 for behavioral health care and \$89.14 for behavioral prescriptions, resulting in a total of \$142.22. Discounting the behavioral health care and behavioral prescription costs by the respective annual cost trend, results in an estimate of a per-member per-month cost of \$225.10 for someone with a serious and persistent mental illness and \$116.59 on average for someone with any mental illness. (See Stephen Melek, Douglas Norris, Jordan Paulus, Katherine Matthews, Alexandra Weaver, & Stoddard Davenport, *Potential Economic Impact of Integrated Medical-Behavioral Healthcare*, Milliman Research Report (Jan. 2018))

billion, while total expenditures for private insurance for depression were \$21.0 billion.⁴⁰³ For illustrative purposes, if it is assumed that the increase in costs associated with MHPAEA had accounted for between 5.0 percent and 9.6 percent of private insurance expenditures for depression in 2021, this would account for between \$1.0 billion and \$2.0 billion of total expenditures for private insurance for depression.⁴⁰⁴

In their estimate of benefits associated with the prevention of suicide fatalities and reduced mortality from the utilization of OUD treatments, the Departments assumed that the effect of these final rules would be approximately 40 percent of the initial impact from MHPAEA. For consistency, applying this proportion to the estimated costs, the Departments estimate that these final rules would be associated with an increase cost for treatment related to depression for private insurers of between \$0.42 billion and \$0.80 billion in 2021 dollars or \$0.43 billion and \$0.84 billion in 2023 dollars.⁴⁰⁵

It is important to note that the benefits estimated in section IV.7.2 and these cost estimates do not necessarily capture the same segment. The benefits related to more frequent treatment of depression are more expansive than the estimated benefits in section IV.7.2 that only focus on suicide prevention. On the other hand, treatment for other types of mental health conditions or substance use disorders may also contribute to the decreased prevalence of suicides, the cost of which is not considered in this illustration.

Additionally, the Departments estimate that the final rules will increase the utilization of substance use disorder services (specifically, OUD), resulting in significant benefits arising from decreased mortality related to substance use disorders. These benefits would arise from approximately 40,000 additional individuals receiving treatment each year. As recent research

⁴⁰³ Agency for Healthcare Research and Quality, *Total Expenditures (\$)* in Millions by Condition and Source of Payment, United States, 2021, Medical Expenditure Panel Survey.

⁴⁰⁴ This is estimated as: \$21.02 billion × 5.0 percent (9.6 percent) = \$1.0 billion (\$2.0 billion).

⁴⁰⁵ The estimates in 2023 dollars are estimated using the Consumer Price Index (CPI) medical care cost.

indicates that cost of treatment for OUD is approximately \$13,500, the Departments estimate that the increased service utilization for OUD would result in an additional cost of approximately \$579 million annually.^{406,407,408}

9. Transfers

Achieving parity in coverage of mental health and substance use disorder benefits has the potential to change the spending patterns of plans and issuers, increase premiums and contributions, and change the utilization patterns of participants, beneficiaries, and enrollees. The Departments recognize these as transfers among participants, beneficiaries, and enrollees; plans and issuers; and mental health and substance use disorder providers and facilities. Specifically, the Departments expect these final rules will result in:

- transfers from plans and issuers to participants, beneficiaries, and enrollees caused by lower out-of-pocket spending;
- transfers from participants, beneficiaries, and enrollees to plans and issuers caused by higher premiums; and
- transfers between primary care providers and mental health and substance use disorder providers for the treatment of mental health and substance use disorders resulting from the anticipated shift of participants, beneficiaries, and enrollees choosing to obtain such treatment from a specialist instead of a primary care provider.

The following sections are primarily qualitative discussions of transfers that the Departments expect to occur due to these final rules. Where possible, the Departments have referenced studies with quantitative results that help indicate the potential magnitude of these

⁴⁰⁶ Mengyao Li, Cora Peterson, Likang Xu, Christina A. Mikosz, & Feijun Luo, *Medical Costs of Substance Use Disorders in the US Employer-Sponsored Insurance Population*, 6(1) JAMA Netw Open (2023), <https://pubmed.ncbi.nlm.nih.gov/36692881/>.

⁴⁰⁷ The OUD treatment cost estimate of \$11,871 has been adjusted using the CPI for medical care cost to 2023 dollars. See Mengyao Li, Cora Peterson, Likang Xu, Christina A. Mikosz, & Feijun Luo, *Medical Costs of Substance Use Disorders in the US Employer-Sponsored Insurance Population*, 6(1) JAMA Netw Open (2023), <https://pubmed.ncbi.nlm.nih.gov/36692881/>.

⁴⁰⁸ \$13,448 OUD treatment cost × 43,054 additional persons receiving treatment = \$578,990,192.

transfers. The Departments requested comment or data in the proposal on how large these transfers might be but did not receive any comments.

9.1 Transfers from Plans and Issuers to Participants, Beneficiaries, and Enrollees

Caused by Lower Out-of-Pocket Spending

As discussed in section IV.7.2 of this regulatory impact analysis, these final rules are expected to increase access to mental health and substance use disorder treatments by improving plan and issuer compliance with the requirements under MHPAEA. This will help ensure that NQTLs are no more restrictive for mental health and substance use disorder benefits than the predominant limitations applicable to substantially all medical/surgical benefits. For individuals who were previously prevented from accessing care because it was not covered by their plan or coverage in a manner that violated these final rules, improved access to treatment is a benefit. However, for individuals who previously resorted to out-of-network treatment, expanded coverage of treatment—resulting in more access to in-network providers or facilities—will result in a transfer from plans and issuers to participants, beneficiaries, and enrollees.

Currently, it is more common for individuals to rely on out-of-network care for mental health and substance use disorder treatment than for medical/surgical treatment. One study found that patients received out-of-network care 3.5 times more often for behavioral health clinician office visits than for medical and surgical clinician office visits (13.4 percent vs. 3.8 percent). Further, the study found that when comparing specialist care, patients received out-of-network care 8.9 times more often for psychiatrist office visits (15.3 percent vs. 1.7 percent) and 10.6 times more often for psychologist office visits (18.2 percent vs. 1.7 percent) than for medical and surgical specialist physicians.⁴⁰⁹

⁴⁰⁹ Tami L. Mark & William Parish, *Behavioral Health Parity—Pervasive Disparities in Access to In-Network Care Continue*, RTI International (Apr. 2024), <https://dpjh8al9zd3a4.cloudfront.net/publication/behavioral-health-parity-pervasive-disparities-access-network-care-continue/fulltext.pdf>.

Receiving out-of-network treatment is costly, and research has found that mental health parity decreases out-of-pocket spending on treatment. For example, a 2013 study that examined the impact of the 2001 parity directive in the FEHB Program found that annual out-of-pocket spending for FEHB enrollees diagnosed with bipolar disorder, major depression, or adjustment disorder decreased by between \$78 and \$86, roughly between 11 percent and 18 percent of average total out-of-pocket spending for enrollees with one of these diagnoses, as compared to before the parity directive.⁴¹⁰

A 2018 study compared commercially insured children ages 3 to 18 years in 2008 who were continuously enrolled in plans newly subject to parity under MHPAEA to children continuously enrolled in plans never subject to MHPAEA. The study found that children with mental health conditions who were enrolled in plans subject to parity had, on average, \$140 lower annual out-of-pocket mental health spending than expected compared to the comparison group. The study further found that children at or above the 85th percentile in total mental health spending who were enrolled in plans subject to MHPAEA had, on average, \$234 lower annual out-of-pocket mental health spending than those in the comparison group.⁴¹¹

A 2019 study examined the impact of MHPAEA on mental health services spending in a commercially insured population diagnosed with mental health disorders and found that MHPAEA resulted in a decrease in the mean out-of-pocket spending per mental health outpatient visit.⁴¹² Additionally, a 2017 study that examined expenditures of patients receiving behavioral health treatment following the implementation of MHPAEA found that the out-of-pocket

⁴¹⁰ Before the parity directive, average out-of-pocket spending was \$787 for someone with bipolar disorder, \$563 for someone with major depression, and \$428 for someone with adjustment disorder. See Alisa B. Busch, Frank Yoon, Colleen L. Barry, Vanessa Azzone, Sharon-Lise T. Normand, Howard H. Goldman, & Haiden A. Huskamp, *The Effects of Parity on Mental Health and Substance Use Disorder Spending and Utilization: Does Diagnosis Matter?*, 170(2) *The American Journal of Psychiatry* p. 180 (2013).

⁴¹¹ Alene Kennedy-Hendricks, Andrew J. Epstein, Elizabeth A. Stuart, Rebecca L. Haffajee, Emma E. McGinty, Alisa B. Busch, Haiden A. Huskamp, & Colleen L. Barry, *Federal Parity and Spending for Mental Illness*, 142(2) *Pediatrics* (2018).

⁴¹² Rebecca L. Haffajee, Michelle M. Mello, Fang Zhang, Alisa B. Busch, Alan M. Zaslavsky, & J. Frank Wharam, *Association of Federal Mental Health Parity Legislation with Health Care Use and Spending Among High Utilizers of Services*, 57(4) *Medical Care* p. 245.

expenditure for patients had decreased and the total expenditure for health plans had increased, with no significant impact on health care utilization, suggesting that the costs had shifted from patients to health plans.⁴¹³

According to the 2019 MEPS-HC, private insurance covered \$33.87 billion of expenditures for treatment of mental health disorders among adults ages 18 and older⁴¹⁴ while all individuals paid \$15.62 billion out-of-pocket.⁴¹⁵ As discussed throughout this analysis, there are many reasons someone might seek care out-of-network or pay out-of-pocket for treatment, such as limited coverage from the issuer or plan, difficulty finding a network provider, or long wait times to see an in-network provider. The Departments acknowledge that these final rules will not address all the reasons that individuals pay out-of-pocket for treatment, and there is significant uncertainty in how these final rules will affect out-of-network spending.

Accordingly, the Departments do not know what proportion of total out-of-pocket spending experienced in the past will be covered by group health plans and health insurance coverage following the applicability of these final rules. However, to illustrate the potential scale of transfers from participants, beneficiaries, and enrollees to plans under this rulemaking, the Departments reference a 2020 study of in-network versus out-of-network psychotherapy employer-sponsored insurance claims which found in-network cost sharing was, on average, \$24.41 less than out-of-network cost-sharing for psychotherapy claims.⁴¹⁶ Utilizing tabulations from the MEPS-HC on events, such as office and outpatient visits for mental, behavioral, or

⁴¹³ Susan L. Ettner, Jessica M. Harwood, Amber Thalmayer, Michael K. Ong, Haiyong Xu, Michael J. Bresolin, Kenneth B. Wells, Chi-Hong Tseng, & Francisca Azocar, *The Mental Health Parity and Addiction Equity Act Evaluation Study: Impact on Specialty Behavioral Health Utilization and Expenditures Among “Carve-Out” Enrollees*, 50 *Journal of Health Economics* pp. 131-143 (2016).

⁴¹⁴ As defined in the MEPS-HC, mental disorders include anxiety, depression, bipolar disorder, schizophrenia, obsessive-compulsive disorder, attention-deficit and/or hyperactivity disorder, substance use disorder, and other mental and neurodevelopmental illnesses.

⁴¹⁵ Anita Soni, *Healthcare Expenditures for Treatment of Mental Disorders: Estimates for Adults Ages 18 and Older, U.S. Civilian Noninstitutionalized Population, 2019*, Agency for Healthcare Research and Quality, Statistical Brief #539 (Feb. 2022), https://meps.ahrq.gov/data_files/publications/st539/stat539.pdf.

⁴¹⁶ Nicole M. Benson & Zirui Song, *Prices and Cost Sharing for Psychotherapy In Network Versus Out Of Network in the United States*, 39(7) *Health Affairs* pp. 1210-1218 (2020).

neurological conditions, there were 530.7 million of these medical events in 2021 for individuals 65 and under with private insurance.⁴¹⁷ Applying the initial out-of-network rates of 13.4 percent from the Marsh and Parish paper would translate into 71.1 million out-of-network claims, which is 9 percentage points higher for mental health and substance use disorders than for medical/surgical treatments.⁴¹⁸ It is assumed that, under these final rules, the out-of-network utilization rates for mental health and substance use disorder benefits fall by just 10 percent to 12.1 percent of claims, this would still represent a transfer from plans and issuers to participants and beneficiaries of \$168.4 million annually in lower cost-sharing.⁴¹⁹

9.2 Transfers from Participants, Beneficiaries, and Enrollees to Plans and Issuers Caused by Higher Premiums

These final rules might also result in a transfer from participants, beneficiaries, and enrollees to plans and issuers in the form of higher premiums. By limiting the ability of plans and issuers to avoid costs of certain mental health and substance use disorder treatments while increasing access to and utilization of these services, these final rules might cause plans and issuers to increase premiums and change cost-sharing requirements (for example, by raising deductibles) to offset these costs. Similarly, plans and issuers might reduce the number of NQTLs employed and increase premiums in order to offset the costs of participants, beneficiaries, and enrollees utilizing more mental health and substance use disorder benefits.

Many studies attempt to isolate the changes in health costs associated with implementing parity requirements. One 2005 study by the Society of Actuaries on State mental health parity laws found that “overall health care costs increased minimally and in some cases were even

⁴¹⁷ Agency for Healthcare Research and Quality, *Number of Events in Thousands by Condition and Insurance Coverage, United States, 2021*, Medical Expenditure Panel Survey, <https://datatools.ahrq.gov/meps-hc?tab=medical-conditions&dash=17>.

⁴¹⁸ Tami L. Mark & William Parish, *Behavioral Health Parity—Pervasive Disparities in Access to In-Network Care Continue*, RTI International (Apr. 2024), <https://dpjh8al9zd3a4.cloudfront.net/publication/behavioral-health-parity-pervasive-disparities-access-network-care-continue/fulltext.pdf>.

⁴¹⁹ This estimate is calculated as follows: 530.7 million medical events × change in share that are out-of-network (13.4 percent – 12.1 percent) × \$24.41 = \$168.4 million.

reduced.”⁴²⁰ As discussed earlier in section IV.8 of this regulatory impact analysis, by removing some of the barriers to access to mental health and substance use disorder treatments caused by existing NQTLs, the Departments expect that the final rules will result in increased utilization of mental health and substance use disorder services, which could increase costs, including premiums. However, as discussed in section IV.7.3 of this regulatory impact analysis, better access to mental health and substance use disorder services can lead to better health outcomes and prevent costly interventions, which may reduce overall health care costs and premiums in the long-term. Thus, the Departments anticipate that these final rules will have a minimal impact on premiums, but there may be instances in which plans and issuers may impose higher premiums.

The Departments requested comments or data on this transfer in the proposal. A few commenters stated that the proposal would hinder the ability of plans to utilize common medical management techniques that improve cost and quality outcomes, such as prior authorization. As a result, commenters stated there would be an increase in premiums for participants, beneficiaries, and enrollees. However, as discussed previously, these final rules do not finalize the substantially all and predominant mathematical tests for NQTLs as proposed. The final rules also do not eliminate the use of prior authorization or other medical management, but the Departments emphasize that they must be designed and applied in parity as required by law.

9.3 Transfers Between Primary Care Providers and Mental Health and Substance Use Disorder Providers

These final rules may result in a transfer from primary care providers to mental health and substance use disorder providers. More specifically, with improved in-network access to mental health and substance use disorder providers, patients may be more likely to seek treatment from a behavioral health specialist rather than a primary care provider.

⁴²⁰ Steve Melek, *The Cost of Mental Health Parity*, Health Section News, Issue 49 (2005), as presented to the Society of Actuaries, <https://www.soa.org/globalassets/assets/library/newsletters/health-section-news/2005/march/hsn-2005-iss49-melek-b.pdf>.

For example, a 2012 study that examined the impact of Oregon’s 2007 parity law on the choice of provider found that the law was associated with a slight increase in the likelihood of patients seeking care “with masters-level specialists, and relatively little change for generalist physicians, psychiatrists, and psychologists,” leading to a shift in the use of nonphysician specialists and away from generalist physicians.⁴²¹ Further, a 2020 study compared mental health outpatient visits of adults in the period between 2008 and 2011 to the period between 2012 and 2015 using data from the MEPS-HC. Between the two time periods, the study found that the percentage of adults who visited only primary care non-physicians, such as physician assistants and nurse practitioners, increased by about 4 percent, whereas the percentage of adults who visited only primary care physicians decreased by about 2 percent.⁴²² The findings of these papers suggest that the final rules may lead to a slight shift in the use of nonphysician specialists, and away from generalist physicians.

9.4 Transfers Associated with the Implementation of the CAA, 2023 Provision That Sunsets the MHPAEA Opt-Out Election for Self-Funded Non-Federal Governmental Plans

HHS anticipates that the rules implementing the CAA, 2023 provision that sunsets the MHPAEA opt-out election for self-funded non-Federal governmental plans will have similar effects as the other provisions examined in this section IV.9 of the regulatory impact analysis. These final rules are generally expected to lead to improved coverage of and lower cost-sharing requirements for mental health and substance use disorder benefits for participants and beneficiaries of self-funded non-Federal governmental plans. This will lead to lower out-of-pocket costs for plan participants and beneficiaries who receive mental health or substance use

⁴²¹ John K. McConnell, Samuel HN Gast, & Bentson H. McFarland, *The Effect of Comprehensive Behavioral Health Parity on Choice of Provider*, 50(6) Medical Care p. 527.

⁴²² The study did not find a statistically significant change in visits to specialty mental health providers. See Hayley D. Germack, Coleman Drake, Julie M. Donohue, Ezra Golberstein, & Susan H. Busch, *National Trends in Outpatient Mental Health Service Use Among Adults Between 2008 and 2015*, 71 Psychiatric Services 11 pp. 1127-1135 (2020).

disorder services, which will be a transfer from self-funded non-Federal governmental plans to participants and beneficiaries.

On the other hand, as noted in section IV.8.2 of this regulatory impact analysis, if the final rules cause plans to remove limits on or offer more generous mental health and substance use disorder benefits, utilization of mental health and substance use disorder services may increase, which may cause in the number of claims submitted, the number of claims paid, and the overall costs incurred by plans to also increase. This, in turn, might lead to higher contributions and/or deductibles for plan participants, which may seem to be a transfer from plan participants to self-funded non-Federal governmental plans, but is instead an indication of the societal cost presented in section IV.8 of this regulatory impact analysis (and who bears it).

10. Uncertainty

It is unclear what percentage of plans and issuers impose greater burdens on mental health and substance use disorder benefits than on medical/surgical benefits. This frequency may differ among small and large plans and issuers. The Departments' experience in enforcing MHPAEA shows that plans and issuers are not in full compliance with MHPAEA, although the extent across all plans and issuers is not known. As documented in the FY 2022 MHPAEA Enforcement Fact Sheet, DOL closed investigations on 145 health plans, with 86 of them subject to MHPAEA, in fiscal year 2022. Of these closed investigations, EBSA cited 18 MHPAEA violations in 11 investigations.⁴²³

One commenter stated that the new requirements of the comparative analyses would require plans to make significant changes to their benefits design and NQTL compliance structure, which could result in more restrictions on medical/surgical benefits and/or higher premiums. The commenter did not provide any data or evidence. The Departments note that

⁴²³ EBSA, FY 2022 MHPAEA Enforcement Fact Sheet, <https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/mental-health-parity/mhpaea-enforcement-2022>.

there is no evidence from previous parity requirements that such actions led to the implementation of new NQTLs, particularly to medical/surgical benefits, and impacted cost sharing, medical management provisions, or medical/surgical coverage.

There is also the possibility that some plans and issuers will stop offering mental health and substance use disorder benefits. In 2010, 2 percent of employers reported discontinuing their coverage of both mental health and substance use disorder treatments or only substance use disorder treatments since MHPAEA was passed.⁴²⁴ Nevertheless, as discussed in section IV.9.1 of this regulatory impact analysis, the Departments anticipate that these final rules will expand the level of coverage for mental health and substance use disorder benefits, which will result in reduced out-of-pocket spending for plan participants, beneficiaries, and enrollees.

Another commenter also stated that the proposed rules would largely eliminate behavioral health carve-out vendors as a business model, because such vendors would not be able to build networks in complete alignment with medical/surgical disorder networks, as required under the proposed network composition NQTL rule. In response, the Departments note that similar claims—that MHPAEA would eliminate behavioral health carve-outs—were made when MHPAEA was first enacted in 2008. Furthermore, studies have found that the number of carve-out plans have increased since the enactment of MHPAEA. A 2016 study examined the impact of MHPAEA on carve-out plans and found that MHPAEA “led to a proliferation of plans and heterogeneity in benefit design in the post-parity period among employer groups choosing to retain the carve-out model for their behavioral health coverage.” The study also found no evidence that carve-out plans dropped coverage altogether for behavioral health treatments.⁴²⁵ A

⁴²⁴ GAO, *Mental Health and Substance Use: Employers’ Insurance Coverage Maintained or Enhanced Since Parity Act, but Effect of Coverage on Enrollees Varied*, GAO-12-63 (Nov. 2011), <https://www.gao.gov/assets/gao-12-63.pdf>.

⁴²⁵ Susan L. Ettner, Jessica M. Harwood, Amber Thalmayer, Michael K. Ong, Haiyong Xu, & Michael J. Bresolin, *The Mental Health Parity and Addiction Equity Act Evaluation Study: Impact on Specialty Behavioral Health Utilization and Expenditures among “Carve-Out” Enrollees*, 50 *Journal of Health Economics* pp. 131-143 (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5127782>.

2020 study also observing the impact of MHPAEA on carve-out plans found that “post-MHPAEA, the number of carve-out plans increased relative to carve-ins” and that MHPAEA was associated with lower copayments and out-of-network coinsurance for emergency room and outpatient services. The findings suggest that MHPAEA led to more generous benefits for carve-out plans. However, the authors also noted an increase in deductibles and in-network outpatient coinsurance, suggesting that some patients experienced higher out-of-pocket costs.⁴²⁶ Nevertheless, these studies suggest that the purported issues referenced by commenters were surmountable.

Additionally, the Departments note that they are not finalizing the proposed special rule for NQTLs related to network composition, and are instead including language in these final rules to explain how plans and issuers are expected to comply with the relevant data evaluation requirements with respect to those NQTLs. Under these final rules, material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits (including for NQTLs related to network composition) will not be treated as a violation; instead, plans and issuers must take reasonable action, as necessary, to address any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, and document those actions in their comparative analyses.

Further, there may be some possible societal spillover effects which may occur as a result of these final rules such as improving public safety in the long-term from an increase in access to mental health and substance use disorder treatments. For example, a 2017 study examined the effect of State parity laws for substance use disorder treatments on fatal traffic accidents and found that enactment of State parity laws were associated with reduced annual total traffic

⁴²⁶ Sarah Friedman, Haiyong Xu, Francisca Azocar, & Susan L. Ettner, *Carve-out Plan Financial Requirements Associated with National Behavioral Health Parity*, 55(6) Health Services Research pp. 924-931 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7704471/>.

fatality rates from 4.1 percent to 5.4 percent.⁴²⁷ Furthermore, a 2021 study which examined the impact of State parity laws on crime between 1994 and 2010 found that the enactment of State parity laws was associated with a reduction of violent crimes by 5 percent to 7 percent and that the resulting lower crime rates were associated with an annual savings of \$3 billion.⁴²⁸ These studies suggest that the benefits of these final rules may go beyond the listed benefits discussed in this regulatory impact analysis.

The Departments face uncertainty in estimating the magnitude of savings for participants, beneficiaries, and enrollees. The Departments requested comments and data in the proposal related to how the Departments may quantify the impact in out-of-pocket spending from these rules, but did not receive any comments.

Additionally, HHS is unable to precisely forecast how many participants and beneficiaries will be affected by the amendments to implement the CAA, 2023 provision that sunsets the MHPAEA opt-out election for self-funded non-Federal governmental plans, as plan sponsors that have elected to opt out of requirements under MHPAEA were not required to report that information to HHS as part of their opt-out filings. See section IV.5.3 of this regulatory impact analysis for further discussion on the affected participants and beneficiaries.

It is possible that some self-funded non-Federal governmental plans will stop offering mental health and substance use disorder benefits in response to the final rules. However, HHS is unable to estimate the potential number of self-funded non-Federal governmental plans that might do so. It is also possible that some self-funded non-Federal governmental plans might increase the financial requirements and treatment limitations that apply to medical/surgical benefits in response to this provision, to ensure that financial requirements and treatment

⁴²⁷ Ioana Popovici, Johanna Catherine Maclean, & Michael T. French, *The Effects of Health Insurance Parity Laws for Substance Use Disorder Treatment on Traffic Fatalities: Evidence of Unintended Benefits*, National Bureau of Economic Research (2017),

https://www.nber.org/system/files/working_papers/w23388/revisions/w23388.rev0.pdf?sy=388.

⁴²⁸ Keshob Sharma, *Do Mental Health Parity Laws Reduce Crime?*, working paper (Nov. 14, 2021).

limitations applicable to mental health and substance use disorder benefits comply with MHPAEA and its implementing regulations. HHS anticipates that this is a less likely outcome of these amendments.

HHS solicited comments on the potential number of self-funded non-Federal governmental plans that might stop offering mental health and substance use disorder benefits, as well as the potential number of self-funded non-Federal governmental plans that might increase financial requirements and treatment limitations for medical/surgical benefits in response to the proposed amendments. HHS also solicited comments on the potential number of participants and beneficiaries that might be affected by these potential plan changes. HHS did not receive any comments that provided this information.

11. Alternatives

In addition to the regulatory approach outlined in these final rules, the Departments considered alternatives when developing policy regarding the implementation of MHPAEA. The Departments considered not expressly incorporating the statutory requirement that NQTLs be no more restrictive for mental health and substance use disorder benefits than for medical/surgical benefits. However, as described earlier in this preamble, it is clear that plans and issuers too often fail to consider the impact of their NQTLs on access to mental health and substance use disorder benefits before designing and applying NQTLs, in a manner that is consistent with MHPAEA's fundamental purpose. While the Departments have seen some improvements in response to their reviews of plans' and issuers' comparative analyses under the CAA, 2021 requirements, they have primarily seen a great deal of confusion about the application of the current regulation to NQTLs and about the parity obligation generally. Based on the experience with plans' and issuers' attempts to comply with the existing regulations and guidance and the CAA, 2021, the Departments have concluded that the existing MHPAEA regulations failed to sufficiently focus attention on the obligation to ensure that NQTLs, and associated processes,

strategies, evidentiary standards, and other factors avoid placing disparate burdens on participants', beneficiaries', and enrollees' access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Accordingly, the Departments are of the view that these final rules will be beneficial to participants, beneficiaries, and enrollees, as plans and issuers revise their policies and remove or amend NQTLs that are inconsistent with MHPAEA.

The Departments also considered not requiring plans and issuers to use specific data elements in designing and applying NQTLs and preparing their comparative analyses or to provide the data to the Departments upon request. However, during their review of comparative analyses as part of their reporting requirements to Congress, the Departments found that many plans and issuers did not initially provide sufficient information to demonstrate compliance of an NQTL as written, in operation, or both. It is often difficult to assess compliance in operation without such data. By requiring the consideration, use, and production of this data, the regulation will improve the review of plans' and issuers' policies and processes, and improved parity outcomes for participants, beneficiaries, and enrollees.

12. Conclusion

The Departments expect that these final rules will provide plans and issuers with a better understanding of the requirements of MHPAEA and improve how they measure, analyze, document, and demonstrate parity with regard to NQTLs. The Departments are of the view that these final rules will help plans and issuers produce NQTL comparative analyses that meet the requirements of the CAA, 2021, resulting in improved access to and coverage of mental health and substance use disorder treatments, which should ultimately result in better health outcomes among those with mental health conditions and substance use disorders.

V. Paperwork Reduction Act

1. Paperwork Reduction Act - Departments of Labor and the Treasury

In accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)), the Departments solicited comments concerning the information collection requests (ICRs) included in the proposed rules. At the same time, the Departments also submitted ICRs to OMB, in accordance with 44 U.S.C. 3507(d).

The Departments received comments that specifically addressed the paperwork burden analysis of the ICRs contained in the proposed rules. Many commenters expressed concern that the Departments underestimated the burden of collecting the required data, the burden required in conducting the substantially all and predominant variation analysis, the number of NQTLs that would need to be analyzed for each plan and issuer, and the amount of time that it would take to conduct those analyses. The Departments reviewed these public comments in developing the paperwork burden analysis discussed here.

The changes made by these final rules affect the existing OMB control number, 1210–0138. A copy of the ICR for OMB Control Number 1210–0138 may be obtained by contacting the PRA addressee listed in the following sentence or at www.RegInfo.gov. For additional information contact, U.S. Department of Labor, Employee Benefits Security Administration, Office of Research and Analysis, Attention: PRA Officer, 200 Constitution Avenue NW, Room N–5718, Washington, DC 20210; or send to ebesa.opr@dol.gov.

1.1 Final Amendments to Existing MHPAEA Regulations (26 CFR 54.9812-1; 29 CFR 2590.712)

These final rules add new definitions, amend existing definitions, specify new requirements related to NQTLs, including by prohibiting discriminatory factors and evidentiary standards, amend existing examples illustrating the rules for NQTLs, and add new examples illustrating the rules for NQTLs, providing clarity to interested parties. The final rules also

specify that the way a plan or issuer defines mental health benefits, substance use disorder benefits, and medical/surgical benefits must be consistent with generally recognized independent standards of current medical practice and add more specificity as to what conditions or disorders plans and issuers must treat as mental health conditions, substance use disorders, and medical conditions and surgical procedures. The final rules also require that plans and issuers provide meaningful benefits for covered mental health conditions or substance use disorders in each classification in which meaningful medical/surgical benefits are provided. Additionally, these final rules require plans and issuers to collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits. Where the relevant data suggest that the NQTL contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, plans and issuers are required to take reasonable action, as necessary, to address the material differences to ensure compliance, in operation, with 26 CFR 54.9812-1(c)(4), 29 CFR 2590.712(c)(4), and 45 CFR 146.136(c)(4). These final rules provide guidance for how to comply with the relevant data evaluation requirements in limited circumstances where data is initially and temporarily unavailable for new and newly imposed NQTLs and where no data exists that can reasonably measure any relevant impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits. In those instances, the plan or issuer must include specific information in their comparative analyses, as explained earlier in this preamble. However, as explained earlier in this preamble, the Departments are of the view that nearly all NQTLs will have some relevant data to collect and evaluate; therefore, the Departments estimate the burden as if every plan and issuer performs the data analysis.

1.2 New Regulation (26 CFR 54.9812-2; 29 CFR 2590.712-1)

These final rules set more specific content and data requirements for the NQTL comparative analyses required by MHPAEA as amended by the CAA, 2021, clarify when the comparative analyses need to be performed, and outline the timeframes and process for plans and issuers to provide their comparative analyses to the Departments or applicable State authority upon request.

For the purpose of this analysis, it is assumed that health insurance issuers will fulfill the data request for fully insured group health plans. This burden is accounted for under HHS' OMB Control number 0938-1393 and is discussed later in this document. It is also assumed that TPAs and other service providers will fulfill the requirements for the vast majority of self-funded group health plans.

1.3 Burden Estimates for Final Rules Requirements

The final rules will affect self-funded plans and MEWAs. The Departments estimate that 709 self-funded plans with 500 or more participants will prepare the comparative analysis and data themselves. The Departments also estimate that 4,076 self-funded plans with 500 or more participants will receive a generic comparative analysis from their TPA or other service provider, which they will subsequently customize to suit their specific needs. Finally, the Departments estimate that 132 plan MEWAs and 21 non-plan MEWAs that are not fully insured will provide assistance to plans in collecting and analyzing the data, and generating the comparative analyses. For more information on how the number of each type of entity is estimated, please refer to the Affected Entities section of the regulatory impact analysis.

Non-grandfathered, fully insured ERISA plans with less than 50 participants that are subject to MHPAEA under the EHB requirements of the ACA are likely to have their issuers prepare their comparative analyses. Issuers can take advantage of economies of scale by preparing the required documents for those plans purchasing coverage. HHS has jurisdiction

over issuers in States that substantially fail to enforce MHPAEA's requirements and therefore is accounting for this portion of the burden in its analysis, in addition to the burden related to non-Federal governmental plans. Accordingly, this analysis considers only the burden associated with ERISA self-funded group health plans, which are under the jurisdiction of the DOL and the Treasury.

These final rules require that a plan or issuer perform and document a comparative analysis of each NQTL applicable to mental health and substance use disorder benefits. In the proposed rules, the Departments estimated that, on average, plans would need to analyze four separate NQTLs and issuers would need to analyze eight NQTLs to satisfy their additional comparative analysis requirements. The Departments further estimated that plans and issuers preparing their own comparative analyses would incur a burden of 20 hours per NQTL in the first year, with 4 hours for a general or operations manager to review the requirements and outline the changes needed for the comparative analyses and 16 hours for a business operations specialist to prepare the comparative analyses. Once the comparative analyses are performed and documented, the Departments estimated that plans and issuers would need to update the analyses when making changes to the terms of the plan or coverage, including changes to the way NQTLs are applied to mental health and substance use disorder benefits as well as medical and surgical benefits. In subsequent years, the Departments estimated plans would incur a burden of 10 hours annually per NQTL to update the analyses, with 2 hours for a general or operations manager and 8 hours for a business operations specialist.

In response to commenters' concerns that the Departments underestimated the number of NQTLs that each plan or issuer would need to create comparative analyses for, and that plans and issuers would on average have the same number NQTLs, the Departments have revised their assumptions to 10 NQTLs for both plans and issuers. One commenter proposed the average number of NQTLs should be more than 15 at a minimum, while another noted that there were at

least 15 NQTLs referenced in the proposed rules and other guidance. However, given that the number of NQTLs vary by issuer and plan, that most plans will not have every NQTL referenced in the proposed rules and other guidance (although some might have more), and that NQTLs can be counted as an umbrella group, the Departments assume 10 NQTLs.

The Departments assume that collecting the data, and reviewing and revising the comparative analyses would require 60 hours per NQTL in the first year and 12 hours per NQTL in subsequent years. For plans that receive a generic comparative analysis that will require customizing to suit the plan’s specific needs, the Departments assume that it will take 30 hours per NQTL in the first year and 6 hours per NQTL in subsequent years. While plans and issuers can use other professionals to fulfill their requirements, for purposes of developing the wage estimate, the Departments assume that it will take a team of data analysts, actuaries, and attorneys to collect the data and prepare the comparative analyses and have estimated a composite wage rate of \$167.48.⁴²⁹ See Table 11 for calculations and burden totals.

Table 11. Hour Burden to Fulfill the Data Requirements and Prepare the Comparative Analyses

| | Number of Entities | Number of NQTLs per Entity | Number of Hours per NQTL for Data and Comparative Analysis | Total Hour Burden | Hourly Wage | Equivalent Cost of Hour Burden |
|---|--------------------|----------------------------|--|-------------------|-------------|--------------------------------|
| | (A) | (B) | (C) | (A × B × C) | (D) | (A × B × C × D) |
| <i>First Year</i> | | | | | | |
| TPAs | 103 | 10 | 60 | 61,800 | \$167.48 | \$10,350,264 |
| Self-funded plans with more than 500 participants that will conduct the comparative analysis themselves | 709 | 10 | 60 | 425,400 | \$167.48 | \$71,245,992 |

⁴²⁹ The wage rate of an attorney, actuary, and data analyst is, respectively, \$165.71, \$177.11, and \$159.61. (Internal DOL calculation based on 2024 labor cost data. For a description of DOL’s methodology for calculating wage rates, see EBSA, *Labor Cost Inputs Used in the Employee Benefits Security Administration, Office of Policy and Research’s Regulatory Impact Analyses and Paperwork Reduction Act Burden Calculations* (June 2019), <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical-appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf>.) The composite wage rate is estimated in the following manner: [$\$165.71 \times (1 \div 3) + \$159.61 \times (1 \div 3) \times \$177.61 \times (1 \div 3) = \167.48].

| | Number of Entities | Number of NQTLs per Entity | Number of Hours per NQTL for Data and Comparative Analysis | Total Hour Burden | Hourly Wage | Equivalent Cost of Hour Burden |
|---|--------------------|----------------------------|--|-------------------|-------------|--------------------------------|
| | (A) | (B) | (C) | (A × B × C) | (D) | (A × B × C × D) |
| Self-funded plans with more than 500 participants that will receive generic comparative analyses from TPAs or service providers, and will then customize it | 4,076 | 10 | 30 | 1,222,800 | \$167.48 | \$204,794,544 |
| Plan MEWAs that are not fully insured | 132 | 10 | 60 | 79,200 | \$167.48 | \$13,264,416 |
| Non-plan MEWAs that are not fully insured | 21 | 10 | 60 | 12,600 | \$167.48 | \$2,110,248 |
| First-year Total | 5,041 | - | - | 1,801,800 | - | \$301,765,464 |
| <i>Subsequent Years</i> | | | | | | |
| TPAs | 103 | 10 | 12 | 12,360 | \$167.48 | \$2,070,053 |
| Self-funded plans with more than 500 participants that will conduct the comparative analysis themselves | 709 | 10 | 12 | 85,080 | \$167.48 | \$14,249,198 |
| Self-funded plans with more than 500 participants that will receive generic comparative analyses from TPAs or service providers, and will then customize it | 4,076 | 10 | 6 | 244,560 | \$167.48 | \$40,958,909 |
| Plan MEWAs that are not fully insured | 132 | 10 | 12 | 15,840 | \$167.48 | \$2,652,883 |
| Non-plan MEWAs that are not fully insured | 21 | 10 | 12 | 2,520 | \$167.48 | \$422,050 |
| Subsequent Years Total | 5,041 | - | - | 360,360 | - | \$60,353,093 |
| Total (3-year average) | 5,041 | - | - | 840,840 | - | \$140,823,883 |

These final rules also require that group health plans offering group health insurance coverage must make a comparative analysis available upon request by the Departments. The

CAA, 2021 requires the Departments to collect no fewer than 20 comparative analyses per year, but it also provides that the Departments shall request that a group health plan or issuer submit the comparative analyses for plans that involve potential MHPAEA violations or complaints regarding noncompliance with MHPAEA that concern NQTLs, and any other instances in which the Departments determine appropriate. Based on its prior experience and current funding, DOL expects to request 20 comparative analyses each year. See Table 12 for calculations and burden totals.

These final rules also require plans and issuers to make the comparative analyses and other applicable information required by the CAA, 2021 available upon request to participants, beneficiaries, and enrollees in all non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage (including a provider or other person acting as a participant's, beneficiary's, or enrollee's authorized representative) in connection with an adverse benefit determination, as well as to participants and beneficiaries in plans subject to ERISA. The Departments estimate that each plan will receive one request per covered health plan annually and that plans will annually incur a burden of 5 minutes for a clerical worker to prepare and send the comparative analyses to each requesting participant or beneficiary. DOL also assumes that 58.3 percent of requests will be delivered electronically, resulting in a de minimis cost.⁴³⁰ The remaining 41.7 percent of requests will be mailed at a cost of \$2.79.⁴³¹ See Table 12 for calculations and burden totals.

⁴³⁰ According to data from NTIA, 37.4 percent of individuals aged 25 and over have access to the internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out of electronic disclosure that are automatically enrolled (for a total of 31.4 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 44.1 percent of individuals aged 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61.0 percent of internet users use online banking, which is used as the proxy for the number of internet users who will affirmatively consent to receiving electronic disclosures (for a total of 26.9 percent receiving electronic disclosure outside of work). Combining the 31.4 percent who will receive electronic disclosure at work with the 26.9 percent who will receive electronic disclosure outside of work produces a total of 58.3 percent who will receive electronic disclosure overall.

⁴³¹ The postage for a first-class mail large envelope letter is \$2.04 and the material cost is \$0.05 per page. Thus, $\$2.04 + (\$0.05 \times 15 \text{ pages}) = \2.79 .

1.4 Recordkeeping Requirement

The Departments posit that plans and issuers already maintain records as part of their regular business practices. Further, ERISA section 107 includes a general 6-year retention requirement. For these reasons, the Departments estimate a minimal additional burden. The Departments estimate that, on average, any additional recordkeeping requirements will take clerical personnel 5 minutes annually. See Table 12 for calculations and burden totals.

Table 12. Hour and Cost Burden of Other Requirements

| | Number of Response | Number of Hours per Responses | Total Hour Burden | Wage Rate | Hour Equivalent of Cost Burden | Mailing Cost per Response | Cost Burden |
|---|--------------------|-------------------------------|-------------------|-----------|--------------------------------|---------------------------|------------------------|
| | (A) | (B) | (A × B) | (C) | (A × B × C) | (D) | (A × D × 41.7 percent) |
| Business operations specialists prepare comparative analysis for audits | 20 | 1 | 20 | \$137.67 | \$2,753 | \$0 | \$0 |
| General operation managers prepare comparative analysis for audits | 20 | 4 | 80 | \$114.36 | \$9,149 | \$0 | \$0 |
| Clerical workers prepare and distribute comparative analyses upon participant request | 2,129,516 | 0.083 | 177,460 | \$65.99 | \$11,710,585 | \$2.79 | \$2,477,543 |
| Clerical workers maintain recordkeeping | 2,129,516 | 0.083 | 177,460 | \$65.99 | \$11,710,585 | \$0 | \$0 |
| Total | 2,129,536 | - | 355,020 | - | \$23,433,073 | - | \$2,477,543 |

1.5 Overall Summary

In summary, the total burden associated with these final rules has a 3-year average hour burden of 1,195,860 hours with an equivalent cost of \$164,256,956 and a cost burden of \$2,477,543.

A summary of paperwork burden estimates follows:

Type of Review: Revision

Agency: Employee Benefits Security Administration, U.S. Department of Labor; Internal Revenue Service, U.S. Department of the Treasury.

Title: MHPAEA Notices

OMB Control Number: 1210-0138

Affected Public: Businesses or other for-profits, Not-for-profit institutions.

Estimated Number of Respondents: 123,1752

Estimated Number of Annual Responses: 123,1752

Frequency of Response: Annual

Estimated Total Annual Burden Hours: 1,195,860 (597,930 for DOL, 597,930 for Treasury)

Estimated Total Annual Burden Cost: \$2,477,543 (\$1,238,771 for DOL, \$1,238,771 for Treasury)

2. Paperwork Reduction Act – Department of HHS

In accordance with the Paperwork Reduction Act of 1995 (PRA 95) (44 U.S.C. 3506(c)(2)(A)), the Department solicited comments concerning the ICRs included in the proposed rules. At the same time, the Departments also submitted ICRs to OMB, in accordance with 44 U.S.C. 3507(d).

The Departments received comments that specifically addressed the paperwork burden analysis of the ICRs contained in the proposed rules. Many commenters expressed concern that the Departments underestimated the burden of collecting the required data, the burden of conducting the substantially all and predominant variation analysis, the number of NQTLs that would need to be analyzed for each plan and issuer, and the amount of time that it would take to conduct those analyses. The Departments reviewed these public comments in developing the paperwork burden analysis discussed here.

The changes made by these final rules affect the existing OMB control number, 0938-1393. HHS will update the information collection to account for the burden related to the provisions in these final rules.

2.1 Final Amendments to Existing MHPAEA Regulations (45 CFR 146.136)

The amendments to the existing MHPAEA regulations in these final rules add new definitions, amend existing definitions, clarify the rules for NQTLs, including by prohibiting discriminatory factors and evidentiary standards, amend existing examples illustrating the rules for NQTLs, and add new examples illustrating the rules for NQTLs, providing clarity to the regulated community. The amendments also clarify that whether a condition or disorder is defined by the plan or issuer as being a mental health condition or a substance use disorder for purposes of MHPAEA must be consistent with generally recognized independent standards of current medical practice. The final rules also require that plans and issuers provide meaningful benefits for covered mental health conditions or substance use disorders in each classification in which meaningful medical/surgical benefits are provided.

These final rules also require plans and issuers to collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits. Relevant data for the majority of NQTLs could include, as appropriate, but are not limited to, the number and percentage of claims denials and any other data relevant to the NQTL required by State law or private accreditation standards. Additionally, relevant data for NQTLs related to network composition could include, as appropriate, but are not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (for comparable services and as benchmarked to a reference standard).

2.2. New Regulations (45 CFR 146.137)

These final rules set forth more specific content and data requirements for the NQTL comparative analyses required by MHPAEA as amended by the CAA, 2021, clarify when the comparative analyses need to be performed, and outline the timeframes and process for plans and issuers to provide their comparative analyses to the Departments or an applicable State authority upon request.

These final rules provide guidance for how to comply with the relevant data evaluation requirements in limited circumstances where data is initially and temporarily unavailable for new and newly imposed NQTLs and where no data exists that can reasonably measure any relevant impact of the NQTL on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits. In those instances, the plan or issuer must include specific information in their comparative analyses, as explained earlier in this preamble. In such instances, providing this justification is likely to be less expensive than the estimated burden for doing an analysis when there is data. However, as explained earlier in this preamble, the Departments are of the view that nearly all NQTLs will have some relevant data to collect and evaluate; therefore, the Departments estimate the burden as if every plan and issuer performs the data analysis.

As discussed earlier in this preamble, HHS enforces applicable provisions of Title XXVII of the PHS Act, including the provisions added by MHPAEA, with respect to health insurance issuers offering group and individual health insurance coverage in States that elect not to enforce or fail to substantially enforce MHPAEA or another PHS Act provision. HHS is therefore accounting for this portion of the burden in its analysis, in addition to accounting for the burden on sponsors of self-funded non-Federal governmental plans.

2.3. Burden Estimates for Final Requirements

These final rules will affect issuers, TPAs, and self-funded non-Federal governmental

plans. Health insurance issuers offering individual or group health insurance coverage usually have multiple products offered in multiple States. HHS estimates a total of 479 health insurance companies offering individual or group health insurance coverage nationwide, with a total of 1,467 issuers (health insurance company/State combinations). In addition, there are an estimated 205 TPAs that provide services to group health plans, particularly for self-funded plans where TPAs often establish provider networks and adjudicate claims, which will be impacted by these final rules. Furthermore, sponsors of self-funded non-Federal governmental plans will be affected by these final rules. HHS estimates that out of the estimated 32,901 self-funded non-Federal governmental plans, 505 self-funded non-Federal governmental plans with 500 or more participants will prepare the comparative analysis and data themselves, and 2,906 self-funded non-Federal governmental plans with 500 or more participants will receive a generic comparative analysis from their TPA, which they will subsequently customize to suit their specific needs. For more information on how the number of each type of entity is estimated, please refer to section IV.5.2 of the regulatory impact analysis.

These final rules require that a plan or issuer perform and document a comparative analysis of each NQTL applicable to mental health and substance use disorder benefits. In the proposed rules, the Departments estimated that, on average, plans would need to analyze four separate NQTLs and issuers would need to analyze eight NQTLs to satisfy their additional comparative analysis requirements. The Departments further estimated that plans and issuers preparing their own comparative analyses would incur a burden of 20 hours per NQTL in the first year, with 4 hours for a general or operations manager to review the requirements and outline the changes needed for the comparative analyses and 16 hours for a business operations specialist to prepare the comparative analyses. Once the comparative analyses are performed and documented, plans and issuers would need to update the analyses when making changes to the terms of the plan or coverage, including changes to the way NQTLs are applied to mental health

and substance use disorder benefits, as well as medical and surgical benefits. In subsequent years, the Departments estimated plans would incur a burden of 10 hours annually per NQTL to update the analyses, with 2 hours for a general or operations manager and 8 hours for a business operations specialist.

In response to commenters' concerns that the Departments underestimated the number of NQTLs that each plan or issuer would need to create comparative analyses for, and that plans and issuers would on average have the same number NQTLs, the Departments have revised their assumptions to 10 NQTLs for both plans and issuers. One commenter proposed the average number of NQTLs should be more than 15 at a minimum, while another noted that there were at least 15 NQTLs referenced in the proposed rules and other guidance. However, because the number of NQTLs varies by issuer and plan, most plans will not have every NQTL referenced in the rules or guidance (although some might use more), and NQTLs can be counted as an umbrella group, the Departments assume 10 NQTLs.

The Departments assume that collecting the data, and reviewing and revising the comparative analyses will require 60 hours per NQTL in the first year and 12 hours per NQTL in subsequent years. For plan sponsors that receive a generic comparative analysis from a TPA that will require customizing to suit the plan's specific needs, the Departments assume that it will take 30 hours per NQTL in the first year and 6 hours per NQTL in subsequent years. While plans and issuers can use other professionals to fulfill their requirements, for purposes of developing the wage estimate, the Departments assume that it will take a team of data analysts, actuaries, and attorneys to collect the data and prepare the comparative analyses, and have estimated a composite wage rate of \$167.48.⁴³² See Table 13 for calculations and burden totals.

⁴³² The wage rate of an attorney, actuary, and data analyst is, respectively, \$165.71, \$177.11, and \$159.61. (Internal DOL calculation based on 2024 labor cost data. For a description of DOL's methodology for calculating wage rates, see EBSA, *Labor Cost Inputs Used in the Employee Benefits Security Administration, Office of Policy and Research's Regulatory Impact Analyses and Paperwork Reduction Act Burden Calculations* (June 2019), <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/rules-and-regulations/technical->

Table 13. Hour Burden to Fulfill the Data Requirements and Prepare the Comparative Analyses

| | Number of Entities | Number of NQTLs per Entity | Number of Hours per NQTL for Data and Comparative Analysis | Total Hour Burden | Hourly Wage | Equivalent Cost of Hour Burden |
|--|---------------------------|-----------------------------------|---|--------------------------|--------------------|---------------------------------------|
| | (A) | (B) | (C) | (A × B × C) | (D) | (A × B × C × D) |
| <i>First Year</i> | | | | | | |
| Issuers (health insurance company/State combinations) | 1,467 | 10 | 60 | 880,200 | \$167.48 | \$147,415,896 |
| TPAs | 103 | 10 | 60 | 61,800 | \$167.48 | \$10,350,264 |
| Self-funded non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves | 505 | 10 | 60 | 303,000 | \$167.48 | \$50,746,440 |
| Self-funded non-Federal governmental plans with more than 500 participants that will receive a generic comparative analysis from TPAs or service providers, and will then customize it | 2,906 | 10 | 30 | 871,800 | \$167.48 | \$146,009,064 |
| First-year Total | 4,981 | - | - | 2,116,800 | - | \$354,521,664 |
| <i>Subsequent Years</i> | | | | | | |
| Issuers | 1,467 | 10 | 12 | 176,040 | \$167.48 | \$29,483,179 |
| TPAs | 103 | 10 | 12 | 12,360 | \$167.48 | \$2,070,053 |
| Self-funded non-Federal governmental plans with more than 500 participants that will conduct the comparative analysis themselves | 505 | 10 | 12 | 60,600 | \$167.48 | \$10,149,288 |
| Self-funded non-Federal governmental plans | 2,906 | 10 | 6 | 174,360 | \$167.48 | \$29,201,813 |

appendices/labor-cost-inputs-used-in-ebsa-opr-ria-and-pra-burden-calculations-june-2019.pdf.) The composite wage rate is estimated in the following manner: [$\$165.71 \times (1 \div 3) + \$159.61 \times (1 \div 3) \times \$177.61 \times (1 \div 3) = \167.48].

| | Number of Entities | Number of NQTLs per Entity | Number of Hours per NQTL for Data and Comparative Analysis | Total Hour Burden | Hourly Wage | Equivalent Cost of Hour Burden |
|---|---------------------------|-----------------------------------|---|--------------------------|--------------------|---------------------------------------|
| | (A) | (B) | (C) | (A × B × C) | (D) | (A × B × C × D) |
| with more than 500 participants that will receive a generic comparative analysis from TPAs or service providers, and will then customize it | | | | | | |
| Subsequent Years Total | 4,981 | - | - | 423,360 | - | \$70,904,333 |
| Total (3-year average) | 4,981 | - | - | 987,840 | - | \$165,443,443 |

These final rules require that plans or issuers make their comparative analyses available upon request to the Departments. The CAA, 2021 requires the Departments to collect not fewer than 20 comparative analyses per year, but it also provides that the Departments shall request that a plan or issuer submit the comparative analyses for plans that involve potential MHPAEA violations or complaints regarding noncompliance with MHPAEA that concern NQTLs, and any other instances in which the Departments determine appropriate. HHS expects to request at least 20 comparative analyses each year. See Table 14 for calculations and burden totals.

These final rules also require plans and issuers to make the comparative analyses and other applicable information required by the CAA, 2021 available upon request to participants, beneficiaries, and enrollees in all non-grandfathered group health plans and non-grandfathered group or individual health insurance coverage (including a provider or other person acting as a participant’s, beneficiary’s, or enrollee’s authorized representative) in connection with an adverse benefit determination, as well as to participants and beneficiaries in plans subject to ERISA. HHS estimates that each non-Federal governmental plan and each issuer will receive one request annually and that plans and issuers will annually incur a burden of 5 minutes for a

clerical worker to prepare and send the comparative analyses to each requesting participant, beneficiary, or enrollee. HHS also assumes that 58.3 percent of requests will be delivered electronically, resulting in a de minimis cost.⁴³³ The remaining 41.7 percent of requests will be mailed.⁴³⁴ The annual cost burden to mail the comparative analyses to the participants and beneficiaries will therefore be approximately \$107,500. See Table 14 for calculations and burden totals.

2.4. Recordkeeping Requirement

HHS posits that plans and issuers already maintain records as part of their regular business practices. HHS therefore estimates a minimal additional burden associated with these final rules. HHS estimates that each non-Federal governmental plan and issuer will annually incur a burden of 5 minutes, on average. See Table 14 for calculations and burden totals.

HHS will revise the information collection approved under OMB Control Number 0938-1393 to account for this burden.⁴³⁵

Table 14. Hour and Cost Burden of Other Requirements

| | Number of Responses | Number of Hours per Response | Total Hour Burden | Wage Rate | Hour Equivalent of Cost Burden | Mailing Cost per Response | Cost Burden |
|---|---------------------|------------------------------|-------------------|-----------|--------------------------------|---------------------------|------------------------|
| | (A) | (B) | (A × B) | (C) | (A × B × C) | (D) | (A × D × 41.7 percent) |
| Business operations specialists prepare comparative analysis for audits | 20 | 4 | 80 | \$114.36 | \$9,149 | \$0 | \$0 |

⁴³³ According to data from NTIA, 37.4 percent of individuals aged 25 and over have access to the internet at work. According to a Greenwald & Associates survey, 84 percent of plan participants find it acceptable to make electronic delivery the default option, which is used as the proxy for the number of participants who will not opt out of electronic disclosure that are automatically enrolled (for a total of 31.4 percent receiving electronic disclosure at work). Additionally, the NTIA reports that 44.1 percent of individuals aged 25 and over have access to the internet outside of work. According to a Pew Research Center survey, 61.0 percent of internet users use online banking, which is used as the proxy for the number of internet users who will affirmatively consent to receiving electronic disclosures (for a total of 26.9 percent receiving electronic disclosure outside of work). Combining the 31.4 percent who will receive electronic disclosure at work with the 26.9 percent who will receive electronic disclosure outside of work produces a total of 58.3 percent who will receive electronic disclosure overall.

⁴³⁴ The postage for a first-class mail large envelope is \$2.04 and the material cost is \$0.05 per page. Thus, \$2.04 + (\$0.05 × 15 pages) = \$2.79.

⁴³⁵ CMS-10773, *Non-Quantitative Treatment Limitation Analyses and Compliance Under MHPAEA*.

| | Number of Responses | Number of Hours per Response | Total Hour Burden | Wage Rate | Hour Equivalent of Cost Burden | Mailing Cost per Response | Cost Burden |
|--|---------------------|------------------------------|-------------------|-----------|--------------------------------|---------------------------|------------------------|
| | (A) | (B) | (A × B) | (C) | (A × B × C) | (D) | (A × D × 41.7 percent) |
| General operation managers prepare comparative analysis for audits | 20 | 1 | 20 | \$137.67 | \$2,753 | \$0 | \$0 |
| Clerical workers prepare comparative analyses upon participant request | 92,354 | 0.083 | 7,696 | \$65.99 | \$507,859 | \$2.79 | \$107,477 |
| Clerical workers maintain recordkeeping | 92,354 | 0.083 | 7,696 | \$65.99 | \$507,859 | \$0 | \$0 |
| Total | 92,374 | - | 15,492 | - | \$1,027,620 | - | \$107,477 |

2.5. ICRs Regarding the Self-Funded Non-Federal Governmental Plan Opt-Out

Provisions (45 CFR 146.180)

2.5.1. Notice to Federal Government of Self-Funded Non-Federal Governmental

Plan Opt-Out: Plan Burden Reduction - Preparation and Processing of Opt-Out Election Notice

The regulatory amendments to implement a provision in the CAA, 2023 that sunsets the election option for sponsors of self-funded non-Federal governmental plans to opt out of requirements under MHPAEA eliminate the need for sponsors to submit a notice to the Federal Government regarding their plan’s opt-out election (or, for sponsors of multiple plans, their plans’ opt-out elections), as long as the sponsors do not elect to permissibly opt out of other requirements.⁴³⁶ HHS estimates that sponsors of 185 plans will no longer need to submit a notice to the Federal Government regarding their plan’s opt-out election. HHS estimates that for each self-funded non-Federal governmental plan whose sponsor has elected to opt out of the requirements, a compensation and benefits manager will need 15 minutes annually to fill out and

⁴³⁶ Based on the HIPAA opt-out filings, sponsors of 46 self-funded non-Federal governmental plans permissibly opt out of other requirements (standards relating to benefits for mothers and newborns, required coverage for reconstructive surgery following mastectomies, and/or coverage of dependent students on medically necessary leave of absence).

electronically submit the model notification form to HHS.⁴³⁷ See Table 14 for calculations and cost savings.

These amendments also generate cost savings for the Federal Government, as HHS will no longer have to process the opt-out notices submitted by plan sponsors. The processing of the opt-out notices is performed by an HHS employee. The average labor rate for the employee who completes this task, which includes the locality pay adjustment for the area of Washington-Baltimore-Arlington, and the cost of fringe benefits and other indirect costs, is \$113.04 per hour for a GS-13, step 1 employee.⁴³⁸ HHS estimates that on average it takes an HHS employee 15 minutes to process an opt-out notice submitted by a plan sponsor. See Table 15 for calculations and cost savings.

*2.5.2. Notice to Plan Participants of Self-Funded Non-Federal Governmental Plan
Opt-Out: Plan Burden Reduction - Preparation and Processing of Opt-Out
Election Notice*

The regulatory amendments to implement the provision in the CAA, 2023 that sunsets the election option for sponsors of self-funded non-Federal governmental plans to opt out of requirements under MHPAEA also eliminate the need for those sponsors to prepare and disseminate an opt-out notice to plan participants regarding their plan sponsors' opt-out election, as long as the sponsors do not elect to permissibly opt out of other requirements. HHS estimates that sponsors of 185 plans will no longer need to prepare and disseminate an opt-out notice to plan participants. HHS estimates that for each self-funded non-Federal governmental plan whose sponsor has elected to opt out of the requirements under MHPAEA, an administrative assistant will need 15 minutes to develop and update the HHS standardized disclosure statement annually.

⁴³⁷ This includes the time required by the individual signing the certification to conduct a thorough review of the election contents.

⁴³⁸ See Office of Personnel Management, *2024 General Schedule (GS) Locality Pay Tables*, https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/DCB_h.pdf.

Further, self-funded non-Federal governmental plan sponsors will no longer be required to print and mail the opt-out notice to plan participants and will therefore no longer incur costs associated with this requirement. As noted earlier in section IV.5.2 of the regulatory impact analysis, HHS estimates that there are approximately 261 participants in each self-funded non-Federal governmental plan, and therefore approximately 48,285 notices⁴³⁹ will no longer have to be printed and mailed. See Table 15 for calculations and cost savings.

The burden related to HIPAA opt-outs is currently approved under OMB Control Number 0938-0702.⁴⁴⁰ HHS will update the information collection to account for this burden reduction.

Table 15. Cost Savings of Preparing and Distributing Opt-Out Election Notice

| | Number of Responses | Number of Hours per Entity | Total Hour Burden | Wage Rate | Mailing Cost per Response | Cost Savings |
|--|---------------------|----------------------------|-------------------|-----------|---------------------------|------------------------|
| | (A) | (B) | (A × B) | (C) | (D) | (A × B × C) or (A × D) |
| General operation managers preparing and processing of opt-out election notice to Federal Government | 185 | 0.25 | 46 | \$131.14 | - | \$6,032 |
| Clerical workers preparing and processing of opt-out election notice to plan participants | 185 | 0.25 | 46 | \$42.58 | - | \$1,959 |
| Clerical workers distributing opt-out election notice to plan participants | 48,285 | - | - | - | \$0.05 | \$2,414 |
| Total | 48,470 | - | 92 | - | - | \$10,405 |

2.6. Overall Summary

In summary, the total new burden imposed by these final rules regarding NQTL comparative analyses and compliance, has a 3-year average hour burden of approximately 1,003,332 hours with an equivalent cost of approximately \$166,471,063 and a total cost burden

⁴³⁹ This estimate is calculated as follows: 185 plans × 261 participants per plan on average = 48,285 notices in total.

⁴⁴⁰ CMS-10430, *Information Collection Requirements for Compliance with Individual and Group Market Reforms under Title XXVII of the Public Health Service Act.*

of approximately \$107,447. The final amendments to implement the CAA, 2023 provision that sunsets the MHPAEA opt-out election for sponsors of self-funded non-Federal governmental plans will result in an annual burden reduction of approximately 92 hours with an equivalent annual cost savings of approximately \$7,991 and total cost savings of approximately \$10,405.

A summary of the change in paperwork burden estimates follows:

Type of Review: Revision

Agency: Centers for Medicare & Medicaid Services, U.S. Department of Health and Human Services.

Title: Non-Quantitative Treatment Limitation Analyses and Compliance Under MHPAEA

OMB Control Number: 0938-1393

Affected Public: Businesses or other for-profits, Not-for-profit institutions, State, Local, or Tribal Governments

Estimated Number of Respondents: 92,457

Estimated Number of Annual Responses: 189,709

Frequency of Response: Annual

Estimated Total Annual Burden Hours: 1,003,332

Estimated Total Annual Burden Cost: \$107,447

Title: Requirements for Compliance with Individual and Group Market Reforms under Title XXVII of the Public Health Service Act

OMB Control Number: 0938-0702

Affected Public: State, Local, or Tribal Governments

Estimated Number of Respondents: (185)

Estimated Number of Annual Responses: (185)

Frequency of Response: Annual

Estimated Total Annual Burden Hours: (92)

Estimated Total Annual Burden Cost: (\$2,414)

Note: Numbers in parentheses denote a burden reduction.

VI. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)⁴⁴¹ imposes certain requirements with respect to Federal rules that are subject to the notice-and-comment requirements of section 553(b) of the Administrative Procedure Act and are likely to have a significant economic impact on a substantial number of small entities. Unless the head of an agency determines that a final rule is not likely to have a significant economic impact on a substantial number of small entities, section 604⁴⁴² of the RFA requires the agency to present a final regulatory flexibility analysis of these final rules.

The Departments certify that these final rules will not have a significant impact on a substantial number of small entities. The Departments have prepared the following justification for this determination.

1. Need for and Objectives of the Rule

As documented in the 2022 MHPAEA Report to Congress and the 2023 MHPAEA Comparative Analysis Report to Congress,⁴⁴³ the Departments found that none of the NQTL comparative analyses they reviewed upon initial receipt contained sufficient information and documentation.

⁴⁴¹ 5 U.S.C. 601 *et seq.* (1980).

⁴⁴² 5 U.S.C. 604 (1980).

⁴⁴³ *2022 MHPAEA Report to Congress*, <https://www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2022-realizing-parity-reducing-stigma-and-raising-awareness.pdf>; *2023 MHPAEA Comparative Analysis Report to Congress*, www.dol.gov/sites/dolgov/files/EBSA/laws-and-regulations/laws/mental-health-parity/report-to-congress-2023-mhpaea-comparative-analysis.pdf.

These final rules clarify existing definitions, add new definitions of key terms, and provide additional examples of the application of MHPAEA to NQTLs to improve the understanding and ability of the regulated community to comply with MHPAEA. The final rules also clarify that plan and issuer definitions of conditions or disorders as mental health conditions and substance use disorders must be consistent with generally recognized independent standards of current medical practice and add more specificity as to what plans and issuers must treat as mental health conditions or substance use disorders. The final rules also require that plans and issuers must provide meaningful benefits for covered mental health conditions or substance use disorders in each such classification in which medical/surgical benefits are provided. These final rules also require plans and issuers to collect and evaluate relevant data in a manner reasonably designed to assess the impact of the NQTL on access to mental health and substance use disorder benefits and medical/surgical benefits. Relevant data for the majority of NQTLs could include, as appropriate, but are not limited to, the number and percentage of claims denials and any other data relevant to the NQTL as required by State law or private accreditation standards. Additionally, for NQTLs related to network composition, relevant data could include, as appropriate, but are not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (for comparable services and as benchmarked to a reference standard). Under these final rules, the Departments may specify the type, form, and manner for the relevant data evaluation requirements in future guidance, which will allow the Departments to adjust the data requirements as needed to account for enforcement experience and industry trends.

These final rules also set more specific content requirements for comparative analyses required by the CAA, 2021, clarify when a comparative analysis needs to be performed and for

which NQTLs, and outline the process for plans and issuers to provide their comparative analyses to the Departments upon request.

The Departments expect that these final rules will result in plans and issuers having a better understanding of the MHPAEA requirements for NQTLs. These final rules will also improve the manner in which parity is measured, compared, and demonstrated by plans and issuers. The Departments are of the view that these final rules will improve the compliance of plans and issuers with these requirements, resulting in greater parity in access to benefits for mental health conditions and substance use disorders as compared with medical/surgical benefits, as intended by MHPAEA.

Additionally, in these final rules, HHS finalizes regulatory amendments to implement a provision in the CAA, 2023 that sunsets the election option for sponsors of self-funded non-Federal governmental plans to opt out of requirements under MHPAEA. HHS is of the view that these regulatory amendments will ultimately increase access to mental health and substance use disorder services, and increase parity of benefits for such services as compared to benefits for medical/surgical services by requiring self-funded non-Federal governmental plans that had previously opted out to come into compliance with the requirements under MHPAEA.

2. Affected Small Entities

For purposes of analysis under the RFA, the Departments consider employee benefit plans with fewer than 100 participants to be small entities. The basis of this definition is found in section 104(a)(2) of ERISA, which permits the Secretary of Labor to prescribe simplified annual reports for plans that cover fewer than 100 participants. Under section 104(a)(3) of ERISA, the Secretary of Labor may also provide for exemptions or simplified annual reporting and disclosure for welfare benefit plans. Under the authority of section 104(a)(3), DOL has previously issued (*see* 29 CFR 2520.104–20, 2520.104–21, 2520.104–41, 2520.104–46, and 2520.104b–10) simplified reporting provisions and limited exemptions from reporting and

disclosure requirements for small plans, including unfunded or insured welfare plans, that cover fewer than 100 participants and satisfy certain requirements. While some large employers have small plans, small plans are maintained generally by small employers. Thus, the Departments are of the view that assessing the impact of these final rules on small plans is an appropriate substitute for evaluating the effect on small entities. The definition of small entity considered appropriate for this purpose differs, however, from the definition of small business based on size standards (revenue or number of employees) issued by the Small Business Administration (SBA) under the Small Business Act.

As discussed in section IV.5.2 of the regulatory impact analysis, these final rules will affect nearly all small ERISA-covered group health plans, including fully insured group health plans and self-funded group health plans, as well as small health insurance issuers and non-Federal governmental plans. The Departments estimate that these final rules will affect approximately 106,000 fully insured plans with 50 to 100 participants,⁴⁴⁴ and approximately 1,719,000 fully insured, non-grandfathered plans with less than 50 participants.⁴⁴⁵

The Departments also estimate that approximately 25,300 self-funded plans with less than 100 participants will be affected by these final rules.⁴⁴⁶ Additionally, the Departments estimate that approximately 18,000 self-funded non-Federal governmental plans with less than

⁴⁴⁴ The Departments estimate that there are 140,998 ERISA-covered group health plans with 50 to 100 participants based on the MEPS-IC and the 2020 County Business Patterns from the Census Bureau. The Departments also estimate that 75 percent of ERISA-covered group health plans with 50 to 100 participants are fully insured based on assumptions referencing these same data. Thus, the Departments have calculated the number of fully insured plans with 50 to 100 participants in the following manner: 140,998 ERISA-covered group health plans with 50 to 100 participants \times 75 percent = 105,749.

⁴⁴⁵ The Departments estimate that there are 2,465,483 ERISA-covered group health plans with less than 50 participants based on data from the 2022 MEPS-IC and the 2020 County Business Patterns from the Census Bureau. The Departments also estimate that 83 percent of group health plans with less than 50 participants are fully insured based on data from the 2022 MEPS-IC. The 2020 KFF Employer Health Benefits Survey reported that in 2020, 16 percent of firms offering health benefits offered at least one grandfathered health plan; therefore, the Departments assume the percent of firms offering at least one non-grandfathered health plan is 84 percent (100 percent – 16 percent). KFF, *2020 Employer Health Benefits Survey* (Oct. 8, 2020), <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf>. Thus, the Departments have calculated the number of fully insured, non-grandfathered plans with less than 50 participants in the following manner: 2,465,483 small ERISA-covered group health plans \times 83 percent \times 84 percent = 1,718,935.

⁴⁴⁶ Estimates based on the 2021 Form 5500 data.

100 participants will also be affected by these final rules.⁴⁴⁷ The Departments assume that these small, self-funded plans will receive assistance with the comparative analyses and data requirements from TPAs or other service providers involved with the plan. Due to many small plans using identical insurance products, these small plans are not expected to be significantly impacted as costs are spread across many small plans.

As discussed in section IV.5.1 of the regulatory impact analysis, these final rules will also affect health insurance issuers. The Departments estimate that these final rules will affect 479 health insurance companies nationwide that provide mental health and substance use disorder benefits in the group and individual health insurance markets, with a total of 1,467 issuers (health insurance company/State combinations).⁴⁴⁸

Health insurance companies are generally classified under the North American Industry Classification System (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of \$47 million or less are considered small entities for this NAICS code.⁴⁴⁹ The Departments expect that few, if any, health insurance companies underwriting health insurance policies fall below these size thresholds. Based on data from MLR annual report submissions for the 2022 MLR reporting year, approximately 87 out of 487 health insurance companies (of which 479 are impacted by these final rules) had total premium revenue of \$47 million or less.⁴⁵⁰ However, it should be noted that

⁴⁴⁷ Based on the 2022 Census of Governments, there are 90,887 non-Federal governmental plans. Based on the 2022 MEPS-IC, the Departments estimate that 36.2 percent of non-Federal governmental plans are self-funded. Thus, 90,887 plans × 36.2 percent = 32,901 self-funded non-Federal governmental plans. Based on the 2021 Form 5500 data, the Departments estimate that 54.6 percent of self-funded health plans with less than 100 participants have filed the Form 5500. The Departments use the percent of self-funded health plans with less than 100 participants that have filed a Form 5500 as a proxy for the percent of self-funded non-Federal governmental plans with less than 100 participants. Thus, 32,901 self-funded non-Federal governmental plans × 54.6 percent = 17,964 self-funded non-Federal governmental plans with less than 100 participants.

⁴⁴⁸ The Departments' estimate of the number of health insurance issuers are based on MLR reports submitted by issuers for the 2022 reporting year. CMS, *Medical Loss Ratio Data and System Resources* (2022), <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr>.

⁴⁴⁹ SBA, *Table of Size Standards*, <https://www.sba.gov/document/support--table-size-standards>, as of March 2023.

⁴⁵⁰ CMS, *Medical Loss Ratio Data and System Resources* (2022), <https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html>.

at least 76 percent of these small companies belong to larger holding groups that may not be small, and many, if not all, of these companies are likely to have non-health lines of business that would result in their revenues exceeding \$47 million.

The amendments to implement the CAA, 2023 provision that sunsets the MHPAEA opt-out election will affect sponsors of self-funded non-Federal governmental plans, some of which might be small entities. As noted in section IV.8.4 of the regulatory impact analysis, the extent to which these plans are out of compliance is unknown, and the costs for them to come into compliance are expected to vary from plan to plan. HHS solicited comments in the proposal on the number of small entities that would be impacted by the implementation of the sunset provision and the potential effects on small entities. HHS did not receive any comments on these estimates.

2.1. Amendments to Existing MHPAEA Regulation (26 CFR 54.9812-1, 29 CFR 2590.712, and 45 CFR 146.136)

These final rules clarify existing definitions, add new definitions, generally ensure that the NQTLs applicable to mental health and substance use disorder benefits are generally no more restrictive than the predominant NQTLs applied to substantially all medical/surgical benefits, and provide additional examples of the application of MHPAEA to NQTLs to improve the understanding and ability of the regulated community to comply with MHPAEA. These final rules also clarify that mental health benefits and substance use disorder benefits must be defined to be consistent with generally recognized independent standards of current medical practice and add more specificity as to what plans and issuers must define as mental health conditions or substance use disorders. The final rules also require that plans and issuers must provide meaningful benefits for covered mental health conditions or substance use disorders in each classification in which medical/ surgical benefits are provided. These final rules also require plans and issuers to collect and evaluate relevant data and include an analysis of the data as part

of each comparative analysis. The Departments are of the view that plans and issuers will incur costs in collecting, preparing, and analyzing the data.

The Departments are of the view that the final amendments might cause small plans and issuers to revise their policies and remove treatment limitations. Therefore, small plans and issuers could incur costs to revise plan provisions, which may result in increased costs from expanded utilization of mental health and substance use disorder services. The Departments face uncertainty in quantifying these costs as they cannot estimate the increase in utilization and which services may see the largest increase in utilization.

2.2 New Regulations (26 CFR 54.9812-2, 29 CFR 2590.712-1, and 45 CFR 146.137 and 146.180)

These final rules codify existing guidance, set more specific content requirements for comparative analyses required by the CAA, 2021, and outline the timeframes and process for plans and issuers to provide their comparative analyses to the Departments upon request. Participants and beneficiaries in ERISA plans may also request a copy of comparative analyses at any time, and all participants, beneficiaries, and enrollees may request a comparative analysis in connection with an adverse benefit determination. Additionally, in these final rules, HHS finalizes regulatory amendments to implement the provision in the CAA, 2023 that sunsets the election option for self-funded non-Federal governmental plans to opt out of requirements under MHPAEA.

In the first year, the Departments estimate that TPAs, MEWAs, issuers, and self-funded group health plans, most if not all of which are large entities, will conduct the comparative analysis themselves will incur an incremental per-entity cost of approximately \$101,600 associated with these final rules. The Departments also estimate an incremental per-entity cost of \$51,300 in the first year for self-funded group health plans that will receive a generic

comparative analysis from their TPA or other service provider and subsequently will customize to suit their specific needs.

In the subsequent years, the Departments estimate that TPAs, MEWAs, issuers, and self-funded group health plans that will conduct the comparative analysis themselves, will incur an incremental per-entity cost of approximately \$20,100 associated with these final rules and amendments. The Departments also estimate an incremental per-entity cost of \$10,100 in subsequent years for self-funded group health plans that will receive a generic comparative analysis from their TPA or other service provider and subsequently will customize it to suit their specific needs.

The Departments note that these per-entity costs are average costs, and these costs are expected to vary by plan or issuer depending on the number of NQTL analyses performed.

3. Comment Summary

In the proposal, commenters expressed concerns that the Departments underestimated the burden of collecting the required data and performing the comparative analyses. One commenter stated that small plans lack access to aggregated claims data. The same commenter suggested that the proposal was burdensome, since it required information that was beyond the possession of small plans. The commenter contended that small employers may decide to stop offering health coverage altogether in favor of having their employees purchase their own individual health insurance coverage through the ACA Exchange, stating that the penalties under the ACA for employers not offering coverage may be preferable compared to the costly requirements under the proposal. The Departments note that there are no such penalties that apply to small employers. The commenter also did not provide any data or evidence.

Another commenter stated that there is a limited market of vendors for conducting the comparative analyses, mentioning that these services could cost upwards of \$100,000. The same commenter expressed concern that the proposal's comparative analysis requirements would

disproportionately consume the health benefits budget of plan sponsors, potentially causing small employers to discontinue offering mental health and substance use disorder benefits. The Departments note that while there is a possibility that some plans and issuers will stop offering mental health and substance use disorder benefits, the Departments anticipate that these final rules will expand the level of coverage for mental health and substance use disorder benefits, which will result in reduced out-of-pocket spending for plan participants, beneficiaries, and enrollees. The Departments also note that the commenter did not cite any data or evidence.

Furthermore, another commenter was concerned that the proposal would disrupt the operations of plans, by forcing plans to change their network composition and eliminate the use of common medical management techniques. The same commenter stated that the burden would fall on small plans, since they may have insufficient resources to cope with this unanticipated cost burden. The commenter did not provide any data or evidence to support these assertions. As discussed earlier in this preamble, these final rules do not eliminate the use of prior authorization or other medical management techniques, but emphasize that they must be developed and used in parity as required by law.

Finally, the Departments did not receive any comments from the Chief Counsel for Advocacy of SBA.

4. Duplicate, Overlapping, or Relevant Federal Rules

There are no duplicate, overlapping, or relevant Federal rules.

VII. Special Analyses – Department of the Treasury

Under the Memorandum of Agreement, Review of Treasury Regulations under Executive Order 12866 (June 9, 2023), tax regulatory actions issued by the Internal Revenue Service (IRS) are not subject to the requirements of section 6 of Executive Order 12866, as amended.

Therefore, a regulatory impact analysis is not required. As required by section 7805(f) of the

Code, these regulations were submitted to the Chief Counsel for Advocacy of SBA for comment on their impact on small business.

VIII. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in an expenditure of \$100 million or more (adjusted annually for inflation with the base year 1995) in any one year by State, local, and Tribal governments, in the aggregate, or by the private sector.⁴⁵¹ For purposes of the UMRA, this rulemaking is expected to have such an impact. For the purposes of this rulemaking, the regulatory impact analysis shall meet the UMRA obligations.

IX. Federalism Statement

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on the States, the relationship between the Federal Government and States, or on the distribution of power and responsibilities among the various levels of government.⁴⁵² Federal agencies promulgating regulations that have federalism implications must consult with State and local officials and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to these final rules.

In the Departments’ view, these final rules have federalism implications because they will have direct effects on the States, on the relationship between the Federal Government and the States, and on the distribution of power and responsibilities among various levels of government. These final rules could also have federalism implications because the Departments

⁴⁵¹ 2 U.S.C. 1501 *et seq.* (1995).

⁴⁵² *Federalism*, 64 FR 153 (Aug. 4, 1999).

remove the reference to State guidelines in the definitions of medical/surgical benefits, mental health benefits, and substance use disorder benefits, and amend these definitions to provide that any condition or procedure defined by the plan or coverage as being or not being a mental health condition or substance use disorder, respectively, must be defined to be consistent with generally recognized independent standards of current medical practice, which for purposes of these final rules are all conditions or disorders under the relevant chapters of the ICD or DSM. Finally, these final rules have federalism implications because the implementation of the CAA, 2023 provision that sunsets the election option for sponsors of self-funded non-Federal governmental plans to opt out of requirements under MHPAEA will require State and local government sponsors of self-funded non-Federal governmental plans that currently opt out of requirements under MHPAEA to come into compliance.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, the preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the MHPAEA requirements are not to be “construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with individual or group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement” of MHPAEA. The conference report accompanying HIPAA indicates that this is intended to be the “narrowest” preemption of State laws. *See* Conf. Rep. No. 104-736, pg. 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018.

States may continue to apply State law requirements except to the extent that such requirements prevent the application of the MHPAEA requirements that are the subject of this

rulemaking. State insurance laws that are more stringent than the Federal requirements are unlikely to “prevent the application of” MHPAEA and be preempted. Accordingly, States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the Federal law.

Throughout the process of developing these final rules, to the extent feasible within the specific preemption provisions of HIPAA as it applies to MHPAEA, the Departments have attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments' view that they have complied with the requirements of Executive Order 13132.

X. Congressional Review Act

In accordance with Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act, 5 U.S.C. 801 et seq.), OIRA has determined that this rule meets the criteria set forth in 5 U.S.C. 804(2). Accordingly, a report containing a copy of the rule along with other specified information has been submitted to each House of the Congress and to the Comptroller General.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 147

Aged, Citizenship and naturalization, Civil rights, Health care, Health insurance, Individuals with disabilities, Intergovernmental relations, Reporting and recordkeeping requirements, Sex discrimination.

Douglas W. O'Donnell,
Deputy Commissioner,
Internal Revenue Service.

Aviva Aron-Dine
Acting Assistant Secretary (Tax Policy),
Department of the Treasury

Lisa M. Gomez,
Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

Accordingly, the Treasury Department and the IRS amend 26 CFR part 54 as follows:

PART 54—PENSION EXCISE TAXES

Paragraph 1. The authority citation for part 54 continues to read as follows:

Authority: 26 U.S.C. 7805 * * *

Par. 2. Amend § 54.9812-1 by:

- a. Redesignating paragraph (a) as paragraph (a)(2) and adding paragraphs (a) heading and (a)(1);
- b. In newly redesignated paragraph (a)(2):
 - i. Revising the introductory text;
 - ii. Adding the definitions of “DSM,” “Evidentiary standards,” “Factors,” and “ICD” in alphabetical order;
 - iii. Revising the definitions of “Medical/surgical benefits” and “Mental health benefits”;
 - iv. Adding the definitions of “Processes” and “Strategies” in alphabetical order; and
 - v. Revising the definitions of “Substance use disorder benefits” and “Treatment limitations”;
- c. Revising paragraphs (c)(1)(ii), (c)(2)(i), and (c)(2)(ii)(A) introductory text;
- d. In paragraph (c)(2)(ii)(C), designating *Examples 1 through 4* as paragraphs (c)(2)(ii)(C)(1) through (4) and revising newly designated paragraphs (c)(2)(ii)(C)(1) through (4);
- e. Adding paragraphs (c)(2)(ii)(C)(5) through (8);

- f. Revising paragraphs (c)(3)(i)(A), (C), and (D);
- g. In paragraph (c)(3)(iii), adding introductory text;
- h. Revising paragraphs (c)(3)(iii)(A) and (B), (c)(3)(iv), (c)(4), (d)(3), (e)(4), and (i)(1); and
- i. Adding paragraph (j).

The revisions and additions read as follows:

§ 54.9812-1 Parity in mental health and substance use disorder benefits.

(a) *Purpose and meaning of terms*—(1) *Purpose*. This section and § 54.9812-2 set forth rules to ensure parity in aggregate lifetime and annual dollar limits, financial requirements, and quantitative and nonquantitative treatment limitations between mental health and substance use disorder benefits and medical/surgical benefits, as required under Code section 9812. A fundamental purpose of Code section 9812, this section, and § 54.9812-2 is to ensure that participants and beneficiaries in a group health plan that offers mental health or substance use disorder benefits are not subject to more restrictive aggregate lifetime or annual dollar limits, financial requirements, or treatment limitations with respect to those benefits than the predominant dollar limits, financial requirements, or treatment limitations that are applied to substantially all medical/surgical benefits covered by the plan in the same classification, as further provided in this section and § 54.9812-2. Accordingly, in complying with the provisions of Code section 9812, this section, and § 54.9812-2, plans must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to mental health or substance use disorder benefits under the plan than they impose on access to medical/surgical benefits in the same classification of benefits. The provisions of

Code section 9812, this section, and § 54.9812-2 should be interpreted in a manner that is consistent with the purpose described in this paragraph (a)(1).

(2) *Meaning of terms.* For purposes of this section and § 54.9812-2, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

* * * * *

DSM means the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders. For the purpose of this definition, the most current version of the DSM as of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** is the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision published in March 2022. A subsequent version of the DSM published after **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is published.

Evidentiary standards are any evidence, sources, or standards that a group health plan considered or relied upon in designing or applying a factor with respect to a nonquantitative treatment limitation, including specific benchmarks or thresholds. Evidentiary standards may be empirical, statistical, or clinical in nature, and include: sources acquired or originating from an objective third party, such as recognized medical literature, professional standards and protocols (which may include comparative effectiveness studies and clinical trials), published research studies, payment rates for items and services (such as publicly available databases of the “usual, customary and reasonable” rates paid for items and services), and clinical treatment guidelines; internal plan data, such as claims or utilization data or criteria for assuring a sufficient mix and number of network providers; and benchmarks or thresholds, such as measures of excessive utilization, cost levels, time or distance standards, or network participation percentage thresholds.

Factors are all information, including processes and strategies (but not evidentiary standards), that a group health plan considered or relied upon to design a nonquantitative treatment limitation, or to determine whether or how the nonquantitative treatment limitation applies to benefits under the plan. Examples of factors include, but are not limited to: provider discretion in determining a diagnosis or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; claim types with a high percentage of fraud; quality measures; treatment outcomes; severity or chronicity of condition; variability in the cost of an episode of treatment; high cost growth; variability in cost and quality; elasticity of demand; and geographic location.

* * * * *

ICD means the World Health Organization's International Classification of Diseases adopted by the Department of Health and Human Services through 45 CFR 162.1002. For the purpose of this definition, the most current version of the ICD as of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** is the International Classification of Diseases, 10th Revision, Clinical Modification adopted for the period beginning on October 1, 2015. Any subsequent version of the ICD adopted through 45 CFR 162.1002 after **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is adopted.

Medical/surgical benefits means benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the group health plan and in accordance with applicable Federal and State law, but does not include mental health benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition or procedure defined by the plan as being or as not being a medical condition or surgical procedure must be defined consistent with generally recognized independent standards of current medical

practice (for example, the most current version of the ICD). To the extent generally recognized independent standards of current medical practice do not address whether a condition or procedure is a medical condition or surgical procedure, plans may define the condition or procedure in accordance with applicable Federal and State law.

Mental health benefits means benefits with respect to items or services for mental health conditions, as defined under the terms of the group health plan and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition defined by the plan as being or as not being a mental health condition must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all conditions covered under the plan, except for substance use disorders, that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a condition is a mental health condition, plans may define the condition in accordance with applicable Federal and State law.

Processes are actions, steps, or procedures that a group health plan uses to apply a nonquantitative treatment limitation, including actions, steps, or procedures established by the plan as requirements in order for a participant or beneficiary to access benefits, including through actions by a participant's or beneficiary's authorized representative or a provider or facility. Examples of processes include, but are not limited to: procedures to submit information to authorize coverage for an item or service prior to receiving the benefit or while treatment is ongoing (including requirements for peer or expert clinical review of that information); provider

referral requirements that are used to determine when and how a participant or beneficiary may access certain services; and the development and approval of a treatment plan used in a concurrent review process to determine whether a specific request should be granted or denied. Processes also include the specific procedures used by staff or other representatives of a plan (or the service provider of a plan) to administer the application of nonquantitative treatment limitations, such as how a panel of staff members applies the nonquantitative treatment limitation (including the qualifications of staff involved, number of staff members allocated, and time allocated), consultations with panels of experts in applying the nonquantitative treatment limitation, and the degree of reviewer discretion in adhering to criteria hierarchy when applying a nonquantitative treatment limitation.

Strategies are practices, methods, or internal metrics that a plan considers, reviews, or uses to design a nonquantitative treatment limitation. Examples of strategies include, but are not limited to: the development of the clinical rationale used in approving or denying benefits; the method of determining whether and how to deviate from generally accepted standards of care in concurrent reviews; the selection of information deemed reasonably necessary to make medical necessity determinations; reliance on treatment guidelines or guidelines provided by third-party organizations in the design of a nonquantitative treatment limitation; and rationales used in selecting and adopting certain threshold amounts to apply a nonquantitative treatment limitation, professional standards and protocols to determine utilization management standards, and fee schedules used to determine provider reimbursement rates, used as part of a nonquantitative treatment limitation. Strategies also include the method of creating and determining the composition of the staff or other representatives of a plan (or the service provider of a plan) that deliberates, or otherwise makes decisions, on the design of nonquantitative treatment limitations, including the plan's methods for making decisions related to the qualifications of staff involved, number of staff members allocated, and time allocated; breadth of sources and evidence

considered; consultations with panels of experts in designing the nonquantitative treatment limitation; and the composition of the panels used to design a nonquantitative treatment limitation.

Substance use disorder benefits means benefits with respect to items or services for substance use disorders, as defined under the terms of the group health plan and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or mental health benefits. Notwithstanding the preceding sentence, any disorder defined by the plan as being or as not being a substance use disorder must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all disorders covered under the plan that fall under any of the diagnostic categories listed as a mental or behavioral disorder due to psychoactive substance use (or equivalent category) in the mental, behavioral and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed as a Substance-Related and Addictive Disorder (or equivalent category) in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a disorder is a substance use disorder, plans may define the disorder in accordance with applicable Federal and State law.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations (such as standards related to network composition), which otherwise limit the scope or duration of benefits for treatment under a plan. (See paragraph (c)(4)(ii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.) A

complete exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

* * * * *

(c) * * *

(1) * * *

(ii) *Type of financial requirement or treatment limitation.* When reference is made in this paragraph (c) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (c)(4)(ii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.

* * * * *

(2) * * *

(i) *General rule.* A group health plan that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. A plan may not impose any financial requirement or treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and not to any medical/surgical benefits in the same benefit classification. The application of the rules of this paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of this

section; the application of the rules of this paragraph (c)(2) to nonquantitative treatment limitations is addressed in paragraph (c)(4) of this section.

(ii) * * *

(A) *In general.* If a plan provides any benefits for a mental health condition or substance use disorder in any classification of benefits described in this paragraph (c)(2)(ii), it must provide meaningful benefits for that mental health condition or substance use disorder in every classification in which medical/surgical benefits are provided. For purposes of this paragraph (c)(2)(ii)(A), whether the benefits provided are meaningful benefits is determined in comparison to the benefits provided for medical conditions and surgical procedures in the classification and requires, at a minimum, coverage of benefits for that condition or disorder in each classification in which the plan provides benefits for one or more medical conditions or surgical procedures. A plan does not provide meaningful benefits under this paragraph (c)(2)(ii)(A) unless it provides benefits for a core treatment for that condition or disorder in each classification in which the plan provides benefits for a core treatment for one or more medical conditions or surgical procedures. For this purpose, a core treatment for a condition or disorder is a standard treatment or course of treatment, therapy, service, or intervention indicated by generally recognized independent standards of current medical practice. If there is no core treatment for a covered mental health condition or substance use disorder with respect to a classification, the plan is not required to provide benefits for a core treatment for such condition or disorder in that classification (but must provide benefits for such condition or disorder in every classification in which medical/surgical benefits are provided). In determining the classification in which a particular benefit belongs, a plan must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a plan provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules

of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations (illustrated in examples in paragraph (c)(2)(ii)(C) of this section). The following classifications of benefits are the only classifications used in applying the rules of this paragraph (c), in addition to the permissible sub-classifications described in paragraph (c)(3)(iii) of this section:

* * * * *

(C) *Examples.* The rules of this paragraph (c)(2)(ii) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits. With regard to these examples, references to any particular core treatment are included for illustrative purposes only. Plans must consult generally recognized independent standards of current medical practice to determine the applicable core treatment, therapy, service, or intervention for any covered condition or disorder.

(1) *Example 1—(i) Facts.* A group health plan offers inpatient and outpatient benefits and does not contract with a network of providers. The plan imposes a \$500 deductible on all benefits. For inpatient medical/surgical benefits, the plan imposes a coinsurance requirement. For outpatient medical/surgical benefits, the plan imposes copayments. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(1) (*Example 1*), because the plan has no network of providers, all benefits provided are out-of-network. Because inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c) apply separately with respect to any financial requirements and treatment limitations, including the deductible, in each classification.

(2) *Example 2—(i) Facts.* A plan imposes a \$500 deductible on all benefits. The plan has no network of providers. The plan generally imposes a 20 percent coinsurance requirement with respect to all benefits, without distinguishing among inpatient, outpatient, emergency care, or prescription drug benefits. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(2) (*Example 2*), because the plan does not impose separate financial requirements (or treatment limitations) based on classification, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance across all benefits.

(3) *Example 3—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(2)(i) of this section (*Example 2*), except the plan exempts emergency care benefits from the 20 percent coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(3) (*Example 3*), because the plan imposes separate financial requirements based on classifications, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance separately for benefits in the emergency care classification and all other benefits.

(4) *Example 4—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(2)(i) of this section (*Example 2*), except the plan also imposes a preauthorization requirement for all inpatient treatment in order for benefits to be paid. No such requirement applies to outpatient treatment.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(4) (*Example 4*), because the plan has no network of providers, all benefits provided are out-of-network. Because the plan imposes a separate treatment limitation based on classifications, the rules of this paragraph (c) apply with respect to the deductible and coinsurance separately for inpatient, out-of-network benefits and all other benefits.

(5) *Example 5—(i) Facts.* A plan covers treatment for autism spectrum disorder (ASD), a mental health condition, and covers outpatient, out-of-network developmental screenings for ASD but excludes all other benefits for outpatient treatment for ASD, including applied behavior analysis (ABA) therapy, when provided on an out-of-network basis. The plan generally covers the full range of outpatient treatments (including core treatments) and treatment settings for medical conditions and surgical procedures when provided on an out-of-network basis. Under the generally recognized independent standards of current medical practice consulted by the plan, developmental screenings alone do not constitute a core treatment for ASD.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(5) (*Example 5*), the plan violates the rules of this paragraph (c)(2)(ii). Although the plan covers benefits for ASD, in the outpatient, out-of-network classification, it only covers developmental screenings, so it does not cover a core treatment for ASD in the classification. Because the plan generally covers the full range of medical/surgical benefits including a core treatment for one or more medical conditions or surgical procedures in the classification, it fails to provide meaningful benefits for treatment of ASD in the classification.

(6) *Example 6—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(5) (*Example 5*) of this section, except that the plan is an HMO that does not cover the full range of medical/surgical benefits, including a core treatment for any medical conditions or surgical procedures in the outpatient, out-of-network classification (except as required under Code sections 9816 and 9817), but covers benefits for medical conditions and surgical procedures in the inpatient, in-network; outpatient, in-network; emergency care; and prescription drug classifications.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(6) (*Example 6*), the plan does not violate the rules of this paragraph (c)(2)(ii). Because the plan does not provide meaningful benefits, including for a core treatment for any medical condition or surgical procedure in the outpatient, out-of-network classification (except as required under Code sections 9816 and 9817), the plan is not required to provide meaningful benefits for any mental health conditions or substance use disorders in that classification. Nevertheless, the plan must provide meaningful benefits for each mental health condition and substance use disorder for which the plan provides benefits in every

classification in which meaningful medical/surgical benefits are provided, as required under paragraph (c)(2)(ii)(A) of this section. This example does not address whether the plan has complied with other applicable requirements of this section in excluding coverage of ABA therapy in the outpatient, out-of-network classification.

(7) *Example 7—(i) Facts.* A plan provides extensive benefits, including for core treatments for many medical conditions and surgical procedures in the outpatient, in-network classification, including nutrition counseling for diabetes and obesity. The plan also generally covers diagnosis and treatment for eating disorders, which are mental health conditions, including coverage for nutrition counseling to treat eating disorders in the outpatient, in-network classification. Nutrition counseling is a core treatment for eating disorders, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(7) (*Example 7*), the plan does not violate the rules of this paragraph (c)(2)(ii). The coverage of diagnosis and treatment for eating disorders, including nutrition counseling, in the outpatient, in-network classification results in the plan providing meaningful benefits for the treatment of eating disorders in the classification, as determined in comparison to the benefits provided for medical conditions or surgical procedures in the classification.

(8) *Example 8—(i) Facts.* A plan provides extensive benefits for the core treatments for many medical conditions and surgical procedures in the outpatient, in-network and prescription drug classifications. The plan provides coverage for diagnosis and treatment for opioid use disorder, a substance use disorder, in the outpatient, in-network classification, by covering counseling and behavioral therapies and, in the prescription drug classification, by covering medications to treat opioid use disorder (MOUD). Counseling and behavioral therapies and MOUD, in combination, are one of the core treatments for opioid use disorder, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(8) (*Example 8*), the plan does not violate the rules of this paragraph (c)(2)(ii). The coverage of counseling and behavioral therapies and MOUD, in combination, in the outpatient, in-network classification and prescription drug classification, respectively, results in the plan providing meaningful benefits for the treatment of opioid use disorder in the outpatient, in-network and prescription drug classifications.

(3) * * *

(i) * * *

(A) *Substantially all.* For purposes of this paragraph (c)(3), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. (For purposes of this paragraph (c)(3)(i)(A), benefits expressed as subject to a zero level of a type of financial requirement are treated as

benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

* * * * *

(C) *Portion based on plan payments.* For purposes of this paragraph (c)(3), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) *Clarifications for certain threshold requirements.* For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of plan payment changes. (See also PHS Act section 2707 and Affordable Care Act section 1302(c), which establish annual limitations on out-of-pocket maximums for all non-grandfathered health plans.)

* * * * *

(iii) *Special rules.* Unless specifically permitted under this paragraph (c)(3)(iii), sub-classifications are not permitted when applying the rules of paragraph (c)(3) of this section.

(A) *Multi-tiered prescription drug benefits.* If a plan applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits, the plan satisfies the parity requirements of this paragraph (c) with respect to prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(B) *Multiple network tiers.* If a plan provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating providers), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect network tiers, if the tiering is based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (such as quality, performance, and market standards) and without regard to whether a provider provides services with respect to medical/surgical benefits or mental health or substance use disorder benefits. After the sub-classifications are established, the plan may not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section.

* * * * *

(iv) *Examples.* The rules of paragraphs (c)(3)(i) through (iii) of this section are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

(A) *Example 1—(1) Facts.* (i) For inpatient, out-of-network medical/surgical benefits, a group health plan imposes five levels of coinsurance. Using a reasonable method, the plan projects its payments for the upcoming year as follows:

Table 1 to Paragraph (c)(3)(iv)(A)(1)(i)

| Coinsurance rate | 0 % | 10% | 15% | 20% | 30% | Total |
|--------------------------------------|--------|----------------------|-----------------------|----------------------|-----------------------|----------|
| Projected payments | \$200x | \$100x | \$450x | \$100x | \$150x | \$1,000x |
| Percent of total plan costs | 20% | 10% | 45% | 10% | 15% | |
| Percent subject to coinsurance level | N/A | 12.5% (100x/800x) | 56.25% (450x/800x) | 12.5% (100x/800x) | 18.75% (150x/800x) | |

(ii) The plan projects plan costs of \$800x to be subject to coinsurance (\$100x + \$450x + \$100x + \$150x = \$800x). Thus, 80 percent (\$800x/\$1,000x) of the benefits are projected to be subject to coinsurance, and 56.25 percent of the benefits subject to coinsurance are projected to be subject to the 15 percent coinsurance level.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(A) (*Example 1*), the two-thirds threshold of the substantially all standard is met for coinsurance because 80 percent of all inpatient, out-of-network medical/surgical benefits are subject to coinsurance. Moreover, the 15 percent coinsurance is the predominant level because it is applicable to more than one-half of inpatient, out-of-network medical/surgical benefits subject to the coinsurance requirement. The plan may not impose any level of coinsurance with respect to inpatient, out-of-network mental health or substance use disorder benefits that is more restrictive than the 15 percent level of coinsurance.

(B) *Example 2—(1) Facts.* (i) For outpatient, in-network medical/surgical benefits, a plan imposes five different copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

Table 2 to Paragraph (c)(3)(iv)(B)(1)(i)

| Copayment amount | \$0 | \$10 | \$15 | \$20 | \$50 | Total |
|-----------------------------|--------|--------|--------|--------|--------|----------|
| Projected payments | \$200x | \$200x | \$200x | \$300x | \$100x | \$1,000x |
| Percent of total plan costs | 20% | 20% | 20% | 30% | 10% | |

| | | | | | | |
|-------------------------------|-----|--------------------|--------------------|----------------------|----------------------|--|
| Percent subject to copayments | N/A | 25% (200x/800x) | 25% (200x/800x) | 37.5% (300x/800x) | 12.5% (100x/800x) | |
|-------------------------------|-----|--------------------|--------------------|----------------------|----------------------|--|

(ii) The plan projects plan costs of \$800x to be subject to copayments ($\$200x + \$200x + \$300x + \$100x = \$800x$). Thus, 80 percent ($\$800x/\$1,000x$) of the benefits are projected to be subject to a copayment.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(B) (*Example 2*), the two-thirds threshold of the substantially all standard is met for copayments because 80 percent of all outpatient, in-network medical/surgical benefits are subject to a copayment. Moreover, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to a copayment (for the \$10 copayment, 25%; for the \$15 copayment, 25%; for the \$20 copayment, 37.5%; and for the \$50 copayment, 12.5%). The plan can combine any levels of copayment, including the highest levels, to determine the predominant level that can be applied to mental health or substance use disorder benefits. If the plan combines the highest levels of copayment, the combined projected payments for the two highest copayment levels, the \$50 copayment and the \$20 copayment, are not more than one-half of the outpatient, in-network medical/surgical benefits subject to a copayment because they are exactly one-half ($\$300x + \$100x = \$400x$; $\$400x/\$800x = 50\%$). The combined projected payments for the three highest copayment levels – the \$50 copayment, the \$20 copayment, and the \$15 copayment – are more than one-half of the outpatient, in-network medical/surgical benefits subject to the copayments ($\$100x + \$300x + \$200x = \$600x$; $\$600x/\$800x = 75\%$). Thus, the plan may not impose any copayment on outpatient, in-network mental health or substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the \$15 copayment.

(C) *Example 3—(1) Facts.* A plan imposes a \$250 deductible on all medical/surgical benefits for self-only coverage and a \$500 deductible on all medical/surgical benefits for family coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(C) (*Example 3*), because the plan has no network of providers, all benefits are provided out-of-network. Because self-only and family coverage are subject to different deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/surgical benefits. Because the coinsurance is applied without regard to coverage units, the predominant coinsurance that applies to substantially all medical/surgical benefits is determined without regard to coverage units.

(D) *Example 4—(1) Facts.* A plan applies the following financial requirements for prescription drug benefits. The requirements are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits. Moreover, the process for certifying a particular drug as “generic”, “preferred brand name”, “non-preferred brand name”, or “specialty” complies with the rules of paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations).

Table 3 to Paragraph (c)(3)(iv)(D)(1)

| | Tier 1 | Tier 2 | Tier 3 | Tier 4 |
|----------------------|---------------|----------------------------|---|-----------------|
| Tier description | Generic drugs | Preferred brand name drugs | Non-preferred brand name drugs (which may have Tier 1 or Tier 2 alternatives) | Specialty drugs |
| Percent paid by plan | 90% | 80% | 60% | 50% |

(2) *Conclusion.* In this paragraph (c)(3)(iv)(D) (*Example 4*), the financial requirements that apply to prescription drug benefits are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits; the process for certifying drugs in different tiers complies with paragraph (c)(4) of this section; and the bases for establishing different levels or types of financial requirements are reasonable. The financial requirements applied to prescription drug benefits do not violate the parity requirements of this paragraph (c)(3).

(E) *Example 5—(1) Facts.* A plan has two-tiers of network of providers: a preferred provider tier and a participating provider tier. Providers are placed in either the preferred tier or participating tier based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section, such as accreditation, quality and performance measures (including customer feedback), and relative reimbursement rates. Furthermore, provider tier placement is determined without regard to whether a provider specializes in the treatment of mental health conditions or substance use disorders, or medical/surgical conditions. The plan divides the in-network classifications into two sub-classifications (in-network/preferred and in-network/participating). The plan does not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(E) (*Example 5*), the division of in-network benefits into sub-classifications that reflect the preferred and participating provider tiers does not violate the parity requirements of this paragraph (c)(3).

(F) *Example 6—(1) Facts.* With respect to outpatient, in-network benefits, a plan imposes a \$25 copayment for office visits and a 20 percent coinsurance requirement for outpatient surgery. The plan divides the outpatient, in-network classification into two sub-classifications (in-network office visits and all other outpatient, in-network items and services). The plan does not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(F) (*Example 6*), the division of outpatient, in-network benefits into sub-classifications for office visits and all other outpatient, in-network items and services does not violate the parity requirements of this paragraph (c)(3).

(G) *Example 7—(1) Facts.* Same facts as in paragraph (c)(3)(iv)(F)(1) of this section (*Example 6*), but for purposes of determining parity, the plan divides the outpatient, in-network classification into outpatient, in-network generalists and outpatient, in-network specialists.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(G) (*Example 7*), the division of outpatient, in-network benefits into any sub-classifications other than office visits and all other outpatient items and services violates the requirements of paragraph (c)(3)(iii)(C) of this section.

* * * * *

(4) *Nonquantitative treatment limitations.* Consistent with paragraph (a)(1) of this section, a group health plan may not impose any nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification. For this purpose, a nonquantitative treatment limitation is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification if the plan fails to meet the requirements of paragraph (c)(4)(i) or (iii) of this section. In such a case, the plan will be considered to violate Code section 9812(a)(3)(A)(ii), and the nonquantitative treatment limitation may not be imposed by the plan with respect to mental health or substance use disorder benefits in the classification.

(i) *Requirements related to design and application of a nonquantitative treatment limitation—(A) In general.* A plan may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan, as written and in operation, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits in the classification.

(B) Prohibition on discriminatory factors and evidentiary standards. For purposes of determining comparability and stringency under paragraph (c)(4)(i)(A) of this section, a plan may not rely upon discriminatory factors or evidentiary standards to design a nonquantitative treatment limitation to be imposed on mental health or substance use disorder benefits. A factor or evidentiary standard is discriminatory if the information, evidence, sources, or standards on which the factor or evidentiary standard are based are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits.

(1) Information, evidence, sources, or standards are considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all the relevant facts and circumstances, the information, evidence, sources, or standards systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. For this purpose, relevant facts and circumstances may include, but are not limited to, the reliability of the source of the information, evidence, sources, or standards, including any underlying data; the independence of the information, evidence, sources, and standards relied upon; the analyses and methodologies employed to select the information and the consistency of their application; and any known safeguards deployed to prevent reliance on skewed data or metrics. Information, evidence, sources, or standards are not considered biased or not objective for this purpose if the plan has taken the steps necessary to correct, cure, or supplement any information, evidence, sources, or standards that would have been biased or not objective in the absence of such steps.

(2) For purposes of paragraph (c)(4)(i)(B) of this section, historical plan data or other historical information from a time when the plan was not subject to Code section 9812 or was not in compliance with Code section 9812 are considered to be biased or not objective in a

manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, if the historical plan data or other historical information systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits, and the plan has not taken the steps necessary to correct, cure, or supplement the data or information.

(3) For purposes of paragraph (c)(4)(i)(B) of this section, generally recognized independent professional medical or clinical standards and carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits are not information, evidence, sources, or standards that are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. However, plans must comply with the other requirements in paragraph (c)(4) of this section, as applicable, with respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation.

(ii) *Illustrative, non-exhaustive list of nonquantitative treatment limitations.*

Nonquantitative treatment limitations include –

(A) Medical management standards (such as prior authorization) limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

(D) Standards related to network composition, including but not limited to, standards for provider and facility admission to participate in a network or for continued network participation,

including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan;

(E) Plan methods for determining out-of-network rates, such as allowed amounts; usual, customary, and reasonable charges; or application of other external benchmarks for out-of-network rates;

(F) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(G) Exclusions based on failure to complete a course of treatment; and

(H) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan.

(iii) *Required use of outcomes data*—(A) *In general*. To ensure that a nonquantitative treatment limitation applicable to mental health or substance use disorder benefits in a classification, in operation, is no more restrictive than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the classification, a plan must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and carefully consider the impact as part of the plan's evaluation. As part of its evaluation, the plan may not disregard relevant outcomes data that it knows or reasonably should know suggest that a nonquantitative treatment limitation is associated with material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits. The Secretary, jointly with the Secretary of Labor and the Secretary of Health and Human Services, may specify in guidance the type, form, and manner of collection and evaluation for the data required under this paragraph (c)(4)(iii)(A).

(1) Relevant data generally. For purposes of this paragraph (c)(4)(iii)(A), relevant data could include, as appropriate, but are not limited to, the number and percentage of claims denials and any other data relevant to the nonquantitative treatment limitation required by State law or private accreditation standards.

(2) Relevant data for nonquantitative treatment limitations related to network composition. In addition to the relevant data set forth in paragraph (c)(4)(iii)(A)(1) of this section, relevant data for nonquantitative treatment limitations related to network composition could include, as appropriate, but are not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (for comparable services and as benchmarked to a reference standard).

(3) Unavailability of data. (i) If a plan newly imposes a nonquantitative treatment limitation for which relevant data is initially temporarily unavailable and the plan therefore cannot comply with paragraph (c)(4)(iii)(A) of this section, the plan must include in its comparative analysis, as required under § 54.9812-2(c)(5)(i)(C), a detailed explanation of the lack of relevant data, the basis for the plan's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed. Such a plan also must comply with paragraph (c)(4)(iii)(A) of this section as soon as practicable once relevant data becomes available.

(ii) If a plan imposes a nonquantitative treatment limitation for which no data exist that can reasonably assess any relevant impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, the plan must include in its comparative analysis, as required under § 54.9812-2(c)(5)(i)(D), a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, why the

nature of the nonquantitative treatment limitation prevents the plan from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the nonquantitative treatment limitation complies with this section. If a plan becomes aware of data that can reasonably assess any relevant impact of the nonquantitative treatment limitation, the plan must comply with paragraph (c)(4)(iii)(A) of this section as soon as practicable.

(iii) Consistent with paragraph (a)(1) of this section, paragraphs (c)(4)(iii)(A)(3)(i) and (ii) of this section shall only apply in very limited circumstances and, where applicable, shall be construed narrowly.

(B) *Material differences.* To the extent the relevant data evaluated under paragraph (c)(4)(iii)(A) of this section suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, such differences will be considered a strong indicator that the plan violates paragraph (c)(4) of this section.

(1) Where the relevant data suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, the plan must take reasonable action, as necessary, to address the material differences to ensure compliance, in operation, with paragraph (c)(4) of this section and must document the actions that have been or are being taken by the plan to address material differences in access to mental health or substance use disorder benefits, as compared to medical/surgical benefits, as required by § 54.9812-2(c)(5)(iv).

(2) For purposes of paragraph (c)(4)(iii)(B) of this section, relevant data are considered to suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all relevant facts and circumstances, and taking into account the considerations outlined

in this paragraph (c)(4)(iii)(B)(2), the difference in the data suggests that the nonquantitative treatment limitation is likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits.

(i) Relevant facts and circumstances, for purposes of this paragraph (c)(4)(iii)(B)(2), may include, but are not limited to, the terms of the nonquantitative treatment limitation at issue, the quality or limitations of the data, causal explanations and analyses, evidence as to the recurring or non-recurring nature of the results, and the magnitude of any disparities.

(ii) Differences in access to mental health or substance use disorder benefits attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits, which are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation, are not considered to be material for purposes of paragraph (c)(4)(iii)(B) of this section. To the extent a plan attributes any differences in access to the application of such standards or measures, the plan must explain the bases for that conclusion in the documentation prepared under § 54.9812-2(c)(5)(iv)(A).

(C) *Nonquantitative treatment limitations related to network composition.* For purposes of applying paragraph (c)(4)(iii)(A) of this section with respect to nonquantitative treatment limitations related to network composition, a plan must collect and evaluate relevant data in a manner reasonably designed to assess the aggregate impact of all such nonquantitative treatment limitations on access to mental health and substance use disorder benefits and medical/surgical benefits. Examples of possible actions that a plan could take to comply with the requirement under paragraph (c)(4)(iii)(B)(1) of this section to take reasonable action, as necessary, to address any material differences in access with respect to nonquantitative treatment limitations

related to network composition, to ensure compliance with paragraph (c)(4) of this section, include, but are not limited to:

(1) Strengthening efforts to recruit and encourage a broad range of available mental health and substance use disorder providers and facilities to join the plan's network of providers, including taking actions to increase compensation or other inducements, streamline credentialing processes, or contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network;

(2) Expanding the availability of telehealth arrangements to mitigate any overall mental health and substance use disorder provider shortages in a geographic area;

(3) Providing additional outreach and assistance to participants and beneficiaries enrolled in the plan to assist them in finding available in-network mental health and substance use disorder providers and facilities; and

(4) Ensuring that provider directories are accurate and reliable.

(iv) *Prohibition on separate nonquantitative treatment limitations applicable only to mental health or substance use disorder benefits.* Consistent with paragraph (c)(2)(i) of this section, a group health plan may not apply any nonquantitative treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and does not apply with respect to any medical/surgical benefits in the same benefit classification.

(v) *Effect of final determination of noncompliance under § 54.9812-2—(A)* If a group health plan receives a final determination from the Secretary that the plan is not in compliance with the requirements of Code section 9812(a)(8) or § 54.9812-2 with respect to a nonquantitative treatment limitation, the nonquantitative treatment limitation violates this paragraph (c)(4) and the Secretary may direct the plan not to impose the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the

relevant classification, unless and until the plan demonstrates to the Secretary compliance with the requirements of this section or takes appropriate action to remedy the violation.

(B) A determination by the Secretary of whether to require cessation of a nonquantitative treatment limitation under this paragraph (c)(4)(v) will be based on an evaluation of the relevant facts and circumstances involved in the specific final determination and the nature of the underlying nonquantitative treatment limitation and will take into account the interest of plan participants and beneficiaries and feedback from the plan.

(vi) *Examples.* The rules of this paragraph (c)(4) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

(A) *Example 1 (Not comparable and more stringent factors for reimbursement rate methodology, in operation)*—(1) *Facts.* A plan's reimbursement rate methodology for outpatient, in-network providers is based on a variety of factors. As written, for mental health, substance use disorder, and medical/surgical benefits, all reimbursement rates for physicians and non-physician practitioners for the same Current Procedural Terminology (CPT) code are based on a combination of factors, such as the nature of the service, duration of the service, intensity and specialization of training, provider licensure and type, number of providers qualified to provide the service in a given geographic area, and market need (demand). In operation, the plan utilizes an additional strategy to further reduce reimbursement rates for mental health and substance use disorder non-physician providers from those paid to mental health and substance use disorder physicians by the same percentage for every CPT code, but does not apply the same reductions for non-physician medical/surgical providers.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(A) (*Example 1*), the plan violates the rules of paragraph (c)(4) of this section. Because the plan reimburses non-physician providers of mental health and substance use disorder services by reducing their reimbursement rate from the rate for physician providers of mental health and substance use disorder services by the same percentage for every CPT code but does not apply the same reductions to non-physician providers of medical/surgical services from the rate for physician providers of medical/surgical services, in operation, the factors used in designing and applying the nonquantitative treatment limitation to mental health and substance use disorder benefits in the outpatient, in-network classification are not comparable to, and are applied more stringently than, the factors used in designing and applying the limitation with respect to medical/surgical benefits in the same classification. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(B) *Example 2 (Strategy for exclusion for experimental or investigative treatment more stringently applied to ABA therapy in operation)*—(1) *Facts*. A plan, as written, generally excludes coverage for all treatments that are experimental or investigative for both medical/surgical benefits and mental health and substance use disorder benefits in the outpatient, in-network classification. As a result, the plan generally excludes, as experimental, a treatment or procedure when no professionally recognized treatment guidelines include the treatment or procedure as a clinically appropriate standard of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment’s use with respect to the given condition or disorder. The plan provides benefits for the treatment of ASD, which is a mental health condition, but, in operation, the plan excludes coverage for ABA therapy to treat children with ASD, deeming it experimental. More than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD and more than two randomized controlled trials are available to support the use of ABA therapy as one intervention to treat certain children with ASD.

(2) *Conclusion*. In this paragraph (c)(4)(vi)(B) (*Example 2*), the plan violates the rules of paragraph (c)(4) of this section. As written, the plan excludes coverage of experimental treatment of medical conditions and surgical procedures, mental health conditions, and substance use disorders when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition or disorder as including the treatment or procedure at issue, and fewer than two randomized controlled trials are available to support the treatment’s use with respect to the given condition or procedure. However, in operation, the plan deviates from this strategy with respect to ABA therapy because more than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD as including ABA therapy to treat certain children with ASD and more than two randomized controlled trials are available to support the use of ABA therapy to treat certain children with ASD. Therefore, in operation, the strategy used to design the nonquantitative treatment limitation for benefits for the treatment of ASD, which is a mental health condition, in the outpatient, in-network classification is not comparable to, and is applied more stringently than, the strategy used to design the nonquantitative treatment limitation for medical/surgical benefits in the same classification. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(C) *Example 3 (Step therapy protocol with exception for severe or irreversible consequences, discriminatory factor)*—(1) *Facts*. A plan’s written terms include a step therapy protocol that requires participants and beneficiaries who are prescribed certain drugs to try and fail a generic or preferred brand name drug before the plan will cover the drug originally prescribed by a participant’s or beneficiary’s attending provider. The plan provides an exception to this protocol that was developed solely based on a methodology developed by an external third-party organization. The third-party organization’s methodology, which is not based on a generally recognized independent professional medical or clinical standard, identifies instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences. However, with respect to a drug prescribed for a mental health condition or a substance use disorder, the third-party organization’s methodology only identifies instances in which a delay in treatment could result in both severe and irreversible consequences, and the plan does not take any steps to correct, cure, or supplement the methodology.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(C) (*Example 3*), the plan violates the rules of paragraph (c)(4)(i)(B) of this section. The source upon which the factor used to apply the step therapy protocol is based is biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits because it addresses instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences, but only addresses instances in which a delay in treatment with a drug prescribed for a mental health condition or substance use disorder could result in both severe and irreversible consequences, and the plan fails to take the steps necessary to correct, cure, or supplement the methodology so that it is not biased and is objective. Based on the relevant facts and circumstances, this source systematically disfavors access or is specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. Therefore, the factor used to apply the step therapy protocol is discriminatory for purposes of determining comparability and stringency under paragraph (c)(4)(i)(A) of this section, and may not be relied upon by the plan.

(D) *Example 4 (Use of historical plan data and plan steps to correct, cure, or supplement)*—(I) *Facts.* A plan’s methodology for calculating provider reimbursement rates relies only on historical plan data on total plan spending for each specialty, divided between mental health and substance use disorder providers and medical/surgical providers, from a time when the plan was not subject to Code section 9812. The plan has used these historical plan data for many years to establish base reimbursement rates in all provider specialties for which it provides medical/surgical, mental health, and substance use disorder benefits in the inpatient, in-network classification. In evaluating the use of these historical plan data in the design of the methodology for calculating provider reimbursement rates, the plan determined, based on all the relevant facts and circumstances, that the historical plan data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. To ensure this information about historical reimbursement rates is not biased and is objective, the plan supplements its methodology to develop the base reimbursement rates for mental health and substance use disorder providers in accordance with additional information, evidence, sources, and standards that reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification and to attract sufficient mental health and substance use disorder providers to the network, so that the relevant facts and circumstances indicate the supplemented information, evidence, sources, or standards do not systematically disfavor access and are not specifically designed to disfavor access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(D) (*Example 4*), the plan does not violate the rules of paragraph (c)(4)(i)(B) of this section with respect to the plan’s methodology for calculating provider reimbursement rates in the inpatient, in-network classification. The relevant facts and circumstances indicate that the plan’s use of only historical plan data to design its methodology for calculating provider reimbursement rates in the inpatient, in-network classification would otherwise be considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits under paragraph (c)(4)(i)(B)(2) of this section, since the historical data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. However, the plan took the steps necessary to supplement the information, evidence, sources, and standards to reasonably reflect the increased demand for mental health and substance use disorder benefits in

the inpatient, in-network classification, and adjust the methodology to increase reimbursement rates for those benefits, thereby ensuring that the information, evidence, sources, and standards relied upon by the plan for this purpose are not biased and are objective. Therefore, the factors and evidentiary standards used to design the plan's methodology for calculating provider reimbursement rates in the inpatient, in-network classification are not discriminatory.

(E) *Example 5 (Generally recognized independent professional medical or clinical standards and more stringent prior authorization requirement in operation)*—(1) *Facts*. The provisions of a plan state that it relies on, and does not deviate from, generally recognized independent professional medical or clinical standards to inform the factor used to design prior authorization requirements for both medical/surgical and mental health and substance use disorder benefits in the prescription drug classification. The generally recognized independent professional medical standard for treatment of opioid use disorder that the plan utilizes—in this case, the American Society of Addiction Medicine national practice guidelines—does not support prior authorization every 30 days for buprenorphine/naloxone. However, in operation, the plan requires prior authorization for buprenorphine/naloxone combination for treatment of opioid use disorder, every 30 days, which is inconsistent with the generally recognized independent professional medical standard on which the factor used to design the limitation is based. The plan's factor used to design prior authorization requirements for medical/surgical benefits in the prescription drug classification relies on, and does not deviate from, generally recognized independent professional medical or clinical standards.

(2) *Conclusion*. In this paragraph (c)(4)(vi)(E) (*Example 5*), the plan violates the rules of paragraph (c)(4) of this section. The American Society of Addiction Medicine national practice guidelines on which the factor used to design prior authorization requirements for substance use disorder benefits is based are generally recognized independent professional medical or clinical standards that are not considered to be biased or not objective in a manner that discriminates against mental health and substance use disorder benefits under paragraph (c)(4)(i)(B)(3) of this section. However, the plan must comply with other requirements in paragraph (c)(4) of this section, as applicable, with respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation. In operation, the plan's factor used to design and apply prior authorization requirements with respect to substance use disorder benefits is not comparable to, and is applied more stringently than, the same factor used to design and apply prior authorization requirements for medical/surgical benefits, because the factor relies on, and does not deviate from, generally recognized independent professional medical or clinical standards for medical/surgical benefits, but deviates from the relevant guidelines for substance use disorder benefits. As a result, the nonquantitative treatment limitation with respect to substance use disorder benefits in the prescription drug classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(F) *Example 6 (Plan claims no data exist to reasonably assess impact of nonquantitative treatment limitation on access; medical necessity criteria)*—(1) *Facts*. A plan approves or denies claims for mental health and substance use disorder benefits and for medical/surgical benefits in the inpatient, in-network and outpatient, in-network classifications based on medical necessity criteria. The plan states in its comparative analysis that no data exist that can reasonably assess any relevant impact of the medical necessity criteria nonquantitative treatment limitation on relevant outcomes related to access to mental health or substance use disorder benefits as compared to the plan's medical necessity criteria nonquantitative treatment limitation's impact

on relevant outcomes related to access to medical/surgical benefits in the relevant classifications, without further explanation.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(F) (*Example 6*), the plan violates paragraph (c)(4) of this section. The plan does not comply with paragraph (c)(4)(iii)(A)(3)(ii) of this section because the plan did not include in its comparative analysis, as required under § 54.9812-2(c)(5)(i)(D), a reasoned justification as to the basis for its conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, an explanation of why the nature of the nonquantitative treatment limitation prevents the plan from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the nonquantitative treatment limitation complies with paragraph (c)(4) of this section. Data that could reasonably assess the medical necessity criteria nonquantitative treatment limitation's impact might include, for example, the number and percentage of claims denials, or the number and percentage of claims that were approved for a lower level of care than the level requested on the initial claim. Therefore, because the plan has not collected and evaluated relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits in the relevant classifications, the plan violates the requirements of paragraph (c)(4)(iii) of this section, and violates the requirements under § 54.9812-2(c)(5)(i)(D) because it did not include sufficient information in its comparative analysis with respect to the lack of relevant data.

(G) *Example 7 (Concurrent review data collection; no material difference in access)*—
(1) *Facts.* A plan follows a written process to apply a concurrent review nonquantitative treatment limitation to all medical/surgical benefits and mental health and substance use disorder benefits within the inpatient, in-network classification. Under this process, a first-level review is conducted in every instance in which concurrent review applies and an authorization request is approved by the first-level reviewer only if the clinical information submitted by the facility meets the plan's criteria for a continued stay. If the first-level reviewer is unable to approve the authorization request because the clinical information submitted by the facility does not meet the plan's criteria for a continued stay, it is sent to a second-level reviewer who will either approve or deny the request. The plan collects relevant data, including the number of referrals to second-level review, and the number of denials of claims for medical/surgical benefits and mental health and substance use disorder benefits subject to concurrent review as compared to the total number of claims subject to concurrent review, in the inpatient, in-network classification. The plan also collects and evaluates the number of denied claims for medical/surgical benefits and mental health and substance use disorder benefits that are overturned on appeal in the inpatient, in-network classification. The plan evaluates the relevant data and determines that, based on the relevant facts and circumstances, the data do not suggest that the concurrent review nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits in the classification. Upon requesting the plan's comparative analysis for the concurrent review nonquantitative treatment limitation and reviewing the relevant data, the Secretary does not request additional data and agrees that the data do not suggest material differences in access.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(G) (*Example 7*), the plan does not violate the rules of paragraph (c)(4)(iii) of this section. The plan collected and evaluated relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and

medical/surgical benefits and considered the impact as part of its evaluation. Because the relevant data evaluated do not suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in the inpatient, in-network classification, under paragraph (c)(4)(iii)(B) of this section, there is no strong indicator that the plan violates paragraph (c)(4) of this section.

(H) *Example 8 (Material difference in access for prior authorization requirement with reasonable action)*—(1) *Facts*. A plan requires prior authorization that a treatment is medically necessary for all inpatient, in-network medical/surgical benefits and for all inpatient, in-network mental health and substance use disorder benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the prior authorization requirement on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits in the inpatient, in-network classification. The plan’s written process for prior authorization states that the plan approves inpatient, in-network benefits for medical conditions and surgical procedures and mental health and substance use disorder benefits for periods of 1, 3, and 7 days, after which a treatment plan must be submitted by the patient’s attending provider and approved by the plan. Approvals for mental health and substance use disorder benefits are most commonly given only for 1 day, after which a treatment plan must be submitted by the patient’s attending provider and approved by the plan. The relevant data show that approvals for 7 days are most common for medical conditions and surgical procedures under this plan. Based on all the relevant facts and circumstances, the difference in the relevant data suggests that the nonquantitative treatment limitation is likely to have a negative impact on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Therefore, the data suggest that the nonquantitative treatment limitation contributes to material differences in access. To address these material differences in access, the plan consults more recent medical guidelines to update the factors that inform its medical necessity nonquantitative treatment limitations. Based on this review, the plan modifies the limitation so that inpatient, in-network prior authorization requests for mental health or substance use disorder benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan includes documentation of this action as part of its comparative analysis.

(2) *Conclusion*. In this paragraph (c)(4)(vi)(H) (*Example 8*), the plan does not violate the rules of paragraph (c)(4)(iii) of this section. While relevant data for the plan’s prior authorization requirements suggested that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to inpatient, in-network medical/surgical benefits under paragraph (c)(4)(iii)(B) of this section, the plan has taken reasonable action, as necessary, to ensure compliance, in operation, with paragraph (c)(4) of this section by updating the factors that inform its prior authorization nonquantitative treatment limitation for inpatient, in-network mental health and substance use disorder benefits so that these benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan also documents its action taken to address material differences in access to inpatient, in-network benefits as required by paragraph (c)(4)(iii)(B)(1) of this section.

(I) *Example 9 (Differences attributable to generally recognized independent professional medical or clinical standards)*—(1) *Facts*. A group health plan develops a medical management requirement for all inpatient, out-of-network benefits for both medical/surgical benefits and mental health and substance use disorder benefits to ensure treatment is medically necessary. The factors and evidentiary standards used to design and apply the medical management requirement

rely on independent professional medical or clinical standards that are generally recognized by health care providers and facilities in relevant clinical specialties. The processes, strategies, evidentiary standards, and other factors used in designing and applying the medical management requirement to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the requirement with respect to medical/surgical benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the medical management nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, and considers the impact as part of the plan's evaluation, as required by paragraph (c)(4)(iii)(A) of this section. Within the inpatient, out-of-network classification, the application of the medical management requirement results in a higher percentage of denials for mental health and substance use disorder claims than medical/surgical claims, because the benefits were found to be medically necessary for a lower percentage of mental health and substance use disorder claims. The plan correctly determines that these differences in access are attributable to the generally recognized independent professional medical or clinical standards used as the basis for the factors and evidentiary standards used to design or apply the limitation and adequately explains the bases for that conclusion as part of its comparative analysis.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(I) (*Example 9*), the plan does not violate the rules of this paragraph (c)(4). Generally recognized independent professional medical or clinical standards of care are not considered to be information, evidence, sources, or standards that are biased and not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, and the plan otherwise complies with the requirements in paragraph (c)(4)(i) of this section. Additionally, the plan does not violate paragraph (c)(4)(iii) of this section because it has collected and evaluated relevant data, the differences in access are attributable to the generally recognized independent professional medical or clinical standards that are used as the basis for the factors and evidentiary standards used to design or apply the medical management nonquantitative treatment limitation, and the plan explains the bases for this conclusion in its comparative analysis. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the inpatient, out-of-network classification is no more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(J) *Example 10 (Material differences in access for standards for provider admission to a network with reasonable action)*—(I) *Facts.* A plan applies nonquantitative treatment limitations related to network composition in the inpatient, in-network and outpatient, in-network classifications. The plan's networks are constructed by separate service providers for medical/surgical benefits and mental health and substance use disorder benefits. The processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations related to network composition for mental health or substance use disorder benefits in the outpatient, in-network and inpatient, in-network classifications are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations with respect to medical/surgical benefits in the classifications, as required under paragraph (c)(4)(i) of this section. In order to ensure, in operation, that the nonquantitative treatment limitations are no more restrictive than the predominant nonquantitative treatment limitations applied to substantially all medical/surgical benefits in the classification, the plan collects and evaluates relevant data in a manner reasonably

designed to assess the aggregate impact of all the nonquantitative treatment limitations related to network composition on relevant outcomes related to access to mental health and substance use disorder benefits as compared with access to medical/surgical benefits and considers the impact as part of the plan's evaluation. The plan considers relevant data that is known, or reasonably should be known, including metrics relating to the time and distance from plan participants and beneficiaries to network providers in rural and urban regions; the number of network providers accepting new patients; the proportions of mental health and substance use disorder and medical/surgical providers and facilities that provide services in rural and urban regions who are in the plan's network; provider reimbursement rates (for comparable services and benchmarked to a reference standard, as appropriate); and in-network and out-of-network utilization rates (including data related to the dollar value and number of provider claims submissions). The plan determines that the relevant data suggest that the nonquantitative treatment limitations in the aggregate contribute to material differences in access to mental health and substance use disorder benefits compared to medical/surgical benefits in the classifications because, based on all the relevant facts and circumstances, the differences in the data suggest that the nonquantitative treatment limitations related to network composition are likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits. The plan takes reasonable actions, as necessary, to address the material differences in access, to ensure compliance, in operation, with paragraph (c)(4) of this section, by strengthening its efforts to recruit and encourage a broad range of available providers and facilities to join the plan's network of providers, including by taking actions to increase compensation and other inducements, streamline credentialing processes, contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network, and develop a process to monitor the effects of such efforts; expanding the availability of telehealth arrangements to mitigate overall provider shortages in certain geographic areas; providing additional outreach and assistance to participants and beneficiaries enrolled in the plan to assist them in finding available in-network providers and facilities; and ensuring that the plan's provider directories are accurate and reliable. The plan documents the efforts that it has taken to address the material differences in access that the data revealed, and the plan includes the documentation as part of its comparative analysis submission.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(J) (*Example 10*), the plan does not violate the rules of this paragraph (c)(4). The plan's nonquantitative treatment limitations related to network composition comply with the rules of paragraph (c)(4)(i) of this section. Additionally, the plan collects and evaluates relevant data, as required under paragraph (c)(4)(iii)(A) of this section, in a manner reasonably designed to assess the aggregate impact of all such nonquantitative treatment limitations on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, as required under paragraph (c)(4)(iii)(C) of this section. While the data suggest that the nonquantitative treatment limitations contribute to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, the plan has taken reasonable action, as necessary, to ensure compliance with paragraph (c)(4) of this section. The plan also documents the actions that have been and are being taken by the plan to address material differences as required by § 54.9812-21(c)(5)(iv). As a result, the network composition nonquantitative treatment limitations with respect to mental health or substance use disorder benefits in the inpatient, in-network and outpatient, in-network classifications are no more restrictive than the predominant nonquantitative treatment limitations that apply to substantially all medical/surgical benefits in the same classifications.

(K) *Example 11 (Separate EAP exhaustion treatment limitation applicable only to mental health or substance use disorder benefits)*—(1) *Facts*. An employer maintains both a major medical plan and an employee assistance program (EAP). The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions, which, together with other benefits provided by the EAP, are not significant benefits in the nature of medical care. Participants are eligible for mental health or substance use disorder benefits under the major medical plan only after exhausting the counseling sessions provided by the EAP. No similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical plan.

(2) *Conclusion*. In this paragraph (c)(4)(vi)(K) (*Example 11*), the requirement that limits eligibility for mental health and substance use disorder benefits under the major medical plan until EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c)(4). Because the limitation does not apply to medical/surgical benefits, it is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits that violates paragraph (c)(4)(iv) of this section. Additionally, this EAP would not qualify as excepted benefits under § 54.9831-1(c)(3)(vi)(B)(I) because participants in the major medical plan are required to use and exhaust benefits under the EAP (making the EAP a gatekeeper) before an individual is eligible for benefits under the plan.

(L) *Example 12 (Separate exclusion for treatment in a residential facility applicable only to mental health and substance use disorder benefits)*—(1) *Facts*. A plan generally covers inpatient, in-network and inpatient, out-of-network treatment without any limitations on setting, including skilled nursing facilities and rehabilitation hospitals, provided other medical necessity standards are satisfied. The plan has an exclusion for treatment at residential facilities, which the plan defines as an inpatient benefit for mental health and substance use disorder benefits. This exclusion was not generated through any broader nonquantitative treatment limitation (such as medical necessity or other clinical guideline).

(2) *Conclusion*. In this paragraph (c)(4)(vi)(L) (*Example 12*), the plan violates the rules of paragraph (c)(4)(iv) of this section. The exclusion of treatment at residential facilities is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits in the inpatient, in-network and inpatient, out-of-network classifications because the plan does not apply a comparable exclusion with respect to any medical/surgical benefits in the same benefit classification.

(M) *Example 13 (Impermissible nonquantitative treatment limitation imposed following a final determination of noncompliance and direction by the Secretary)*—(1) *Facts*. Following an initial request by the Secretary for a plan's comparative analysis of the plan's exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification under § 54.9812-2(d), the plan submits a comparative analysis for the nonquantitative treatment limitation. After review of the comparative analysis, as well as additional information submitted by the plan after the Secretary determines that the plan has not submitted sufficient information to be responsive to the request, the Secretary makes an initial determination that the comparative analysis fails to demonstrate that the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the inpatient, in-network classification are comparable to, and applied no more stringently than, those used in designing and applying the limitation to medical/surgical benefits in the classification. Under § 54.9812-2(d)(3), the plan submits a corrective action plan and additional

comparative analyses within 45 calendar days after the initial determination. However, the corrective action plan does not alter or eliminate the exclusion or alter the processes, strategies, evidentiary standards, and other factors used in designing and applying the exclusion. Moreover, the additional comparative analysis still does not include sufficient information. The Secretary then determines that the additional comparative analyses do not demonstrate compliance with the requirements of this paragraph (c)(4). Accordingly, the plan receives a final determination of noncompliance with Code section 9812(a)(8) and § 54.9812-2 from the Secretary, which concludes that the plan did not demonstrate compliance through the comparative analysis process. After considering the relevant facts and circumstances, and considering the interests of plan participants and beneficiaries, as well as feedback from the plan, the Secretary directs the plan not to impose the nonquantitative treatment limitation by a certain date, unless and until the plan demonstrates compliance to the Secretary or takes appropriate action to remedy the violation. The plan makes no changes to its plan terms by that date and continues to impose the exclusion of benefits for failure to complete a course of treatment in the inpatient, in-network classification.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(M) (*Example 13*), by continuing to impose the exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification after the Secretary directs the plan not to impose this nonquantitative treatment limitation, the plan violates the requirements of paragraph (c)(4)(v) of this section.

* * * * *

(d) * * *

(3) *Provisions of other law.* Compliance with the disclosure requirements in paragraphs (d)(1) and (2) of this section is not determinative of compliance with any other provision of applicable Federal or State law. In particular, in addition to those disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example, ERISA section 104 and 29 CFR 2520.104b-1 of this chapter provide that, for plans subject to ERISA, instruments under which the plan is established or operated must generally be furnished to plan participants within 30 days of request. Instruments under which the plan is established or operated include documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits; the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan;

and the comparative analyses and other applicable information required by § 54.9812-2. In addition, 29 CFR 2560.503-1 and § 54.9815-2719 set forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) who have received an adverse benefit determination (or a final internal adverse benefit determination) to be provided, upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan and the comparative analyses and other applicable information required by § 54.9812-2.

(e) * * *

(4) *Coordination with EHB requirements.* Nothing in paragraph (f) or (g) of this section or § 54.9812-2(g) changes the requirements of 45 CFR 147.150 and 156.115 providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market that is required to provide mental health and substance use disorder services, including behavioral health treatment services, as part of essential health benefits required under 45 CFR 156.110(a)(5) and 156.115(a), must comply with the requirements under section 2726 of the Public Health Service Act and its implementing regulations to satisfy the requirement to provide coverage for mental health and substance use disorder services, including behavioral health treatment, as part of essential health benefits.

* * * * *

(i) * * *

(1) *In general.* Except as provided in paragraph (i)(2) of this section—

(i) This section applies to group health plans on the first day of the first plan year beginning on or after January 1, 2025, except that the requirements of paragraphs (c)(2)(ii)(A), (c)(4)(i)(B), and (c)(4)(iii) of this section apply on the first day of the first plan year beginning on or after January 1, 2026.

(ii) Until the applicability date in paragraph (i)(1)(i) of this section, plans are required to continue to comply with 26 CFR 54.9812-1, revised as of July 1, 2022.

* * * * *

(j) *Severability.* If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

Par. 3. Add § 54.9812-2 to read as follows:

§ 54.9812-2 Nonquantitative treatment limitation comparative analysis requirements.

(a) *Meaning of terms.* Unless otherwise stated in this section, the terms of this section have the meanings indicated in § 54.9812-1(a)(2).

(b) *In general.* In the case of a group health plan that provides both medical/surgical benefits and mental health or substance use disorder benefits and that imposes any nonquantitative treatment limitation on mental health or substance use disorder benefits, the plan must perform and document a comparative analysis of the design and application of each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits. Each comparative analysis must comply with the content requirements of paragraph (c)

of this section and be made available to the Secretary, upon request, in the manner required by paragraphs (d) and (e) of this section.

(c) *Comparative analysis content requirements.* With respect to each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits under a group health plan, the comparative analysis performed by the plan must include, at minimum, the elements specified in this paragraph (c). In addition to the comparative analysis for each nonquantitative treatment limitation, each plan must prepare and make available to the Secretary, upon request, a written list of all nonquantitative treatment limitations imposed under the plan.

(1) *Description of the nonquantitative treatment limitation.* The comparative analysis must include, with respect to the nonquantitative treatment limitation that is the subject of the comparative analysis:

(i) Identification of the nonquantitative treatment limitation, including the specific terms of the plan or other relevant terms regarding the nonquantitative treatment limitation, the policies or guidelines (internal or external) in which the nonquantitative treatment limitation appears or is described, and the applicable sections of any other relevant documents, such as provider contracts, that describe the nonquantitative treatment limitation;

(ii) Identification of all mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation applies, including a list of which benefits are considered mental health or substance use disorder benefits and which benefits are considered medical/surgical benefits; and

(iii) A description of which benefits are included in each classification set forth in § 54.9812-1(c)(2)(ii)(A).

(2) *Identification and definition of the factors and evidentiary standards used to design or apply the nonquantitative treatment limitation.* The comparative analysis must include, with respect to every factor considered or relied upon to design the nonquantitative treatment

limitation or apply the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits:

(i) Identification of every factor considered or relied upon, as well as the evidentiary standards considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived, in determining which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation; and

(ii) A definition of each factor, including:

(A) A detailed description of the factor;

(B) A description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard) identified under paragraph (c)(2)(i) of this section; and

(C) A description of any steps the plan has taken to correct, cure, or supplement any information, evidence, sources, or standards that would otherwise have been considered biased or not objective under § 54.9812-1(c)(4)(i)(B)(I) in the absence of such steps.

(3) *Description of how factors are used in the design and application of the nonquantitative treatment limitation.* The comparative analysis must include a description of how each factor identified and defined under paragraph (c)(2) of this section is used in the design or application of the nonquantitative treatment limitation to mental health and substance use disorder benefits and medical/surgical benefits in a classification, including:

(i) A detailed explanation of how each factor identified and defined in paragraph (c)(2) of this section is used to determine which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation;

(ii) An explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the nonquantitative treatment limitation, including in the determination of whether and

how mental health or substance use disorder benefits or medical/surgical benefits are subject to the nonquantitative treatment limitation;

(iii) If the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designations and qualifications of each decision maker;

(iv) If more than one factor is identified and defined in paragraph (c)(2) of this section, an explanation of:

(A) How all of the factors relate to each other;

(B) The order in which all the factors are applied, including when they are applied;

(C) Whether and how any factors are given more weight than others; and

(D) The reasons for the ordering or weighting of the factors; and

(v) Any deviations or variations from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which each evidentiary standard was derived), such as how the factor is used differently to apply the nonquantitative treatment limitation to mental health or substance use disorder benefits as compared to medical/surgical benefits, and a description of how the plan establishes such deviations or variations.

(4) *Demonstration of comparability and stringency as written.* The comparative analysis must evaluate whether, in any classification, under the terms of the plan as written, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits. The comparative analysis must include, with

respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) Documentation of each factor identified and defined in paragraph (c)(2) of this section that was applied to determine whether the nonquantitative treatment limitation applies to mental health or substance use disorder benefits and medical/surgical benefits in a classification, including, as relevant:

(A) Quantitative data, calculations, or other analyses showing whether, in each classification in which the nonquantitative treatment limitation applies, mental health or substance use disorder benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard to determine that the nonquantitative treatment limitation would or would not apply; and

(B) Records maintained by the plan documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application;

(ii) In each classification in which the nonquantitative treatment limitation applies to mental health or substance use disorder benefits, a comparison of how the nonquantitative treatment limitation, as written, is designed and applied to mental health or substance use disorder benefits and to medical/surgical benefits, including the specific provisions of any forms, checklists, procedure manuals, or other documentation used in designing and applying the nonquantitative treatment limitation or that address the application of the nonquantitative treatment limitation;

(iii) Documentation demonstrating how the factors are comparably applied, as written, to mental health or substance use disorder benefits and medical/surgical benefits in each classification, to determine which benefits are subject to the nonquantitative treatment limitation; and

(iv) An explanation of the reasons for any deviations or variations in the application of a factor used to apply the nonquantitative treatment limitation, or the application of the nonquantitative treatment limitation, to mental health or substance use disorder benefits as compared to medical/surgical benefits, and how the plan establishes such deviations or variations, including:

(A) In the definition of the factors, the evidentiary standards used to define the factors, and the sources from which the evidentiary standards were derived;

(B) In the design of the factors or evidentiary standards; or

(C) In the application or design of the nonquantitative treatment limitation.

(5) *Demonstration of comparability and stringency in operation.* The comparative analysis must evaluate whether, in any classification, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) A comprehensive explanation of how the plan evaluates whether, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits, including:

(A) An explanation of any methodology and underlying data used to demonstrate the application of the nonquantitative treatment limitation, in operation;

(B) The sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation is applicable;

(C) With respect to a nonquantitative treatment limitation for which relevant data is temporarily unavailable as described in § 54.9812-1(c)(4)(iii)(A)(3)(i), a detailed explanation of the lack of relevant data, the basis for the plan's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed; and

(D) With respect to a nonquantitative treatment limitation for which no data exist that can reasonably assess any relevant impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits as described in § 54.9812-1(c)(4)(iii)(A)(3)(ii), a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, an explanation of why the nature of the nonquantitative treatment limitation prevents the plan from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure that the nonquantitative treatment limitation complies with § 54.9812-1(c)(4);

(ii) Identification of the relevant data collected and evaluated, as required under § 54.9812-1(c)(4)(iii)(A);

(iii) Documentation of the outcomes that resulted from the application of the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits, including:

(A) The evaluation of relevant data as required under § 54.9812-1(c)(4)(iii)(A); and

(B) A reasoned justification and analysis that explains why the plan concluded that any differences in the relevant data do or do not suggest the nonquantitative treatment limitation

contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, in accordance with § 54.9812-1(c)(4)(iii)(B)(2);

(iv) A detailed explanation of any material differences in access demonstrated by the outcomes evaluated under paragraph (c)(5)(iii) of this section, including:

(A) A reasoned explanation of any material differences in access that are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation as applied to mental health or substance use disorder benefits and medical/surgical benefits (including any considerations beyond a plan's control that contribute to the existence of material differences) and a detailed explanation of the bases for concluding that material differences are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation; and

(B) To the extent differences in access to mental health or substance use disorder benefits are attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits, and such standards or measures are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation, documentation explaining how any such differences are attributable to those standards or measures, as required in § 54.9812-1(c)(4)(iii)(B)(2)(ii); and

(v) A discussion of the actions that have been or are being taken by the plan to address any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, including the actions the plan has taken or is taking under § 54.9812-1(c)(4)(iii)(B)(1) to address material differences to comply, in operation, with § 54.9812-1(c)(4), including, as applicable:

(A) A reasoned explanation of any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits that persist despite reasonable actions that have been or are being taken; and

(B) For a plan designing and applying one or more nonquantitative treatment limitations related to network composition, a discussion of the actions that have been or are being taken to address material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits, including those listed in § 54.9812-1(c)(4)(iii)(C).

(6) *Findings and conclusions.* The comparative analysis must address the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation, and include:

(i) Any findings or conclusions indicating that the plan is or is not (or might or might not be) in compliance with the requirements of § 54.9812-1(c)(4), including any additional actions the plan has taken or intends to take to address any potential areas of concern or noncompliance;

(ii) A reasoned and detailed discussion of the findings and conclusions described in paragraph (c)(6)(i) of this section;

(iii) Citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described in paragraph (c)(6)(i) of this section not otherwise discussed in the comparative analysis;

(iv) The date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and

(v) If the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan to be an expert, an assessment of each expert's qualifications and the

extent to which the plan ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

(d) *Requirements related to submission of comparative analyses to the Secretary upon request*—(1) *Initial request by the Secretary for comparative analysis.* A group health plan must make the comparative analysis required by paragraph (b) of this section available and submit it to the Secretary within 10 business days of receipt of a request from the Secretary (or an additional period of time specified by the Secretary).

(2) *Additional information required after a comparative analysis is deemed to be insufficient.* In instances in which the Secretary determines that the plan has not submitted sufficient information under paragraph (d)(1) of this section for the Secretary to determine whether the comparative analysis required in paragraph (b) of this section complies with paragraph (c) of this section or whether the plan complies with § 54.9812-1(c)(4), the Secretary will specify to the plan the additional information the plan must submit to the Secretary to be responsive to the request under paragraph (d)(1) of this section. Any such information must be provided to the Secretary by the plan within 10 business days after the Secretary specifies the additional information to be submitted (or an additional period of time specified by the Secretary).

(3) *Initial determination of noncompliance, required action, and corrective action plan.* In instances in which the Secretary reviewed the comparative analysis submitted under paragraph (d)(1) of this section and any additional information submitted under paragraph (d)(2) of this section, and made an initial determination that the plan is not in compliance with the requirements of § 54.9812-1(c)(4) or this section, the plan must respond to the initial determination by the Secretary and specify the actions the plan will take to bring the plan into

compliance, and provide to the Secretary additional comparative analyses meeting the requirements of paragraph (c) of this section that demonstrate compliance with § 54.9812-1(c)(4), not later than 45 calendar days after the Secretary's initial determination that the plan is not in compliance.

(4) *Requirement to notify participants and beneficiaries of final determination of noncompliance*—(i) *In general.* If the Secretary makes a final determination of noncompliance, the plan must notify all participants and beneficiaries enrolled in the plan that the plan has been determined to not be in compliance with the requirements of § 54.9812-1(c)(4) or this section with respect to such plan. Such notice must be provided within 7 business days of receipt of the final determination of noncompliance, and the plan must provide a copy of the notice to the Secretary, any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within the same timeframe.

(ii) *Content of notice.* The notice to participants and beneficiaries required in paragraph (d)(4)(i) of this section shall be written in a manner calculated to be understood by the average plan participant and must include, in plain language, the following information in a standalone notice:

(A) The following statement prominently displayed on the first page, in no less than 14-point font: “Attention! The Department of the Treasury has determined that [insert the name of group health plan] is not in compliance with the Mental Health Parity and Addiction Equity Act.”;

(B) A summary of changes the plan has made as part of its corrective action plan specified to the Secretary following the initial determination of noncompliance, including an explanation of any opportunity for a participant or beneficiary to have a claim for benefits submitted or reprocessed;

(C) A summary of the Secretary's final determination that the plan is not in compliance with § 54.9812-1(c)(4) or this section, including any provisions or practices identified as being in violation of § 54.9812-1(c)(4) or this section, additional corrective actions identified by the Secretary in the final determination notice, and information on how participants and beneficiaries can obtain from the plan a copy of the final determination of noncompliance;

(D) Any additional actions the plan is taking to come into compliance with § 54.9812-1(c)(4) or this section, when the plan will take such actions, and a clear and accurate statement explaining whether the Secretary has concurred with those actions; and

(E) Contact information for questions and complaints, and a statement explaining how participants and beneficiaries can obtain more information about the notice, including:

(1) The plan's phone number and an email or web portal address; and

(2) The Employee Benefits Security Administration's phone number and email or web portal address.

(iii) *Manner of notice.* The plan must make the notice required under paragraph (d)(4)(i) of this section available in paper form, or electronically (such as by email or an Internet posting) if:

(A) The format is readily accessible;

(B) The notice is provided in paper form free of charge upon request; and

(C) In a case in which the electronic form is an internet posting, the plan timely notifies the participant or beneficiary in paper form (such as a postcard) or email, that the documents are available on the internet, provides the internet address, includes the statement required in paragraph (d)(4)(ii)(A) of this section, and notifies the participant or beneficiary that the documents are available in paper form upon request.

(e) *Requests for a copy of a comparative analysis.* In addition to making a comparative analysis available upon request to the Secretary, a plan must make available a copy of the comparative analysis required by paragraph (b) of this section when requested by:

(1) Any applicable State authority; and

(2) A participant or beneficiary (including a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit determination related to mental health or substance use disorder benefits.

(f) *Rule of construction.* Nothing in this section or § 54.9812-1 shall be construed to prevent the Secretary from acting within the scope of existing authorities to address violations of § 54.9812-1 or this section.

(g) *Applicability.* The provisions of this section apply to group health plans described in § 54.9812-1(e), to the extent the plan is not exempt under § 54.9812-1(f) or (g), on the first day of the first plan year beginning on or after January 1, 2025, except the requirements of paragraphs (c)(2)(ii)(C), (c)(5)(i)(C) and (D), and (c)(5)(ii) through (v) of this section apply on the first day of the first plan year beginning on or after January 1, 2026.

(h) *Severability.* If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

For the reasons set forth in the preamble, the Department of Labor amends 29 CFR part 2590 as set forth below:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

4. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a-n, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104-191, 110 Stat. 1936; sec. 401(b), Pub. L. 105-200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110-343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111-148, 124 Stat. 119, as amended by Pub. L. 111-152, 124 Stat. 1029; Division M, Pub. L. 113-235, 128 Stat. 2130; Pub. L. 116-260 134 Stat. 1182; Secretary of Labor’s Order 1-2011, 77 FR 1088 (Jan. 9, 2012).

5. Amend § 2590.712 by:

- a. Redesignating paragraph (a) as paragraph (a)(2) and adding paragraphs (a) heading and (a)(1);
- b. In newly redesignated paragraph (a)(2):
 - i. Revising the introductory text;
 - ii. Adding the definitions of “DSM,” “Evidentiary standards,” “Factors,” and “ICD” in alphabetical order;
 - iii. Revising the definitions of “Medical/surgical benefits” and “Mental health benefits”;
 - iv. Adding the definitions of “Processes” and “Strategies” in alphabetical order; and
 - v. Revising the definitions of “Substance use disorder benefits” and “Treatment limitations”;
- c. Revising paragraphs (c)(1)(ii), (c)(2)(i), and (c)(2)(ii)(A) introductory text;
- d. In paragraph (c)(2)(ii)(C), designating *Examples 1 through 4* as paragraphs

(c)(2)(ii)(C)(1) through (4) and revising newly designated paragraphs (c)(2)(ii)(C)(1) through (4);

e. Adding paragraphs (c)(2)(ii)(C)(5) through (8);

f. Revising paragraphs (c)(3)(i)(A), (C), and (D);

g. In paragraph (c)(3)(iii), adding introductory text;

h. Revising paragraphs (c)(3)(iii)(A) and (B), (c)(3)(iv), (c)(4), (d)(3), (e)(4), and (i)(1); and

i. Adding paragraph (j).

The revisions and additions read as follows:

§ 2590.712 Parity in mental health and substance use disorder benefits.

(a) *Purpose and meaning of terms*—(1) *Purpose*. This section and § 2590.712-1 set forth rules to ensure parity in aggregate lifetime and annual dollar limits, financial requirements, and quantitative and nonquantitative treatment limitations between mental health and substance use disorder benefits and medical/surgical benefits, as required under ERISA section 712. A fundamental purpose of ERISA section 712, this section, and § 2590.712-1 is to ensure that participants and beneficiaries in a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that offers mental health or substance use disorder benefits are not subject to more restrictive aggregate lifetime or annual dollar limits, financial requirements, or treatment limitations with respect to those benefits than the predominant dollar limits, financial requirements, or treatment limitations that are applied to substantially all medical/surgical benefits covered by the plan or coverage in the same classification, as further provided in this section and § 2590.712-1. Accordingly, in complying with the provisions of ERISA section 712, this section, and § 2590.712-1, plans and issuers must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to mental health or substance use disorder benefits under the plan or

coverage than they impose on access to medical/surgical benefits in the same classification of benefits. The provisions of ERISA section 712, this section, and § 2590.712-1 should be interpreted in a manner that is consistent with the purpose described in this paragraph (a)(1).

(2) *Meaning of terms.* For purposes of this section and § 2590.712-1, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

* * * * *

DSM means the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders. For the purpose of this definition, the most current version of the DSM as of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** is the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision published in March 2022. A subsequent version of the DSM published after **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is published.

Evidentiary standards are any evidence, sources, or standards that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon in designing or applying a factor with respect to a nonquantitative treatment limitation, including specific benchmarks or thresholds. Evidentiary standards may be empirical, statistical, or clinical in nature, and include: sources acquired or originating from an objective third party, such as recognized medical literature, professional standards and protocols (which may include comparative effectiveness studies and clinical trials), published research studies, payment rates for items and services (such as publicly available databases of the “usual, customary and reasonable” rates paid for items and services), and clinical treatment guidelines; internal plan or issuer data, such as claims or utilization data or criteria for assuring a sufficient mix and number

of network providers; and benchmarks or thresholds, such as measures of excessive utilization, cost levels, time or distance standards, or network participation percentage thresholds.

Factors are all information, including processes and strategies (but not evidentiary standards), that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon to design a nonquantitative treatment limitation, or to determine whether or how the nonquantitative treatment limitation applies to benefits under the plan or coverage. Examples of factors include, but are not limited to: provider discretion in determining a diagnosis or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; claim types with a high percentage of fraud; quality measures; treatment outcomes; severity or chronicity of condition; variability in the cost of an episode of treatment; high cost growth; variability in cost and quality; elasticity of demand; and geographic location.

* * * * *

ICD means the World Health Organization's International Classification of Diseases adopted by the Department of Health and Human Services through 45 CFR 162.1002. For the purpose of this definition, the most current version of the ICD as of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** is the International Classification of Diseases, 10th Revision, Clinical Modification adopted for the period beginning on October 1, 2015. Any subsequent version of the ICD adopted through 45 CFR 162.1002 after **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is adopted.

Medical/surgical benefits means benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with

applicable Federal and State law, but does not include mental health benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition or procedure defined by the plan or coverage as being or as not being a medical condition or surgical procedure must be defined consistent with generally recognized independent standards of current medical practice (for example, the most current version of the ICD). To the extent generally recognized independent standards of current medical practice do not address whether a condition or procedure is a medical condition or surgical procedure, plans and issuers may define the condition or procedure in accordance with applicable Federal and State law.

Mental health benefits means benefits with respect to items or services for mental health conditions, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition defined by the plan or coverage as being or as not being a mental health condition must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all conditions covered under the plan or coverage, except for substance use disorders, that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a condition is a mental health condition, plans and issuers may define the condition in accordance with applicable Federal and State law.

Processes are actions, steps, or procedures that a group health plan (or health insurance issuer offering coverage in connection with such a plan) uses to apply a nonquantitative

treatment limitation, including actions, steps, or procedures established by the plan or issuer as requirements in order for a participant or beneficiary to access benefits, including through actions by a participant's or beneficiary's authorized representative or a provider or facility. Examples of processes include, but are not limited to: procedures to submit information to authorize coverage for an item or service prior to receiving the benefit or while treatment is ongoing (including requirements for peer or expert clinical review of that information); provider referral requirements that are used to determine when and how a participant or beneficiary may access certain services; and the development and approval of a treatment plan used in a concurrent review process to determine whether a specific request should be granted or denied. Processes also include the specific procedures used by staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) to administer the application of nonquantitative treatment limitations, such as how a panel of staff members applies the nonquantitative treatment limitation (including the qualifications of staff involved, number of staff members allocated, and time allocated), consultations with panels of experts in applying the nonquantitative treatment limitation, and the degree of reviewer discretion in adhering to criteria hierarchy when applying a nonquantitative treatment limitation.

Strategies are practices, methods, or internal metrics that a plan (or health insurance issuer offering coverage in connection with such a plan) considers, reviews, or uses to design a nonquantitative treatment limitation. Examples of strategies include, but are not limited to: the development of the clinical rationale used in approving or denying benefits; the method of determining whether and how to deviate from generally accepted standards of care in concurrent reviews; the selection of information deemed reasonably necessary to make medical necessity determinations; reliance on treatment guidelines or guidelines provided by third-party organizations in the design of a nonquantitative treatment limitation; and rationales used in selecting and adopting certain threshold amounts to apply a nonquantitative treatment limitation,

professional standards and protocols to determine utilization management standards, and fee schedules used to determine provider reimbursement rates, used as part of a nonquantitative treatment limitation. Strategies also include the method of creating and determining the composition of the staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) that deliberates, or otherwise makes decisions, on the design of nonquantitative treatment limitations, including the plan's or issuer's methods for making decisions related to the qualifications of staff involved, number of staff members allocated, and time allocated; breadth of sources and evidence considered; consultations with panels of experts in designing the nonquantitative treatment limitation; and the composition of the panels used to design a nonquantitative treatment limitation.

Substance use disorder benefits means benefits with respect to items or services for substance use disorders, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or mental health benefits. Notwithstanding the preceding sentence, any disorder defined by the plan or coverage as being or as not being a substance use disorder must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all disorders covered under the plan or coverage that fall under any of the diagnostic categories listed as a mental or behavioral disorder due to psychoactive substance use (or equivalent category) in the mental, behavioral and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed as a Substance-Related and Addictive Disorder (or equivalent category) in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not

address whether a disorder is a substance use disorder, plans and issuers may define the disorder in accordance with applicable Federal and State law.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations (such as standards related to network composition), which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. (See paragraph (c)(4)(ii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.) A complete exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

* * * * *

(c) * * *

(1) * * *

(ii) *Type of financial requirement or treatment limitation.* When reference is made in this paragraph (c) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (c)(4)(ii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.

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(2) * * *

(i) *General rule.* A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment

limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. A plan or issuer may not impose any financial requirement or treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and not to any medical/surgical benefits in the same benefit classification. The application of the rules of this paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of this section; the application of the rules of this paragraph (c)(2) to nonquantitative treatment limitations is addressed in paragraph (c)(4) of this section.

(ii) * * *

(A) *In general.* If a plan (or health insurance coverage) provides any benefits for a mental health condition or substance use disorder in any classification of benefits described in this paragraph (c)(2)(ii), it must provide meaningful benefits for that mental health condition or substance use disorder in every classification in which medical/surgical benefits are provided. For purposes of this paragraph (c)(2)(ii)(A), whether the benefits provided are meaningful benefits is determined in comparison to the benefits provided for medical conditions and surgical procedures in the classification and requires, at a minimum, coverage of benefits for that condition or disorder in each classification in which the plan (or coverage) provides benefits for one or more medical conditions or surgical procedures. A plan (or coverage) does not provide meaningful benefits under this paragraph (c)(2)(ii)(A) unless it provides benefits for a core treatment for that condition or disorder in each classification in which the plan (or coverage) provides benefits for a core treatment for one or more medical conditions or surgical procedures.

For this purpose, a core treatment for a condition or disorder is a standard treatment or course of treatment, therapy, service, or intervention indicated by generally recognized independent standards of current medical practice. If there is no core treatment for a covered mental health condition or substance use disorder with respect to a classification, the plan (or coverage) is not required to provide benefits for a core treatment for such condition or disorder in that classification (but must provide benefits for such condition or disorder in every classification in which medical/surgical benefits are provided). In determining the classification in which a particular benefit belongs, a plan (or health insurance issuer) must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a plan (or health insurance coverage) provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations (illustrated in examples in paragraph (c)(2)(ii)(C) of this section). The following classifications of benefits are the only classifications used in applying the rules of this paragraph (c), in addition to the permissible sub-classifications described in paragraph (c)(3)(iii) of this section:

* * * * *

(C) *Examples.* The rules of this paragraph (c)(2)(ii) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits. With regard to these examples, references to any particular core treatment are included for illustrative purposes only. Plans and issuers must consult generally recognized independent standards of current medical practice to determine the applicable core treatment, therapy, service, or intervention for any covered condition or disorder.

(1) *Example 1—(i) Facts.* A group health plan offers inpatient and outpatient benefits and does not contract with a network of providers. The plan imposes a \$500 deductible on all benefits. For inpatient medical/surgical benefits, the plan imposes a coinsurance requirement. For outpatient medical/surgical benefits, the plan imposes copayments. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(1) (*Example 1*), because the plan has no network of providers, all benefits provided are out-of-network. Because inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c) apply separately with respect to any financial requirements and treatment limitations, including the deductible, in each classification.

(2) *Example 2—(i) Facts.* A plan imposes a \$500 deductible on all benefits. The plan has no network of providers. The plan generally imposes a 20 percent coinsurance requirement with respect to all benefits, without distinguishing among inpatient, outpatient, emergency care, or prescription drug benefits. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(2) (*Example 2*), because the plan does not impose separate financial requirements (or treatment limitations) based on classification, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance across all benefits.

(3) *Example 3—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(2)(i) of this section (*Example 2*), except the plan exempts emergency care benefits from the 20 percent coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(3) (*Example 3*), because the plan imposes separate financial requirements based on classifications, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance separately for benefits in the emergency care classification and all other benefits.

(4) *Example 4—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(2)(i) of this section (*Example 2*), except the plan also imposes a preauthorization requirement for all inpatient treatment in order for benefits to be paid. No such requirement applies to outpatient treatment.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(4) (*Example 4*), because the plan has no network of providers, all benefits provided are out-of-network. Because the plan imposes a separate treatment limitation based on classifications, the rules of this paragraph (c) apply with respect to the deductible and coinsurance separately for inpatient, out-of-network benefits and all other benefits.

(5) *Example 5—(i) Facts.* A plan covers treatment for autism spectrum disorder (ASD), a mental health condition, and covers outpatient, out-of-network developmental screenings for ASD but excludes all other benefits for outpatient treatment for ASD, including applied behavior analysis (ABA) therapy, when provided on an out-of-network basis. The plan generally covers the full range of outpatient treatments (including core treatments) and treatment settings for medical conditions and surgical procedures when provided on an out-of-network basis. Under

the generally recognized independent standards of current medical practice consulted by the plan, developmental screenings alone do not constitute a core treatment for ASD.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(5) (*Example 5*), the plan violates the rules of this paragraph (c)(2)(ii). Although the plan covers benefits for ASD in the outpatient, out-of-network classification, it only covers developmental screenings, so it does not cover a core treatment for ASD in the classification. Because the plan generally covers the full range of medical/surgical benefits, including a core treatment for one or more medical conditions or surgical procedures in the classification, it fails to provide meaningful benefits for treatment of ASD in the classification.

(6) *Example 6—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(5) (*Example 5*) of this section, except that the plan is an HMO that does not cover the full range of medical/surgical benefits, including a core treatment for any medical conditions or surgical procedures in the outpatient, out-of-network classification (except as required under ERISA sections 716 and 717), but covers benefits for medical conditions and surgical procedures in the inpatient, in-network; outpatient, in-network; emergency care; and prescription drug classifications.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(6) (*Example 6*), the plan does not violate the rules of this paragraph (c)(2)(ii). Because the plan does not provide meaningful benefits, including for a core treatment for any medical condition or surgical procedure in the outpatient, out-of-network classification (except as required under ERISA sections 716 and 717), the plan is not required to provide meaningful benefits for any mental health conditions or substance use disorders in that classification. Nevertheless, the plan must provide meaningful benefits for each mental health condition and substance use disorder for which the plan provides benefits in every classification in which meaningful medical/surgical benefits are provided as required under paragraph (c)(2)(ii)(A) of this section. This example does not address whether the plan has complied with other applicable requirements of this section in excluding coverage of ABA therapy in the outpatient, out-of-network classification.

(7) *Example 7—(i) Facts.* A plan provides extensive benefits, including for core treatments for many medical conditions and surgical procedures in the outpatient, in-network classification, including nutrition counseling for diabetes and obesity. The plan also generally covers diagnosis and treatment for eating disorders, which are mental health conditions, including coverage for nutrition counseling to treat eating disorders in the outpatient, in-network classification. Nutrition counseling is a core treatment for eating disorders, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(7) (*Example 7*), the plan does not violate the rules of this paragraph (c)(2)(ii). The coverage of diagnosis and treatment for eating disorders, including nutrition counseling, in the outpatient, in-network classification results in the plan providing meaningful benefits for the treatment of eating disorders in the classification, as determined in comparison to the benefits provided for medical conditions or surgical procedures in the classification.

(8) *Example 8—(i) Facts.* A plan provides extensive benefits for the core treatments for many medical conditions and surgical procedures in the outpatient, in-network and prescription drug classifications. The plan provides coverage for diagnosis and treatment for opioid use disorder, a substance use disorder, in the outpatient, in-network classification, by covering counseling and behavioral therapies and, in the prescription drug classification, by covering

medications to treat opioid use disorder (MOUD). Counseling and behavioral therapies and MOUD, in combination, are one of the core treatments for opioid use disorder, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(8) (*Example 8*), the plan does not violate the rules of this paragraph (c)(2)(ii). The coverage of counseling and behavioral therapies and MOUD, in combination, in the outpatient, in-network classification and prescription drug classification, respectively, results in the plan providing meaningful benefits for the treatment of opioid use disorder in the outpatient, in-network and prescription drug classifications.

(3) * * *

(i) * * *

(A) *Substantially all.* For purposes of this paragraph (c)(3), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. (For purposes of this paragraph (c)(3)(i)(A), benefits expressed as subject to a zero level of a type of financial requirement are treated as benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

* * * * *

(C) *Portion based on plan payments.* For purposes of this paragraph (c)(3), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for

the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) *Clarifications for certain threshold requirements.* For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of plan payment changes. (See also PHS Act section 2707 and Affordable Care Act section 1302(c), which establish annual limitations on out-of-pocket maximums for all non-grandfathered health plans.)

* * * * *

(iii) *Special rules.* Unless specifically permitted under this paragraph (c)(3)(iii), subclassifications are not permitted when applying the rules of paragraph (c)(3) of this section.

(A) *Multi-tiered prescription drug benefits.* If a plan (or health insurance coverage) applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits, the plan (or health insurance coverage) satisfies the parity requirements of this paragraph (c) with respect to prescription drug benefits.

Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(B) *Multiple network tiers.* If a plan (or health insurance coverage) provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating providers), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect network tiers, if the tiering is based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (such as quality, performance, and market standards) and without regard to whether a provider provides services with respect to medical/surgical benefits or mental health or substance use disorder benefits. After the sub-classifications are established, the plan or issuer may not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section.

* * * * *

(iv) *Examples.* The rules of paragraphs (c)(3)(i) through (iii) of this section are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

(A) *Example 1—(I) Facts.* (i) For inpatient, out-of-network medical/surgical benefits, a group health plan imposes five levels of coinsurance. Using a reasonable method, the plan projects its payments for the upcoming year as follows:

Table 1 to Paragraph (c)(3)(iv)(A)(I)(i)

| Coinsurance rate | 0 % | 10% | 15% | 20% | 30% | Total |
|--------------------------------------|--------|--------|--------|--------|--------|----------|
| Projected payments | \$200x | \$100x | \$450x | \$100x | \$150x | \$1,000x |
| Percent of total plan costs | 20% | 10% | 45% | 10% | 15% | |
| Percent subject to coinsurance level | N/A | 12.5% | 56.25% | 12.5% | 18.75% | |

| | | | | | |
|--|-------------|-------------|-------------|-------------|--|
| | (100x/800x) | (450x/800x) | (100x/800x) | (150x/800x) | |
|--|-------------|-------------|-------------|-------------|--|

(ii) The plan projects plan costs of \$800x to be subject to coinsurance ($\$100x + \$450x + \$100x + \$150x = \$800x$). Thus, 80 percent ($\$800x/\$1,000x$) of the benefits are projected to be subject to coinsurance, and 56.25 percent of the benefits subject to coinsurance are projected to be subject to the 15 percent coinsurance level.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(A) (*Example 1*), the two-thirds threshold of the substantially all standard is met for coinsurance because 80 percent of all inpatient, out-of-network medical/surgical benefits are subject to coinsurance. Moreover, the 15 percent coinsurance is the predominant level because it is applicable to more than one-half of inpatient, out-of-network medical/surgical benefits subject to the coinsurance requirement. The plan may not impose any level of coinsurance with respect to inpatient, out-of-network mental health or substance use disorder benefits that is more restrictive than the 15 percent level of coinsurance.

(B) *Example 2—(1) Facts.* (i) For outpatient, in-network medical/surgical benefits, a plan imposes five different copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

Table 2 to Paragraph (c)(3)(iv)(B)(1)(i)

| Copayment amount | \$0 | \$10 | \$15 | \$20 | \$50 | Total |
|-------------------------------|--------|--------------------|--------------------|----------------------|----------------------|----------|
| Projected payments | \$200x | \$200x | \$200x | \$300x | \$100x | \$1,000x |
| Percent of total plan costs | 20% | 20% | 20% | 30% | 10% | |
| Percent subject to copayments | N/A | 25% (200x/800x) | 25% (200x/800x) | 37.5% (300x/800x) | 12.5% (100x/800x) | |

(ii) The plan projects plan costs of \$800x to be subject to copayments ($\$200x + \$200x + \$300x + \$100x = \$800x$). Thus, 80 percent ($\$800x/\$1,000x$) of the benefits are projected to be subject to a copayment.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(B) (*Example 2*), the two-thirds threshold of the substantially all standard is met for copayments because 80 percent of all outpatient, in-network medical/surgical benefits are subject to a copayment. Moreover, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to a copayment (for the \$10 copayment, 25%; for the \$15 copayment, 25%; for the \$20 copayment, 37.5%; and for the \$50 copayment, 12.5%). The plan can combine any levels of copayment, including the highest levels, to determine the predominant level that can be applied to mental health or substance use disorder benefits. If the plan combines the highest levels of copayment, the combined projected payments for the two highest copayment levels, the \$50 copayment and the \$20 copayment, are not more than one-half of the outpatient, in-network medical/surgical benefits subject to a copayment because they are exactly one-half ($\$300x + \$100x = \$400x$; $\$400x/\$800x = 50\%$). The combined projected payments for the three highest copayment levels – the \$50 copayment, the \$20 copayment, and the \$15 copayment – are more than one-half of the outpatient, in-network medical/surgical benefits subject to the copayments ($\$100x + \$300x +$

\$200x = \$600x; \$600x/\$800x = 75%). Thus, the plan may not impose any copayment on outpatient, in-network mental health or substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the \$15 copayment.

(C) *Example 3—(1) Facts.* A plan imposes a \$250 deductible on all medical/surgical benefits for self-only coverage and a \$500 deductible on all medical/surgical benefits for family coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(C) (*Example 3*), because the plan has no network of providers, all benefits are provided out-of-network. Because self-only and family coverage are subject to different deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/surgical benefits. Because the coinsurance is applied without regard to coverage units, the predominant coinsurance that applies to substantially all medical/surgical benefits is determined without regard to coverage units.

(D) *Example 4—(1) Facts.* A plan applies the following financial requirements for prescription drug benefits. The requirements are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits. Moreover, the process for certifying a particular drug as “generic”, “preferred brand name”, “non-preferred brand name”, or “specialty” complies with the rules of paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations).

Table 3 to Paragraph (c)(3)(iv)(D)(1)

| | Tier 1 | Tier 2 | Tier 3 | Tier 4 |
|----------------------|---------------|----------------------------|---|-----------------|
| Tier description | Generic drugs | Preferred brand name drugs | Non-preferred brand name drugs (which may have Tier 1 or Tier 2 alternatives) | Specialty drugs |
| Percent paid by plan | 90% | 80% | 60% | 50% |

(2) *Conclusion.* In this paragraph (c)(3)(iv)(D) (*Example 4*), the financial requirements that apply to prescription drug benefits are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits; the process for certifying drugs in different tiers complies with paragraph (c)(4) of this section; and the bases for establishing different levels or types of financial requirements are reasonable. The financial requirements applied to prescription drug benefits do not violate the parity requirements of this paragraph (c)(3).

(E) *Example 5—(1) Facts.* A plan has two -tiers of network of providers: a preferred provider tier and a participating provider tier. Providers are placed in either the preferred tier or participating tier based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section, such as accreditation, quality and performance measures

(including customer feedback), and relative reimbursement rates. Furthermore, provider tier placement is determined without regard to whether a provider specializes in the treatment of mental health conditions or substance use disorders, or medical/surgical conditions. The plan divides the in-network classifications into two sub-classifications (in-network/preferred and in-network/participating). The plan does not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(E) (*Example 5*), the division of in-network benefits into sub-classifications that reflect the preferred and participating provider tiers does not violate the parity requirements of this paragraph (c)(3).

(F) *Example 6—(1) Facts.* With respect to outpatient, in-network benefits, a plan imposes a \$25 copayment for office visits and a 20 percent coinsurance requirement for outpatient surgery. The plan divides the outpatient, in-network classification into two sub-classifications (in-network office visits and all other outpatient, in-network items and services). The plan or issuer does not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(F) (*Example 6*), the division of outpatient, in-network benefits into sub-classifications for office visits and all other outpatient, in-network items and services does not violate the parity requirements of this paragraph (c)(3).

(G) *Example 7—(1) Facts.* Same facts as in paragraph (c)(3)(iv)(F)(1) of this section (*Example 6*), but for purposes of determining parity, the plan divides the outpatient, in-network classification into outpatient, in-network generalists and outpatient, in-network specialists.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(G) (*Example 7*), the division of outpatient, in-network benefits into any sub-classifications other than office visits and all other outpatient items and services violates the requirements of paragraph (c)(3)(iii)(C) of this section.

* * * * *

(4) *Nonquantitative treatment limitations.* Consistent with paragraph (a)(1) of this section, a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) may not impose any nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification. For this purpose, a nonquantitative treatment limitation is more restrictive than the predominant nonquantitative

treatment limitation that applies to substantially all medical/surgical benefits in the same classification if the plan or issuer fails to meet the requirements of paragraph (c)(4)(i) or (iii) of this section. In such a case, the plan (or health insurance coverage) will be considered to violate ERISA section 712(a)(3)(A)(ii), and the nonquantitative treatment limitation may not be imposed by the plan (or health insurance coverage) with respect to mental health or substance use disorder benefits in the classification.

(i) *Requirements related to design and application of a nonquantitative treatment limitation—(A) In general.* A plan (or health insurance coverage) may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage), as written and in operation, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits in the classification.

(B) *Prohibition on discriminatory factors and evidentiary standards.* For purposes of determining comparability and stringency under paragraph (c)(4)(i)(A) of this section, a plan (or health insurance coverage) may not rely upon discriminatory factors or evidentiary standards to design a nonquantitative treatment limitation to be imposed on mental health or substance use disorder benefits. A factor or evidentiary standard is discriminatory if the information, evidence, sources, or standards on which the factor or evidentiary standard are based are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits.

(I) Information, evidence, sources, or standards are considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits

as compared to medical/surgical benefits if, based on all the relevant facts and circumstances, the information, evidence, sources, or standards systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. For this purpose, relevant facts and circumstances may include, but are not limited to, the reliability of the source of the information, evidence, sources, or standards, including any underlying data; the independence of the information, evidence, sources, and standards relied upon; the analyses and methodologies employed to select the information and the consistency of their application; and any known safeguards deployed to prevent reliance on skewed data or metrics. Information, evidence, sources, or standards are not considered biased or not objective for this purpose if the plan or issuer has taken the steps necessary to correct, cure, or supplement any information, evidence, sources, or standards that would have been biased or not objective in the absence of such steps.

(2) For purposes of paragraph (c)(4)(i)(B) of this section, historical plan data or other historical information from a time when the plan or coverage was not subject to ERISA section 712 or was not in compliance with ERISA section 712 are considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, if the historical plan data or other historical information systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits, and the plan or issuer has not taken the steps necessary to correct, cure, or supplement the data or information.

(3) For purposes of paragraph (c)(4)(i)(B) of this section, generally recognized independent professional medical or clinical standards and carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder

benefits are not information, evidence, sources, or standards that are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. However, plans and issuers must comply with the other requirements in paragraph (c)(4) of this section, as applicable, with respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation.

(ii) *Illustrative, non-exhaustive list of nonquantitative treatment limitations.*

Nonquantitative treatment limitations include –

(A) Medical management standards (such as prior authorization) limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

(D) Standards related to network composition, including but not limited to, standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan or coverage;

(E) Plan or issuer methods for determining out-of-network rates, such as allowed amounts; usual, customary, and reasonable charges; or application of other external benchmarks for out-of-network rates;

(F) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(G) Exclusions based on failure to complete a course of treatment; and

(H) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage.

(iii) *Required use of outcomes data—(A) In general.* To ensure that a nonquantitative treatment limitation applicable to mental health or substance use disorder benefits in a classification, in operation, is no more restrictive than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the classification, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and carefully consider the impact as part of the plan's or issuer's evaluation. As part of its evaluation, the plan or issuer may not disregard relevant outcomes data that it knows or reasonably should know suggest that a nonquantitative treatment limitation is associated with material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits. The Secretary, jointly with the Secretary of the Treasury and the Secretary of Health and Human Services, may specify in guidance the type, form, and manner of collection and evaluation for the data required under this paragraph (c)(4)(iii)(A).

(1) *Relevant data generally.* For purposes of this paragraph (c)(4)(iii)(A), relevant data could include, as appropriate, but are not limited to, the number and percentage of claims denials and any other data relevant to the nonquantitative treatment limitation required by State law or private accreditation standards.

(2) *Relevant data for nonquantitative treatment limitations related to network composition.* In addition to the relevant data set forth in paragraph (c)(4)(iii)(A)(1) of this section, relevant data for nonquantitative treatment limitations related to network composition could include, as appropriate, but are not limited to, in-network and out-of-network utilization

rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (for comparable services and as benchmarked to a reference standard).

(3) *Unavailability of data.* (i) If a plan or issuer newly imposes a nonquantitative treatment limitation for which relevant data is initially temporarily unavailable and the plan or issuer therefore cannot comply with paragraph (c)(4)(iii)(A) of this section, the plan or issuer must include in its comparative analysis, as required under § 2590.712-1(c)(5)(i)(C), a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed. Such a plan or issuer also must comply with paragraph (c)(4)(iii)(A) of this section as soon as practicable once relevant data becomes available.

(ii) If a plan or issuer imposes a nonquantitative treatment limitation for which no data exist that can reasonably assess any relevant impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, the plan or issuer must include in its comparative analysis, as required under § 2590.712-1(c)(5)(i)(D), a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, why the nature of the nonquantitative treatment limitation prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the nonquantitative treatment limitation complies with this section. If a plan or issuer becomes aware of data that can reasonably assess any relevant impact of the nonquantitative treatment limitation, the plan or issuer must comply with paragraph (c)(4)(iii)(A) of this section as soon as practicable.

(iii) Consistent with paragraph (a)(1) of this section, paragraphs (c)(4)(iii)(A)(3)(i) and (ii) of this section shall only apply in very limited circumstances and, where applicable, shall be construed narrowly.

(B) *Material differences.* To the extent the relevant data evaluated under paragraph (c)(4)(iii)(A) of this section suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, such differences will be considered a strong indicator that the plan or issuer violates paragraph (c)(4) of this section.

(1) Where the relevant data suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, the plan or issuer must take reasonable action, as necessary, to address the material differences to ensure compliance, in operation, with paragraph (c)(4) of this section and must document the actions that have been or are being taken by the plan or issuer to address material differences in access to mental health or substance use disorder benefits, as compared to medical/surgical benefits, as required by § 2590.712-1(c)(5)(iv).

(2) For purposes of paragraph (c)(4)(iii)(B) of this section, relevant data are considered to suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all relevant facts and circumstances, and taking into account the considerations outlined in this paragraph (c)(4)(iii)(B)(2), the difference in the data suggests that the nonquantitative treatment limitation is likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits.

(i) Relevant facts and circumstances, for purposes of this paragraph (c)(4)(iii)(B)(2), may include, but are not limited to, the terms of the nonquantitative treatment limitation at issue, the

quality or limitations of the data, causal explanations and analyses, evidence as to the recurring or non-recurring nature of the results, and the magnitude of any disparities.

(ii) Differences in access to mental health or substance use disorder benefits attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits, which are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation, are not considered to be material for purposes of paragraph (c)(4)(iii)(B) of this section. To the extent a plan or issuer attributes any differences in access to the application of such standards or measures, the plan or issuer must explain the bases for that conclusion in the documentation prepared under § 2590.712-1(c)(5)(iv)(A).

(C) *Nonquantitative treatment limitations related to network composition.* For purposes of applying paragraph (c)(4)(iii)(A) of this section with respect to nonquantitative treatment limitations related to network composition, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the aggregate impact of all such nonquantitative treatment limitations on access to mental health and substance use disorder benefits and medical/surgical benefits. Examples of possible actions that a plan or issuer could take to comply with the requirement under paragraph (c)(4)(iii)(B)(I) of this section to take reasonable action, as necessary, to address any material differences in access with respect to nonquantitative treatment limitations related to network composition, to ensure compliance with paragraph (c)(4) of this section, include, but are not limited to:

(I) Strengthening efforts to recruit and encourage a broad range of available mental health and substance use disorder providers and facilities to join the plan's or issuer's network of providers, including taking actions to increase compensation or other inducements, streamline

credentialing processes, or contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network;

(2) Expanding the availability of telehealth arrangements to mitigate any overall mental health and substance use disorder provider shortages in a geographic area;

(3) Providing additional outreach and assistance to participants and beneficiaries enrolled in the plan or coverage to assist them in finding available in-network mental health and substance use disorder providers and facilities; and

(4) Ensuring that provider directories are accurate and reliable.

(iv) *Prohibition on separate nonquantitative treatment limitations applicable only to mental health or substance use disorder benefits.* Consistent with paragraph (c)(2)(i) of this section, a group health plan (or health insurance coverage offered by an issuer in connection with such a plan) may not apply any nonquantitative treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and does not apply with respect to any medical/surgical benefits in the same benefit classification.

(v) *Effect of final determination of noncompliance under § 2590.712-1—*(A) If a group health plan (or health insurance issuer offering coverage in connection with a group health plan) receives a final determination from the Secretary that the plan or issuer is not in compliance with the requirements of ERISA section 712(a)(8) or § 2590.712-1 with respect to a nonquantitative treatment limitation, the nonquantitative treatment limitation violates this paragraph (c)(4) and the Secretary may direct the plan or issuer not to impose the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the relevant classification, unless and until the plan or issuer demonstrates to the Secretary compliance with the requirements of this section or takes appropriate action to remedy the violation.

(B) A determination by the Secretary of whether to require cessation of a nonquantitative treatment limitation under this paragraph (c)(4)(v) will be based on an evaluation of the relevant

facts and circumstances involved in the specific final determination and the nature of the underlying nonquantitative treatment limitation and will take into account the interest of plan participants and beneficiaries and feedback from the plan or issuer.

(vi) *Examples.* The rules of this paragraph (c)(4) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

(A) *Example 1 (Not comparable and more stringent factors for reimbursement rate methodology, in operation)*—(1) *Facts.* A plan’s reimbursement rate methodology for outpatient, in-network providers is based on a variety of factors. As written, for mental health, substance use disorder, and medical/surgical benefits, all reimbursement rates for physicians and non-physician practitioners for the same Current Procedural Terminology (CPT) code are based on a combination of factors, such as the nature of the service, duration of the service, intensity and specialization of training, provider licensure and type, number of providers qualified to provide the service in a given geographic area, and market need (demand). In operation, the plan utilizes an additional strategy to further reduce reimbursement rates for mental health and substance use disorder non-physician providers from those paid to mental health and substance use disorder physicians by the same percentage for every CPT code, but does not apply the same reductions for non-physician medical/surgical providers.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(A) (*Example 1*), the plan violates the rules of paragraph (c)(4) of this section. Because the plan reimburses non-physician providers of mental health and substance use disorder services by reducing their reimbursement rate from the rate for physician providers of mental health and substance use disorder services by the same percentage for every CPT code but does not apply the same reductions to non-physician providers of medical/surgical services from the rate for physician providers of medical/surgical services, in operation, the factors used in designing and applying the nonquantitative treatment limitation to mental health and substance use disorder benefits in the outpatient, in-network classification are not comparable to, and are applied more stringently than, the factors used in designing and applying the limitation with respect to medical/surgical benefits in the same classification. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(B) *Example 2 (Strategy for exclusion for experimental or investigative treatment more stringently applied to ABA therapy in operation)*—(1) *Facts.* A plan, as written, generally excludes coverage for all treatments that are experimental or investigative for both medical/surgical benefits and mental health and substance use disorder benefits in the outpatient, in-network classification. As a result, the plan generally excludes, as experimental, a treatment or procedure when no professionally recognized treatment guidelines include the treatment or procedure as a clinically appropriate standard of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment’s use with respect to the

given condition or disorder. The plan provides benefits for the treatment of ASD, which is a mental health condition, but, in operation, the plan excludes coverage for ABA therapy to treat children with ASD, deeming it experimental. More than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD and more than two randomized controlled trials are available to support the use of ABA therapy as one intervention to treat certain children with ASD.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(B) (*Example 2*), the plan violates the rules of paragraph (c)(4) of this section. As written, the plan excludes coverage of experimental treatment of medical conditions and surgical procedures, mental health conditions, and substance use disorders when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition or disorder as including the treatment or procedure at issue, and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or procedure. However, in operation, the plan deviates from this strategy with respect to ABA therapy because more than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD as including ABA therapy to treat certain children with ASD and more than two randomized controlled trials are available to support the use of ABA therapy to treat certain children with ASD. Therefore, in operation, the strategy used to design the nonquantitative treatment limitation for benefits for the treatment of ASD, which is a mental health condition, in the outpatient, in-network classification is not comparable to, and is applied more stringently than, the strategy used to design the nonquantitative treatment limitation for medical/surgical benefits in the same classification. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(C) *Example 3 (Step therapy protocol with exception for severe or irreversible consequences, discriminatory factor)*—(1) *Facts.* A plan's written terms include a step therapy protocol that requires participants and beneficiaries who are prescribed certain drugs to try and fail a generic or preferred brand name drug before the plan will cover the drug originally prescribed by a participant's or beneficiary's attending provider. The plan provides an exception to this protocol that was developed solely based on a methodology developed by an external third-party organization. The third-party organization's methodology, which is not based on a generally recognized independent professional medical or clinical standard, identifies instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences. However, with respect to a drug prescribed for a mental health condition or a substance use disorder, the third-party organization's methodology only identifies instances in which a delay in treatment could result in both severe and irreversible consequences, and the plan does not take any steps to correct, cure, or supplement the methodology.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(C) (*Example 3*), the plan violates the rules of paragraph (c)(4)(i)(B) of this section. The source upon which the factor used to apply the step therapy protocol is based is biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits because it addresses instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences, but only addresses instances in which a delay in treatment with a drug prescribed for a mental health condition or substance use disorder could result in both severe and irreversible consequences,

and the plan fails to take the steps necessary to correct, cure, or supplement the methodology so that it is not biased and is objective. Based on the relevant facts and circumstances, this source systematically disfavors access or is specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. Therefore, the factor used to apply the step therapy protocol is discriminatory for purposes of determining comparability and stringency under paragraph (c)(4)(i)(A) of this section, and may not be relied upon by the plan.

(D) *Example 4 (Use of historical plan data and plan steps to correct, cure, or supplement)*—(1) *Facts*. A plan’s methodology for calculating provider reimbursement rates relies only on historical plan data on total plan spending for each specialty, divided between mental health and substance use disorder providers and medical/surgical providers, from a time when the plan was not subject to ERISA section 712. The plan has used these historical plan data for many years to establish base reimbursement rates in all provider specialties for which it provides medical/surgical, mental health, and substance use disorder benefits in the inpatient, in-network classification. In evaluating the use of these historical plan data in the design of the methodology for calculating provider reimbursement rates, the plan determined, based on all the relevant facts and circumstances, that the historical plan data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. To ensure this information about historical reimbursement rates is not biased and is objective, the plan supplements its methodology to develop the base reimbursement rates for mental health and substance use disorder providers in accordance with additional information, evidence, sources, and standards that reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification and to attract sufficient mental health and substance use disorder providers to the network, so that the relevant facts and circumstances indicate the supplemented information, evidence, sources, or standards do not systematically disfavor access and are not specifically designed to disfavor access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

(2) *Conclusion*. In this paragraph (c)(4)(vi)(D) (*Example 4*), the plan does not violate the rules of paragraph (c)(4)(i)(B) of this section with respect to the plan’s methodology for calculating provider reimbursement rates in the inpatient, in-network classification. The relevant facts and circumstances indicate that the plan’s use of only historical plan data to design its methodology for calculating provider reimbursement rates in the inpatient, in-network classification would otherwise be considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits under paragraph (c)(4)(i)(B)(2) of this section, since the historical data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. However, the plan took the steps necessary to supplement the information, evidence, sources, and standards to reasonably reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification, and adjust the methodology to increase reimbursement rates for those benefits, thereby ensuring that the information, evidence, sources, and standards relied upon by the plan for this purpose are not biased and are objective. Therefore, the factors and evidentiary standards used to design the plan’s methodology for calculating provider reimbursement rates in the inpatient, in-network classification are not discriminatory.

(E) *Example 5 (Generally recognized independent professional medical or clinical standards and more stringent prior authorization requirement in operation)*—(1) *Facts*. The

provisions of a plan state that it relies on, and does not deviate from, generally recognized independent professional medical or clinical standards to inform the factor used to design prior authorization requirements for both medical/surgical and mental health and substance use disorder benefits in the prescription drug classification. The generally recognized independent professional medical standard for treatment of opioid use disorder that the plan utilizes—in this case, the American Society of Addiction Medicine national practice guidelines—does not support prior authorization every 30 days for buprenorphine/naloxone. However, in operation, the plan requires prior authorization for buprenorphine/naloxone combination for treatment of opioid use disorder, every 30 days, which is inconsistent with the generally recognized independent professional medical standard on which the factor used to design the limitation is based. The plan’s factor used to design prior authorization requirements for medical/surgical benefits in the prescription drug classification relies on, and does not deviate from, generally recognized independent professional medical or clinical standards.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(E) (*Example 5*), the plan violates the rules of paragraph (c)(4) of this section. The American Society of Addiction Medicine national practice guidelines on which the factor used to design prior authorization requirements for substance use disorder benefits is based are generally recognized independent professional medical or clinical standards that are not considered to be biased or not objective in a manner that discriminates against mental health and substance use disorder benefits under paragraph (c)(4)(i)(B)(3) of this section. However, the plan must comply with other requirements in paragraph (c)(4) of this section, as applicable, with respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation. In operation, the plan’s factor used to design and apply prior authorization requirements with respect to substance use disorder benefits is not comparable to, and is applied more stringently than, the same factor used to design and apply prior authorization requirements for medical/surgical benefits, because the factor relies on, and does not deviate from, generally recognized independent professional medical or clinical standards for medical/surgical benefits, but deviates from the relevant guidelines for substance use disorder benefits. As a result, the nonquantitative treatment limitation with respect to substance use disorder benefits in the prescription drug classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(F) *Example 6 (Plan claims no data exist to reasonably assess impact of nonquantitative treatment limitation on access; medical necessity criteria)*—(1) *Facts.* A plan approves or denies claims for mental health and substance use disorder benefits and for medical/surgical benefits in the inpatient, in-network and outpatient, in-network classifications based on medical necessity criteria. The plan states in its comparative analysis that no data exist that can reasonably assess any relevant impact of the medical necessity criteria nonquantitative treatment limitation on relevant outcomes related to access to mental health or substance use disorder benefits as compared to the plan’s medical necessity criteria nonquantitative treatment limitation’s impact on relevant outcomes related to access to medical/surgical benefits in the relevant classifications, without further explanation.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(F) (*Example 6*), the plan violates paragraph (c)(4) of this section. The plan does not comply with paragraph (c)(4)(iii)(A)(3)(ii) of this section because the plan did not include in its comparative analysis, as required under § 2590.712-1(c)(5)(i)(D), a reasoned justification as to the basis for its conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation’s impact, an explanation of why

the nature of the nonquantitative treatment limitation prevents the plan from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the nonquantitative treatment limitation complies with paragraph (c)(4) of this section. Data that could reasonably assess the medical necessity criteria nonquantitative treatment limitation's impact might include, for example, the number and percentage of claims denials, or the number and percentage of claims that were approved for a lower level of care than the level requested on the initial claim. Therefore, because the plan has not collected and evaluated relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits in the relevant classifications, the plan violates the requirements of paragraph (c)(4)(iii) of this section, and violates the requirements under § 2590.712-1(c)(5)(i)(D) because it did not include sufficient information in its comparative analysis with respect to the lack of relevant data.

(G) *Example 7 (Concurrent review data collection; no material difference in access)—(1) Facts.* A plan follows a written process to apply a concurrent review nonquantitative treatment limitation to all medical/surgical benefits and mental health and substance use disorder benefits within the inpatient, in-network classification. Under this process, a first-level review is conducted in every instance in which concurrent review applies and an authorization request is approved by the first-level reviewer only if the clinical information submitted by the facility meets the plan's criteria for a continued stay. If the first-level reviewer is unable to approve the authorization request because the clinical information submitted by the facility does not meet the plan's criteria for a continued stay, it is sent to a second-level reviewer who will either approve or deny the request. The plan collects relevant data, including the number of referrals to second-level review, and the number of denials of claims for medical/surgical benefits and mental health and substance use disorder benefits subject to concurrent review as compared to the total number of claims subject to concurrent review, in the inpatient, in-network classification. The plan also collects and evaluates the number of denied claims for medical/surgical benefits and mental health and substance use disorder benefits that are overturned on appeal in the inpatient, in-network classification. The plan evaluates the relevant data and determines that, based on the relevant facts and circumstances, the data do not suggest that the concurrent review nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits in the classification. Upon requesting the plan's comparative analysis for the concurrent review nonquantitative treatment limitation and reviewing the relevant data, the Secretary does not request additional data and agrees that the data do not suggest material differences in access.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(G) (*Example 7*), the plan does not violate the rules of paragraph (c)(4)(iii) of this section. The plan collected and evaluated relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and considered the impact as part of its evaluation. Because the relevant data evaluated do not suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in the inpatient, in-network classification, under paragraph (c)(4)(iii)(B) of this section, there is no strong indicator that the plan violates paragraph (c)(4) of this section.

(H) *Example 8 (Material difference in access for prior authorization requirement with reasonable action)*—(1) *Facts*. A plan requires prior authorization that a treatment is medically necessary for all inpatient, in-network medical/surgical benefits and for all inpatient, in-network mental health and substance use disorder benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the prior authorization requirement on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits in the inpatient, in-network classification. The plan’s written process for prior authorization states that the plan approves inpatient, in-network benefits for medical conditions and surgical procedures and mental health and substance use disorder benefits for periods of 1, 3, and 7 days, after which a treatment plan must be submitted by the patient’s attending provider and approved by the plan. Approvals for mental health and substance use disorder benefits are most commonly given only for 1 day, after which a treatment plan must be submitted by the patient’s attending provider and approved by the plan. The relevant data show that approvals for 7 days are most common for medical conditions and surgical procedures under this plan. Based on all the relevant facts and circumstances, the difference in the relevant data suggests that the nonquantitative treatment limitation is likely to have a negative impact on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Therefore, the data suggest that the nonquantitative treatment limitation contributes to material differences in access. To address these material differences in access, the plan consults more recent medical guidelines to update the factors that inform its medical necessity nonquantitative treatment limitations. Based on this review, the plan modifies the limitation so that inpatient, in-network prior authorization requests for mental health or substance use disorder benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan includes documentation of this action as part of its comparative analysis.

(2) *Conclusion*. In this paragraph (c)(4)(vi)(H) (*Example 8*), the plan does not violate the rules of paragraph (c)(4)(iii) of this section. While relevant data for the plan’s prior authorization requirements suggested that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to inpatient, in-network medical/surgical benefits under paragraph (c)(4)(iii)(B) of this section, the plan has taken reasonable action, as necessary, to ensure compliance, in operation, with paragraph (c)(4) of this section by updating the factors that inform its prior authorization nonquantitative treatment limitation for inpatient, in-network mental health and substance use disorder benefits so that these benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan also documents its action taken to address material differences in access to inpatient, in-network benefits as required by paragraph (c)(4)(iii)(B)(1) of this section.

(I) *Example 9 (Differences attributable to generally recognized independent professional medical or clinical standards)*—(1) *Facts*. A group health plan develops a medical management requirement for all inpatient, out-of-network benefits for both medical/surgical benefits and mental health and substance use disorder benefits to ensure treatment is medically necessary. The factors and evidentiary standards used to design and apply the medical management requirement rely on independent professional medical or clinical standards that are generally recognized by health care providers and facilities in relevant clinical specialties. The processes, strategies, evidentiary standards, and other factors used in designing and applying the medical management requirement to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the requirement with respect to medical/surgical benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the

impact of the medical management nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, and considers the impact as part of the plan's evaluation, as required by paragraph (c)(4)(iii)(A) of this section. Within the inpatient, out-of-network classification, the application of the medical management requirement results in a higher percentage of denials for mental health and substance use disorder claims than medical/surgical claims, because the benefits were found to be medically necessary for a lower percentage of mental health and substance use disorder claims. The plan correctly determines that these differences in access are attributable to the generally recognized independent professional medical or clinical standards used as the basis for the factors and evidentiary standards used to design or apply the limitation and adequately explains the bases for that conclusion as part of its comparative analysis.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(I) (*Example 9*), the plan does not violate the rules of this paragraph (c)(4). Generally recognized independent professional medical or clinical standards of care are not considered to be information, evidence, sources, or standards that are biased and not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, and the plan otherwise complies with the requirements in paragraph (c)(4)(i) of this section. Additionally, the plan does not violate paragraph (c)(4)(iii) of this section because it has collected and evaluated relevant data, the differences in access are attributable to the generally recognized independent professional medical or clinical standards that are used as the basis for the factors and evidentiary standards used to design or apply the medical management nonquantitative treatment limitation, and the plan explains the bases for this conclusion in its comparative analysis. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the inpatient, out-of-network classification is no more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(J) *Example 10 (Material differences in access for standards for provider admission to a network with reasonable action)—(1) Facts.* A plan applies nonquantitative treatment limitations related to network composition in the inpatient, in-network and outpatient, in-network classifications. The plan's networks are constructed by separate service providers for medical/surgical benefits and mental health and substance use disorder benefits. The processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations related to network composition for mental health or substance use disorder benefits in the outpatient, in-network and inpatient, in-network classifications are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations with respect to medical/surgical benefits in the classifications, as required under paragraph (c)(4)(i) of this section. In order to ensure, in operation, that the nonquantitative treatment limitations are no more restrictive than the predominant nonquantitative treatment limitations applied to substantially all medical/surgical benefits in the classification, the plan collects and evaluates relevant data in a manner reasonably designed to assess the aggregate impact of all the nonquantitative treatment limitations related to network composition on relevant outcomes related to access to mental health and substance use disorder benefits as compared with access to medical/surgical benefits and considers the impact as part of the plan's evaluation. The plan considers relevant data that is known, or reasonably should be known, including metrics relating to the time and distance from plan participants and beneficiaries to network providers in rural and urban regions; the number of network providers accepting new patients; the proportions of mental health and substance use disorder and

medical/surgical providers and facilities that provide services in rural and urban regions who are in the plan's network; provider reimbursement rates (for comparable services and benchmarked to a reference standard, as appropriate); and in-network and out-of-network utilization rates (including data related to the dollar value and number of provider claims submissions). The plan determines that the relevant data suggest that the nonquantitative treatment limitations in the aggregate contribute to material differences in access to mental health and substance use disorder benefits compared to medical/surgical benefits in the classifications because, based on all the relevant facts and circumstances, the differences in the data suggest that the nonquantitative treatment limitations related to network composition are likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits. The plan takes reasonable actions, as necessary, to address the material differences in access, to ensure compliance, in operation, with paragraph (c)(4) of this section, by strengthening its efforts to recruit and encourage a broad range of available providers and facilities to join the plan's network of providers, including by taking actions to increase compensation and other inducements, streamline credentialing processes, contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network, and develop a process to monitor the effects of such efforts; expanding the availability of telehealth arrangements to mitigate overall provider shortages in certain geographic areas; providing additional outreach and assistance to participants and beneficiaries enrolled in the plan to assist them in finding available in-network providers and facilities; and ensuring that the plan's provider directories are accurate and reliable. The plan documents the efforts that it has taken to address the material differences in access that the data revealed, and the plan includes the documentation as part of its comparative analysis submission.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(J) (*Example 10*), the plan does not violate the rules of this paragraph (c)(4). The plan's nonquantitative treatment limitations related to network composition comply with the rules of paragraph (c)(4)(i) of this section. Additionally, the plan collects and evaluates relevant data, as required under paragraph (c)(4)(iii)(A) of this section, in a manner reasonably designed to assess the aggregate impact of all such nonquantitative treatment limitations on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, as required under paragraph (c)(4)(iii)(C) of this section. While the data suggest that the nonquantitative treatment limitations contribute to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, the plan has taken reasonable action, as necessary, to ensure compliance with paragraph (c)(4) of this section. The plan also documents the actions that have been and are being taken by the plan to address material differences as required by § 2590.712-1(c)(5)(iv). As a result, the network composition nonquantitative treatment limitations with respect to mental health or substance use disorder benefits in the inpatient, in-network and outpatient, in-network classifications are no more restrictive than the predominant nonquantitative treatment limitations that apply to substantially all medical/surgical benefits in the same classifications.

(K) *Example 11 (Separate EAP exhaustion treatment limitation applicable only to mental health or substance use disorder benefits)*—(1) *Facts.* An employer maintains both a major medical plan and an employee assistance program (EAP). The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions, which, together with other benefits provided by the EAP, are not significant benefits in the nature of medical care. Participants are eligible for mental health or substance use disorder benefits under the major medical plan only after exhausting the counseling sessions provided by the EAP. No

similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical plan.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(K) (*Example 11*), the requirement that limits eligibility for mental health and substance use disorder benefits under the major medical plan until EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c)(4). Because the limitation does not apply to medical/surgical benefits, it is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits that violates paragraph (c)(4)(iv) of this section. Additionally, this EAP would not qualify as excepted benefits under § 2590.732(c)(3)(vi)(B)(I) because participants in the major medical plan are required to use and exhaust benefits under the EAP (making the EAP a gatekeeper) before an individual is eligible for benefits under the plan.

(L) *Example 12 (Separate exclusion for treatment in a residential facility applicable only to mental health and substance use disorder benefits)—(1) Facts.* A plan generally covers inpatient, in-network and inpatient, out-of-network treatment without any limitations on setting, including skilled nursing facilities and rehabilitation hospitals, provided other medical necessity standards are satisfied. The plan has an exclusion for treatment at residential facilities, which the plan defines as an inpatient benefit for mental health and substance use disorder benefits. This exclusion was not generated through any broader nonquantitative treatment limitation (such as medical necessity or other clinical guideline).

(2) *Conclusion.* In this paragraph (c)(4)(vi)(L) (*Example 12*), the plan violates the rules of paragraph (c)(4)(iv) of this section. The exclusion of treatment at residential facilities is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits in the inpatient, in-network and inpatient, out-of-network classifications because the plan does not apply a comparable exclusion with respect to any medical/surgical benefits in the same benefit classification.

(M) *Example 13 (Impermissible nonquantitative treatment limitation imposed following a final determination of noncompliance and direction by the Secretary)—(1) Facts.* Following an initial request by the Secretary for a plan's comparative analysis of the plan's exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification under § 2590.712-1(d), the plan submits a comparative analysis for the nonquantitative treatment limitation. After review of the comparative analysis, as well as additional information submitted by the plan after the Secretary determines that the plan has not submitted sufficient information to be responsive to the request, the Secretary makes an initial determination that the comparative analysis fails to demonstrate that the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the inpatient, in-network classification are comparable to, and applied no more stringently than, those used in designing and applying the limitation to medical/surgical benefits in the classification. Under § 2590.712-1(d)(3), the plan submits a corrective action plan and additional comparative analyses within 45 calendar days after the initial determination. However, the corrective action plan does not alter or eliminate the exclusion or alter the processes, strategies, evidentiary standards, and other factors used in designing and applying the exclusion. Moreover, the additional comparative analysis still does not include sufficient information. The Secretary then determines that the additional comparative analyses do not demonstrate compliance with the requirements of this paragraph (c)(4). Accordingly, the plan receives a final determination of noncompliance with ERISA section 712(a)(8) and § 2590.712-1 from the Secretary, which

concludes that the plan did not demonstrate compliance through the comparative analysis process. After considering the relevant facts and circumstances, and considering the interests of plan participants and beneficiaries, as well as feedback from the plan, the Secretary directs the plan not to impose the nonquantitative treatment limitation by a certain date, unless and until the plan demonstrates compliance to the Secretary or takes appropriate action to remedy the violation. The plan makes no changes to its plan terms by that date and continues to impose the exclusion of benefits for failure to complete a course of treatment in the inpatient, in-network classification.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(M) (*Example 13*), by continuing to impose the exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification after the Secretary directs the plan not to impose this nonquantitative treatment limitation, the plan violates the requirements of paragraph (c)(4)(v) of this section.

* * * * *

(d) * * *

(3) *Provisions of other law.* Compliance with the disclosure requirements in paragraphs (d)(1) and (2) of this section is not determinative of compliance with any other provision of applicable Federal or State law. In particular, in addition to those disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example, ERISA section 104 and § 2520.104b-1 of this chapter provide that, for plans subject to ERISA, instruments under which the plan is established or operated must generally be furnished to plan participants within 30 days of request. Instruments under which the plan is established or operated include documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits; the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan; and the comparative analyses and other applicable information required by § 2590.712-1. In addition, § 2560.503-1 of this chapter and § 2590.715-2719 set forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) who have received an adverse benefit determination (or a final internal adverse benefit determination) to be provided, upon request and

free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan and the comparative analyses and other applicable information required by § 2590.712-1.

(e) * * *

(4) *Coordination with EHB requirements.* Nothing in paragraph (f) or (g) of this section or § 2590.712-1(g) changes the requirements of 45 CFR 147.150 and 156.115 providing that a health insurance issuer offering non-grandfathered health insurance coverage in the individual or small group market that is required to provide mental health and substance use disorder services, including behavioral health treatment services, as part of essential health benefits required under 45 CFR 156.110(a)(5) and 156.115(a), must comply with the requirements under section 2726 of the Public Health Service Act and its implementing regulations to satisfy the requirement to provide coverage for mental health and substance use disorder services, including behavioral health treatment, as part of essential health benefits.

* * * * *

(i) * * *

(1) *In general.* Except as provided in paragraph (i)(2) of this section—

(i) This section applies to group health plans and health insurance issuers offering group health insurance coverage on the first day of the first plan year beginning on or after January 1, 2025, except that the requirements of paragraphs (c)(2)(ii)(A), (c)(4)(i)(B), and (c)(4)(iii) of this section apply on the first day of the first plan year beginning on or after January 1, 2026.

(ii) Until the applicability date in paragraph (i)(1)(i) of this section, plans and issuers are required to continue to comply with 29 CFR 2590.712, revised as of July 1, 2022.

* * * * *

(j) *Severability.* If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

6. Add § 2590.712-1 to read as follows:

§ 2590.712-1 Nonquantitative treatment limitation comparative analysis requirements.

(a) *Meaning of terms.* Unless otherwise stated in this section, the terms of this section have the meanings indicated in § 2590.712(a)(2).

(b) *In general.* In the case of a group health plan (or health insurance issuer offering coverage in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits and that imposes any nonquantitative treatment limitation on mental health or substance use disorder benefits, the plan or issuer must perform and document a comparative analysis of the design and application of each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits. Each comparative analysis must comply with the content requirements of paragraph (c) of this section and be made available to the Secretary, upon request, in the manner required by paragraphs (d) and (e) of this section.

(c) *Comparative analysis content requirements.* With respect to each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits under a group

health plan (or health insurance coverage offered in connection with a group health plan), the comparative analysis performed by the plan or issuer must include, at minimum, the elements specified in this paragraph (c). In addition to the comparative analysis for each nonquantitative treatment limitation, each plan or issuer must prepare and make available to the Secretary, upon request, a written list of all nonquantitative treatment limitations imposed under the plan or coverage, which must be provided to the named fiduciaries of the plan who are required to include a certification as part of each comparative analysis, as required under paragraph (c)(6)(vi) of this section.

(1) *Description of the nonquantitative treatment limitation.* The comparative analysis must include, with respect to the nonquantitative treatment limitation that is the subject of the comparative analysis:

(i) Identification of the nonquantitative treatment limitation, including the specific terms of the plan or coverage or other relevant terms regarding the nonquantitative treatment limitation, the policies or guidelines (internal or external) in which the nonquantitative treatment limitation appears or is described, and the applicable sections of any other relevant documents, such as provider contracts, that describe the nonquantitative treatment limitation;

(ii) Identification of all mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation applies, including a list of which benefits are considered mental health or substance use disorder benefits and which benefits are considered medical/surgical benefits; and

(iii) A description of which benefits are included in each classification set forth in § 2590.712(c)(2)(ii)(A).

(2) *Identification and definition of the factors and evidentiary standards used to design or apply the nonquantitative treatment limitation.* The comparative analysis must include, with respect to every factor considered or relied upon to design the nonquantitative treatment

limitation or apply the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits:

(i) Identification of every factor considered or relied upon, as well as the evidentiary standards considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived, in determining which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation; and

(ii) A definition of each factor, including:

(A) A detailed description of the factor;

(B) A description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard) identified under paragraph (c)(2)(i) of this section; and

(C) A description of any steps the plan or issuer has taken to correct, cure, or supplement any information, evidence, sources, or standards that would otherwise have been considered biased or not objective under § 2590.712(c)(4)(i)(B)(I) in the absence of such steps.

(3) *Description of how factors are used in the design and application of the nonquantitative treatment limitation.* The comparative analysis must include a description of how each factor identified and defined under paragraph (c)(2) of this section is used in the design or application of the nonquantitative treatment limitation to mental health and substance use disorder benefits and medical/surgical benefits in a classification, including:

(i) A detailed explanation of how each factor identified and defined in paragraph (c)(2) of this section is used to determine which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation;

(ii) An explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the nonquantitative treatment limitation, including in the determination of whether and

how mental health or substance use disorder benefits or medical/surgical benefits are subject to the nonquantitative treatment limitation;

(iii) If the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designations and qualifications of each decision maker;

(iv) If more than one factor is identified and defined in paragraph (c)(2) of this section, an explanation of:

(A) How all of the factors relate to each other;

(B) The order in which all the factors are applied, including when they are applied;

(C) Whether and how any factors are given more weight than others; and

(D) The reasons for the ordering or weighting of the factors; and

(v) Any deviations or variations from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which each evidentiary standard was derived), such as how the factor is used differently to apply the nonquantitative treatment limitation to mental health or substance use disorder benefits as compared to medical/surgical benefits, and a description of how the plan or issuer establishes such deviations or variations.

(4) *Demonstration of comparability and stringency as written.* The comparative analysis must evaluate whether, in any classification, under the terms of the plan (or health insurance coverage) as written, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits. The comparative

analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) Documentation of each factor identified and defined in paragraph (c)(2) of this section that was applied to determine whether the nonquantitative treatment limitation applies to mental health or substance use disorder benefits and medical/surgical benefits in a classification, including, as relevant:

(A) Quantitative data, calculations, or other analyses showing whether, in each classification in which the nonquantitative treatment limitation applies, mental health or substance use disorder benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard to determine that the nonquantitative treatment limitation would or would not apply; and

(B) Records maintained by the plan or issuer documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application;

(ii) In each classification in which the nonquantitative treatment limitation applies to mental health or substance use disorder benefits, a comparison of how the nonquantitative treatment limitation, as written, is designed and applied to mental health or substance use disorder benefits and to medical/surgical benefits, including the specific provisions of any forms, checklists, procedure manuals, or other documentation used in designing and applying the nonquantitative treatment limitation or that address the application of the nonquantitative treatment limitation;

(iii) Documentation demonstrating how the factors are comparably applied, as written, to mental health or substance use disorder benefits and medical/surgical benefits in each classification, to determine which benefits are subject to the nonquantitative treatment limitation; and

(iv) An explanation of the reasons for any deviations or variations in the application of a factor used to apply the nonquantitative treatment limitation, or the application of the nonquantitative treatment limitation, to mental health or substance use disorder benefits as compared to medical/surgical benefits, and how the plan or issuer establishes such deviations or variations, including:

(A) In the definition of the factors, the evidentiary standards used to define the factors, and the sources from which the evidentiary standards were derived;

(B) In the design of the factors or evidentiary standards; or

(C) In the application or design of the nonquantitative treatment limitation.

(5) *Demonstration of comparability and stringency in operation.* The comparative analysis must evaluate whether, in any classification, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) A comprehensive explanation of how the plan or issuer evaluates whether, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits, including:

(A) An explanation of any methodology and underlying data used to demonstrate the application of the nonquantitative treatment limitation, in operation;

(B) The sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation is applicable;

(C) With respect to a nonquantitative treatment limitation for which relevant data is temporarily unavailable as described in § 2590.712(c)(4)(iii)(A)(3)(i), a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed; and

(D) With respect to a nonquantitative treatment limitation for which no data exist that can reasonably assess any relevant impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits as described in § 2590.712(c)(4)(iii)(A)(3)(ii), a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, an explanation of why the nature of the nonquantitative treatment limitation prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure that the nonquantitative treatment limitation complies with § 2590.712(c)(4);

(ii) Identification of the relevant data collected and evaluated, as required under § 2590.712(c)(4)(iii)(A);

(iii) Documentation of the outcomes that resulted from the application of the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits, including:

(A) The evaluation of relevant data as required under § 2590.712(c)(4)(iii)(A); and

(B) A reasoned justification and analysis that explains why the plan or issuer concluded that any differences in the relevant data do or do not suggest the nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, in accordance with § 2590.712(c)(4)(iii)(B)(2);

(iv) A detailed explanation of any material differences in access demonstrated by the outcomes evaluated under paragraph (c)(5)(iii) of this section, including:

(A) A reasoned explanation of any material differences in access that are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation as applied to mental health or substance use disorder benefits and medical/surgical benefits (including any considerations beyond a plan's or issuer's control that contribute to the existence of material differences) and a detailed explanation of the bases for concluding that material differences are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation; and

(B) To the extent differences in access to mental health or substance use disorder benefits are attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits, and such standards or measures are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation, documentation explaining how any such differences are attributable to those standards or measures, as required in § 2590.712(c)(4)(iii)(B)(2)(ii); and

(v) A discussion of the actions that have been or are being taken by the plan or issuer to address any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, including the actions the plan or issuer has taken or is

taking under § 2590.712(c)(4)(iii)(B)(I) to address material differences to comply, in operation, with § 2590.712(c)(4), including, as applicable:

(A) A reasoned explanation of any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits that persist despite reasonable actions that have been or are being taken; and

(B) For a plan or issuer designing and applying one or more nonquantitative treatment limitations related to network composition, a discussion of the actions that have been or are being taken to address material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits, including those listed in § 2590.712(c)(4)(iii)(C).

(6) *Findings and conclusions.* The comparative analysis must address the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation, and include:

(i) Any findings or conclusions indicating that the plan or coverage is or is not (or might or might not be) in compliance with the requirements of § 2590.712(c)(4), including any additional actions the plan or issuer has taken or intends to take to address any potential areas of concern or noncompliance;

(ii) A reasoned and detailed discussion of the findings and conclusions described in paragraph (c)(6)(i) of this section;

(iii) Citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described in paragraph (c)(6)(i) of this section not otherwise discussed in the comparative analysis;

(iv) The date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis;

(v) If the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits; and

(vi) A certification by one or more named fiduciaries that they have engaged in a prudent process to select one or more qualified service providers to perform and document a comparative analysis in connection with the imposition of any nonquantitative treatment limitations that apply to mental health and substance use disorder benefits under the plan in accordance with applicable law and regulations, and have satisfied their duty to monitor those service providers as required under part 4 of ERISA with respect to the performance and documentation of such comparative analysis.

(d) *Requirements related to submission of comparative analyses to the Secretary upon request*—(1) *Initial request by the Secretary for comparative analysis.* A group health plan (or health insurance issuer offering coverage in connection with a group health plan) must make the comparative analysis required by paragraph (b) of this section available and submit it to the Secretary within 10 business days of receipt of a request from the Secretary (or an additional period of time specified by the Secretary).

(2) *Additional information required after a comparative analysis is deemed to be insufficient.* In instances in which the Secretary determines that the plan or issuer has not submitted sufficient information under paragraph (d)(1) of this section for the Secretary to determine whether the comparative analysis required in paragraph (b) of this section complies

with paragraph (c) of this section or whether the plan or issuer complies with § 2590.712(c)(4), the Secretary will specify to the plan or issuer the additional information the plan or issuer must submit to the Secretary to be responsive to the request under paragraph (d)(1) of this section. Any such information must be provided to the Secretary by the plan or issuer within 10 business days after the Secretary specifies the additional information to be submitted (or an additional period of time specified by the Secretary).

(3) Initial determination of noncompliance, required action, and corrective action plan.

In instances in which the Secretary reviewed the comparative analysis submitted under paragraph (d)(1) of this section and any additional information submitted under paragraph (d)(2) of this section, and made an initial determination that the plan or issuer is not in compliance with the requirements of § 2590.712(c)(4) or this section, the plan or issuer must respond to the initial determination by the Secretary and specify the actions the plan or issuer will take to bring the plan or coverage into compliance, and provide to the Secretary additional comparative analyses meeting the requirements of paragraph (c) of this section that demonstrate compliance with § 2590.712(c)(4), not later than 45 calendar days after the Secretary's initial determination that the plan or issuer is not in compliance.

(4) Requirement to notify participants and beneficiaries of final determination of noncompliance—(i) In general. If the Secretary makes a final determination of noncompliance, the plan or issuer must notify all participants and beneficiaries enrolled in the plan or coverage that the plan or issuer has been determined to not be in compliance with the requirements of § 2590.712(c)(4) or this section with respect to such plan or coverage. Such notice must be provided within 7 business days of receipt of the final determination of noncompliance, and the plan or issuer must provide a copy of the notice to the Secretary, any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within the same timeframe.

(ii) *Content of notice.* The notice to participants and beneficiaries required in paragraph (d)(4)(i) of this section shall be written in a manner calculated to be understood by the average plan participant and must include, in plain language, the following information in a standalone notice:

(A) The following statement prominently displayed on the first page, in no less than 14-point font: “Attention! The Department of Labor has determined that [insert the name of group health plan or health insurance issuer] is not in compliance with the Mental Health Parity and Addiction Equity Act.”;

(B) A summary of changes the plan or issuer has made as part of its corrective action plan specified to the Secretary following the initial determination of noncompliance, including an explanation of any opportunity for a participant or beneficiary to have a claim for benefits submitted or reprocessed;

(C) A summary of the Secretary’s final determination that the plan or issuer is not in compliance with § 2590.712(c)(4) or this section, including any provisions or practices identified as being in violation of § 2590.712(c)(4) or this section, additional corrective actions identified by the Secretary in the final determination notice, and information on how participants and beneficiaries can obtain from the plan or issuer a copy of the final determination of noncompliance;

(D) Any additional actions the plan or issuer is taking to come into compliance with § 2590.712(c)(4) or this section, when the plan or issuer will take such actions, and a clear and accurate statement explaining whether the Secretary has concurred with those actions; and

(E) Contact information for questions and complaints, and a statement explaining how participants and beneficiaries can obtain more information about the notice, including:

(I) The plan’s or issuer’s phone number and an email or web portal address; and

(2) The Employee Benefits Security Administration's phone number and email or web portal address.

(iii) *Manner of notice.* The plan or issuer must make the notice required under paragraph (d)(4)(i) of this section available in paper form, or electronically (such as by email or an Internet posting) if:

(A) The format is readily accessible;

(B) The notice is provided in paper form free of charge upon request; and

(C) In a case in which the electronic form is an internet posting, the plan or issuer timely notifies the participant or beneficiary in paper form (such as a postcard) or email, that the documents are available on the internet, provides the internet address, includes the statement required in paragraph (d)(4)(ii)(A) of this section, and notifies the participant or beneficiary that the documents are available in paper form upon request.

(e) *Requests for a copy of a comparative analysis.* In addition to making a comparative analysis available upon request to the Secretary, a plan or issuer must make available a copy of the comparative analysis required by paragraph (b) of this section when requested by:

(1) Any applicable State authority;

(2) A participant or beneficiary (including a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit determination related to mental health or substance use disorder benefits; and

(3) Participants and beneficiaries, who may request the comparative analysis at any time under ERISA section 104.

(f) *Rule of construction.* Nothing in this section or § 2590.712 shall be construed to prevent the Secretary from acting within the scope of existing authorities to address violations of § 2590.712 or this section.

(g) *Applicability.* The provisions of this section apply to group health plans and health insurance issuers offering group health insurance coverage described in § 2590.712(e), to the extent the plan or issuer is not exempt under § 2590.712(f) or (g), on the first day of the first plan year beginning on or after January 1, 2025, except the requirements of paragraphs (c)(2)(ii)(C), (c)(5)(i)(C) and (D), and (c)(5)(ii) through (v) of this section apply on the first day of the first plan year beginning on or after January 1, 2026.

(h) *Severability.* If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR parts 146 and 147 as set forth below:

7. The authority citation for part 146 continues to read as follows:

Authority: 42 U.S.C. 300gg-1 through 300gg-5, 300gg-11 through 300gg-23, 300gg-91, and 300gg-92.

8. Amend § 146.136 by:

a. Redesignating paragraph (a) as paragraph (a)(2) and adding paragraphs (a) heading and (a)(1);

b. In newly redesignated paragraph (a)(2):

i. Revising the introductory text;

ii. Adding the definitions of “DSM,” “Evidentiary standards,” “Factors,” and “ICD” in alphabetical order;

iii. Revising the definitions of “Medical/surgical benefits” and “Mental health benefits”;

iv. Adding the definitions of “Processes” and “Strategies” in alphabetical order; and

v. Revising the definitions of “Substance use disorder benefits” and “Treatment limitations”;

c. Revising paragraphs (c)(1)(ii), (c)(2)(i), and (c)(2)(ii)(A) introductory text;

d. In paragraph (c)(2)(ii)(C), designating *Examples 1 through 4* as paragraphs (c)(2)(ii)(C)(1) through (4) and revising newly designated paragraphs (c)(2)(ii)(C)(1) through (4);

e. Adding paragraphs (c)(2)(ii)(C)(5) through (8);

f. Revising paragraphs (c)(3)(i)(A), (C), and (D);

g. In paragraph (c)(3)(iii), adding introductory text;

- h. Revising paragraphs (c)(3)(iii)(A) and (B), (c)(3)(iv), (c)(4), (d)(3), (e)(4), and (i)(1); and
- i. Adding paragraph (j).

The revisions and additions read as follows:

§ 146.136 Parity in mental health and substance use disorder benefits.

(a) *Purpose and meaning of terms*—(1) *Purpose*. This section and § 146.137 set forth rules to ensure parity in aggregate lifetime and annual dollar limits, financial requirements, and quantitative and nonquantitative treatment limitations between mental health and substance use disorder benefits and medical/surgical benefits, as required under PHS Act section 2726. A fundamental purpose of PHS Act section 2726, this section, and § 146.137 is to ensure that participants and beneficiaries in a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that offers mental health or substance use disorder benefits are not subject to more restrictive aggregate lifetime or annual dollar limits, financial requirements, or treatment limitations with respect to those benefits than the predominant dollar limits, financial requirements, or treatment limitations that are applied to substantially all medical/surgical benefits covered by the plan or coverage in the same classification, as further provided in this section and § 146.137. Accordingly, in complying with the provisions of PHS Act section 2726, this section, and § 146.137, plans and issuers must not design or apply financial requirements and treatment limitations that impose a greater burden on access (that is, are more restrictive) to mental health or substance use disorder benefits under the plan or coverage than they impose on access to medical/surgical benefits in the same classification of

benefits. The provisions of PHS Act section 2726, this section, and § 146.137 should be interpreted in a manner that is consistent with the purpose described in this paragraph (a)(1).

(2) *Meaning of terms.* For purposes of this section and § 146.137, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

* * * * *

DSM means the American Psychiatric Association’s Diagnostic and Statistical Manual of Mental Disorders. For the purpose of this definition, the most current version of the DSM as of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** is the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision published in March 2022. A subsequent version of the DSM published after **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is published.

Evidentiary standards are any evidence, sources, or standards that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon in designing or applying a factor with respect to a nonquantitative treatment limitation, including specific benchmarks or thresholds. Evidentiary standards may be empirical, statistical, or clinical in nature, and include: sources acquired or originating from an objective third party, such as recognized medical literature, professional standards and protocols (which may include comparative effectiveness studies and clinical trials), published research studies, payment rates for items and services (such as publicly available databases of the “usual, customary and reasonable” rates paid for items and services), and clinical treatment guidelines; internal plan or issuer data, such as claims or utilization data or criteria for assuring a sufficient mix and number of network providers; and benchmarks or thresholds, such as measures of excessive utilization, cost levels, time or distance standards, or network participation percentage thresholds.

Factors are all information, including processes and strategies (but not evidentiary standards), that a group health plan (or health insurance issuer offering coverage in connection with such a plan) considered or relied upon to design a nonquantitative treatment limitation, or to determine whether or how the nonquantitative treatment limitation applies to benefits under the plan or coverage. Examples of factors include, but are not limited to: provider discretion in determining a diagnosis or type or length of treatment; clinical efficacy of any proposed treatment or service; licensing and accreditation of providers; claim types with a high percentage of fraud; quality measures; treatment outcomes; severity or chronicity of condition; variability in the cost of an episode of treatment; high cost growth; variability in cost and quality; elasticity of demand; and geographic location.

* * * * *

ICD means the World Health Organization's International Classification of Diseases adopted by the Department of Health and Human Services through § 162.1002 of this subtitle. For the purpose of this definition, the most current version of the ICD as of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** is the International Classification of Diseases, 10th Revision, Clinical Modification adopted for the period beginning on October 1, 2015. Any subsequent version of the ICD adopted through § 162.1002 of this subtitle after **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]** will be considered the most current version beginning on the first day of the plan year that is one year after the date the subsequent version is adopted.

Medical/surgical benefits means benefits with respect to items or services for medical conditions or surgical procedures, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include mental health benefits or substance use

disorder benefits. Notwithstanding the preceding sentence, any condition or procedure defined by the plan or coverage as being or as not being a medical condition or surgical procedure must be defined consistent with generally recognized independent standards of current medical practice (for example, the most current version of the ICD). To the extent generally recognized independent standards of current medical practice do not address whether a condition or procedure is a medical condition or surgical procedure, plans and issuers may define the condition or procedure in accordance with applicable Federal and State law.

Mental health benefits means benefits with respect to items or services for mental health conditions, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or substance use disorder benefits. Notwithstanding the preceding sentence, any condition defined by the plan or coverage as being or as not being a mental health condition must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all conditions covered under the plan or coverage, except for substance use disorders, that fall under any of the diagnostic categories listed in the mental, behavioral, and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a condition is a mental health condition, plans and issuers may define the condition in accordance with applicable Federal and State law.

Processes are actions, steps, or procedures that a group health plan (or health insurance issuer offering coverage in connection with such a plan) uses to apply a nonquantitative treatment limitation, including actions, steps, or procedures established by the plan or issuer as

requirements in order for a participant or beneficiary to access benefits, including through actions by a participant's or beneficiary's authorized representative or a provider or facility. Examples of processes include, but are not limited to: procedures to submit information to authorize coverage for an item or service prior to receiving the benefit or while treatment is ongoing (including requirements for peer or expert clinical review of that information); provider referral requirements that are used to determine when and how a participant or beneficiary may access certain services; and the development and approval of a treatment plan used in a concurrent review process to determine whether a specific request should be granted or denied. Processes also include the specific procedures used by staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) to administer the application of nonquantitative treatment limitations, such as how a panel of staff members applies the nonquantitative treatment limitation (including the qualifications of staff involved, number of staff members allocated, and time allocated), consultations with panels of experts in applying the nonquantitative treatment limitation, and the degree of reviewer discretion in adhering to criteria hierarchy when applying a nonquantitative treatment limitation.

Strategies are practices, methods, or internal metrics that a plan (or health insurance issuer offering coverage in connection with such a plan) considers, reviews, or uses to design a nonquantitative treatment limitation. Examples of strategies include, but are not limited to: the development of the clinical rationale used in approving or denying benefits; the method of determining whether and how to deviate from generally accepted standards of care in concurrent reviews; the selection of information deemed reasonably necessary to make medical necessity determinations; reliance on treatment guidelines or guidelines provided by third-party organizations in the design of a nonquantitative treatment limitation; and rationales used in selecting and adopting certain threshold amounts to apply a nonquantitative treatment limitation, professional standards and protocols to determine utilization management standards, and fee

schedules used to determine provider reimbursement rates, used as part of a nonquantitative treatment limitation. Strategies also include the method of creating and determining the composition of the staff or other representatives of a plan or issuer (or the service provider of a plan or issuer) that deliberates, or otherwise makes decisions, on the design of nonquantitative treatment limitations, including the plan's or issuer's methods for making decisions related to the qualifications of staff involved, number of staff members allocated, and time allocated; breadth of sources and evidence considered; consultations with panels of experts in designing the nonquantitative treatment limitation; and the composition of the panels used to design a nonquantitative treatment limitation.

Substance use disorder benefits means benefits with respect to items or services for substance use disorders, as defined under the terms of the group health plan (or health insurance coverage offered by an issuer in connection with such a plan) and in accordance with applicable Federal and State law, but does not include medical/surgical benefits or mental health benefits. Notwithstanding the preceding sentence, any disorder defined by the plan or coverage as being or as not being a substance use disorder must be defined consistent with generally recognized independent standards of current medical practice. For the purpose of this definition, to be consistent with generally recognized independent standards of current medical practice, the definition must include all disorders covered under the plan or coverage that fall under any of the diagnostic categories listed as a mental or behavioral disorder due to psychoactive substance use (or equivalent category) in the mental, behavioral and neurodevelopmental disorders chapter (or equivalent chapter) of the most current version of the ICD or that are listed as a Substance-Related and Addictive Disorder (or equivalent category) in the most current version of the DSM. To the extent generally recognized independent standards of current medical practice do not address whether a disorder is a substance use disorder, plans and issuers may define the disorder in accordance with applicable Federal and State law.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations (such as standards related to network composition), which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. (See paragraph (c)(4)(ii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.) A complete exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

* * * * *

(c) * * *

(1) * * *

(ii) *Type of financial requirement or treatment limitation.* When reference is made in this paragraph (c) to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. See paragraph (c)(4)(ii) of this section for an illustrative, non-exhaustive list of nonquantitative treatment limitations.

* * * * *

(2) * * *

(i) *General rule.* A group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits may not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied

to substantially all medical/surgical benefits in the same classification. Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. A plan or issuer may not impose any financial requirement or treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and not to any medical/surgical benefits in the same benefit classification. The application of the rules of this paragraph (c)(2) to financial requirements and quantitative treatment limitations is addressed in paragraph (c)(3) of this section; the application of the rules of this paragraph (c)(2) to nonquantitative treatment limitations is addressed in paragraph (c)(4) of this section.

(ii) * * *

(A) *In general.* If a plan (or health insurance coverage) provides any benefits for a mental health condition or substance use disorder in any classification of benefits described in this paragraph (c)(2)(ii), it must provide meaningful benefits for that mental health condition or substance use disorder in every classification in which medical/surgical benefits are provided. For purposes of this paragraph (c)(2)(ii)(A), whether the benefits provided are meaningful benefits is determined in comparison to the benefits provided for medical conditions and surgical procedures in the classification and requires, at a minimum, coverage of benefits for that condition or disorder in each classification in which the plan (or coverage) provides benefits for one or more medical conditions or surgical procedures. A plan (or coverage) does not provide meaningful benefits under this paragraph (c)(2)(ii)(A) unless it provides benefits for a core treatment for that condition or disorder in each classification in which the plan (or coverage) provides benefits for a core treatment for one or more medical conditions or surgical procedures. For this purpose, a core treatment for a condition or disorder is a standard treatment or course of treatment, therapy, service, or intervention indicated by generally recognized independent

standards of current medical practice. If there is no core treatment for a covered mental health condition or substance use disorder with respect to a classification, the plan (or coverage) is not required to provide benefits for a core treatment for such condition or disorder in that classification (but must provide benefits for such condition or disorder in every classification in which medical/surgical benefits are provided). In determining the classification in which a particular benefit belongs, a plan (or health insurance issuer) must apply the same standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a plan (or health insurance coverage) provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this paragraph (c) apply separately with respect to that classification for all financial requirements or treatment limitations (illustrated in examples in paragraph (c)(2)(ii)(C) of this section). The following classifications of benefits are the only classifications used in applying the rules of this paragraph (c), in addition to the permissible sub-classifications described in paragraph (c)(3)(iii) of this section:

* * * * *

(C) *Examples.* The rules of this paragraph (c)(2)(ii) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits. With regard to these examples, references to any particular core treatment are included for illustrative purposes only. Plans and issuers must consult generally recognized independent standards of current medical practice to determine the applicable core treatment, therapy, service, or intervention for any covered condition or disorder.

(1) *Example 1—(i) Facts.* A group health plan offers inpatient and outpatient benefits and does not contract with a network of providers. The plan imposes a \$500 deductible on all benefits. For inpatient medical/surgical benefits, the plan imposes a coinsurance requirement.

For outpatient medical/surgical benefits, the plan imposes copayments. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(1) (*Example 1*), because the plan has no network of providers, all benefits provided are out-of-network. Because inpatient, out-of-network medical/surgical benefits are subject to separate financial requirements from outpatient, out-of-network medical/surgical benefits, the rules of this paragraph (c) apply separately with respect to any financial requirements and treatment limitations, including the deductible, in each classification.

(2) *Example 2—(i) Facts.* A plan imposes a \$500 deductible on all benefits. The plan has no network of providers. The plan generally imposes a 20 percent coinsurance requirement with respect to all benefits, without distinguishing among inpatient, outpatient, emergency care, or prescription drug benefits. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(2) (*Example 2*), because the plan does not impose separate financial requirements (or treatment limitations) based on classification, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance across all benefits.

(3) *Example 3—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(2)(i) of this section (*Example 2*), except the plan exempts emergency care benefits from the 20 percent coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(3) (*Example 3*), because the plan imposes separate financial requirements based on classifications, the rules of this paragraph (c) apply with respect to the deductible and the coinsurance separately for benefits in the emergency care classification and all other benefits.

(4) *Example 4—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(2)(i) of this section (*Example 2*), except the plan also imposes a preauthorization requirement for all inpatient treatment in order for benefits to be paid. No such requirement applies to outpatient treatment.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(4) (*Example 4*), because the plan has no network of providers, all benefits provided are out-of-network. Because the plan imposes a separate treatment limitation based on classifications, the rules of this paragraph (c) apply with respect to the deductible and coinsurance separately for inpatient, out-of-network benefits and all other benefits.

(5) *Example 5—(i) Facts.* A plan covers treatment for autism spectrum disorder (ASD), a mental health condition, and covers outpatient, out-of-network developmental screenings for ASD but excludes all other benefits for outpatient treatment for ASD, including applied behavior analysis (ABA) therapy, when provided on an out-of-network basis. The plan generally covers the full range of outpatient treatments (including core treatments) and treatment settings for medical conditions and surgical procedures when provided on an out-of-network basis. Under the generally recognized independent standards of current medical practice consulted by the plan, developmental screenings alone do not constitute a core treatment for ASD.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(5) (*Example 5*), the plan violates the rules of this paragraph (c)(2)(ii). Although the plan covers benefits for ASD in the outpatient, out-of-network classification, it only covers developmental screenings, so it does not cover a core treatment for ASD in the classification. Because the plan generally covers the full range of medical/surgical benefits, including a core treatment for one or more medical conditions or surgical procedures in the classification, it fails to provide meaningful benefits for treatment of ASD in the classification.

(6) *Example 6—(i) Facts.* Same facts as in paragraph (c)(2)(ii)(C)(5) (*Example 5*) of this section, except that the plan is an HMO that does not cover the full range of medical/surgical benefits including a core treatment for any medical conditions or surgical procedures in the outpatient, out-of-network classification (except as required under PHS Act sections 2799A-1 and 2799A-2), but covers benefits for medical conditions and surgical procedures in the inpatient, in-network; outpatient, in-network; emergency care; and prescription drug classifications.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(6) (*Example 6*), the plan does not violate the rules of this paragraph (c)(2)(ii). Because the plan does not provide meaningful benefits including for a core treatment for any medical condition or surgical procedure in the outpatient, out-of-network classification (except as required under PHS Act sections 2799A-1 and 2799A-2), the plan is not required to provide meaningful benefits for any mental health conditions or substance use disorders in that classification. Nevertheless, the plan must provide meaningful benefits for each mental health condition and substance use disorder for which the plan provides benefits in every classification in which meaningful medical/surgical benefits are provided as required under paragraph (c)(2)(ii)(A) of this section. This example does not address whether the plan has complied with other applicable requirements of this section in excluding coverage of ABA therapy in the outpatient, out-of-network classification.

(7) *Example 7—(i) Facts.* A plan provides extensive benefits, including for core treatments for many medical conditions and surgical procedures in the outpatient, in-network classification, including nutrition counseling for diabetes and obesity. The plan also generally covers diagnosis and treatment for eating disorders, which are mental health conditions, including coverage for nutrition counseling to treat eating disorders in the outpatient, in-network classification. Nutrition counseling is a core treatment for eating disorders, in accordance with generally recognized independent standards of current medical practice consulted by the plan.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(7) (*Example 7*), the plan does not violate the rules of this paragraph (c)(2)(ii). The coverage of diagnosis and treatment for eating disorders, including nutrition counseling, in the outpatient, in-network classification results in the plan providing meaningful benefits for the treatment of eating disorders in the classification, as determined in comparison to the benefits provided for medical conditions or surgical procedures in the classification.

(8) *Example 8—(i) Facts.* A plan provides extensive benefits for the core treatments for many medical conditions and surgical procedures in the outpatient, in-network and prescription drug classifications. The plan provides coverage for diagnosis and treatment for opioid use disorder, a substance use disorder, in the outpatient, in-network classification, by covering counseling and behavioral therapies and, in the prescription drug classification, by covering medications to treat opioid use disorder (MOUD). Counseling and behavioral therapies and MOUD, in combination, are one of the core treatments for opioid use disorder, in accordance

with generally recognized independent standards of current medical practice consulted by the plan.

(ii) *Conclusion.* In this paragraph (c)(2)(ii)(C)(8) (*Example 8*), the plan does not violate the rules of this paragraph (c)(2)(ii). The coverage of counseling and behavioral therapies and MOUD, in combination, in the outpatient, in-network classification and prescription drug classification, respectively, results in the plan providing meaningful benefits for the treatment of opioid use disorder in the outpatient, in-network and prescription drug classifications.

(3) * * *

(i) * * *

(A) *Substantially all.* For purposes of this paragraph (c)(3), a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. (For purposes of this paragraph (c)(3)(i)(A), benefits expressed as subject to a zero level of a type of financial requirement are treated as benefits not subject to that type of financial requirement, and benefits expressed as subject to a quantitative treatment limitation that is unlimited are treated as benefits not subject to that type of quantitative treatment limitation.) If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

* * * * *

(C) *Portion based on plan payments.* For purposes of this paragraph (c)(3), the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the dollar amount of all plan payments for medical/surgical benefits in the classification expected to be paid under the plan for the plan year (or for the portion of the plan year after a change in plan benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(D) *Clarifications for certain threshold requirements.* For any deductible, the dollar amount of plan payments includes all plan payments with respect to claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of plan payments includes all plan payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all plan payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of plan payment changes. (See also PHS Act section 2707 and Affordable Care Act section 1302(c), which establish annual limitations on out-of-pocket maximums for all non-grandfathered health plans.)

* * * * *

(iii) *Special rules.* Unless specifically permitted under this paragraph (c)(3)(iii), sub-classifications are not permitted when applying the rules of paragraph (c)(3) of this section.

(A) *Multi-tiered prescription drug benefits.* If a plan (or health insurance coverage) applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits, the plan (or health insurance coverage) satisfies the parity requirements of this paragraph (c) with respect to prescription drug benefits.

Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up.

(B) *Multiple network tiers.* If a plan (or health insurance coverage) provides benefits through multiple tiers of in-network providers (such as an in-network tier of preferred providers with more generous cost-sharing to participants than a separate in-network tier of participating

providers), the plan may divide its benefits furnished on an in-network basis into sub-classifications that reflect network tiers, if the tiering is based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section (such as quality, performance, and market standards) and without regard to whether a provider provides services with respect to medical/surgical benefits or mental health or substance use disorder benefits. After the sub-classifications are established, the plan or issuer may not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(3)(i) of this section.

* * * * *

(iv) *Examples.* The rules of paragraphs (c)(3)(i) through (iii) of this section are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

(A) *Example 1—(1) Facts.* (i) For inpatient, out-of-network medical/surgical benefits, a group health plan imposes five levels of coinsurance. Using a reasonable method, the plan projects its payments for the upcoming year as follows:

Table 1 to Paragraph (c)(3)(iv)(A)(1)(i)

| Coinsurance rate | 0 % | 10% | 15% | 20% | 30% | Total |
|--------------------------------------|--------|----------------------|-----------------------|----------------------|-----------------------|----------|
| Projected payments | \$200x | \$100x | \$450x | \$100x | \$150x | \$1,000x |
| Percent of total plan costs | 20% | 10% | 45% | 10% | 15% | |
| Percent subject to coinsurance level | N/A | 12.5% (100x/800x) | 56.25% (450x/800x) | 12.5% (100x/800x) | 18.75% (150x/800x) | |

(ii) The plan projects plan costs of \$800x to be subject to coinsurance (\$100x + \$450x + \$100x + \$150x = \$800x). Thus, 80 percent (\$800x/\$1,000x) of the benefits are projected to be subject to coinsurance, and 56.25 percent of the benefits subject to coinsurance are projected to be subject to the 15 percent coinsurance level.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(A) (*Example 1*), the two-thirds threshold of the substantially all standard is met for coinsurance because 80 percent of all inpatient, out-of-network medical/surgical benefits are subject to coinsurance. Moreover, the 15 percent coinsurance is the predominant level because it is applicable to more than one-half of inpatient, out-of-network medical/surgical benefits subject to the coinsurance requirement. The plan may not impose any level of coinsurance with respect to inpatient, out-of-network mental health or substance use disorder benefits that is more restrictive than the 15 percent level of coinsurance.

(B) *Example 2—(1) Facts.* (i) For outpatient, in-network medical/surgical benefits, a plan imposes five different copayment levels. Using a reasonable method, the plan projects payments for the upcoming year as follows:

Table 2 to Paragraph (c)(3)(iv)(B)(1)(i)

| Copayment amount | \$0 | \$10 | \$15 | \$20 | \$50 | Total |
|-------------------------------|--------|--------------------|--------------------|----------------------|----------------------|----------|
| Projected payments | \$200x | \$200x | \$200x | \$300x | \$100x | \$1,000x |
| Percent of total plan costs | 20% | 20% | 20% | 30% | 10% | |
| Percent subject to copayments | N/A | 25% (200x/800x) | 25% (200x/800x) | 37.5% (300x/800x) | 12.5% (100x/800x) | |

(ii) The plan projects plan costs of \$800x to be subject to copayments (\$200x + \$200x + \$300x + \$100x = \$800x). Thus, 80 percent (\$800x/\$1,000x) of the benefits are projected to be subject to a copayment.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(B) (*Example 2*), the two-thirds threshold of the substantially all standard is met for copayments because 80 percent of all outpatient, in-network medical/surgical benefits are subject to a copayment. Moreover, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to a copayment (for the \$10 copayment, 25%; for the \$15 copayment, 25%; for the \$20 copayment, 37.5%; and for the \$50 copayment, 12.5%). The plan can combine any levels of copayment, including the highest levels, to determine the predominant level that can be applied to mental health or substance use disorder benefits. If the plan combines the highest levels of copayment, the combined projected payments for the two highest copayment levels, the \$50 copayment and the \$20 copayment, are not more than one-half of the outpatient, in-network medical/surgical benefits subject to a copayment because they are exactly one-half (\$300x + \$100x = \$400x; \$400x/\$800x = 50%). The combined projected payments for the three highest copayment levels – the \$50 copayment, the \$20 copayment, and the \$15 copayment – are more than one-half of the outpatient, in-network medical/surgical benefits subject to the copayments (\$100x + \$300x + \$200x = \$600x; \$600x/\$800x = 75%). Thus, the plan may not impose any copayment on outpatient, in-network mental health or substance use disorder benefits that is more restrictive than the least restrictive copayment in the combination, the \$15 copayment.

(C) *Example 3—(1) Facts.* A plan imposes a \$250 deductible on all medical/surgical benefits for self-only coverage and a \$500 deductible on all medical/surgical benefits for family

coverage. The plan has no network of providers. For all medical/surgical benefits, the plan imposes a coinsurance requirement. The plan imposes no other financial requirements or treatment limitations.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(C) (*Example 3*), because the plan has no network of providers, all benefits are provided out-of-network. Because self-only and family coverage are subject to different deductibles, whether the deductible applies to substantially all medical/surgical benefits is determined separately for self-only medical/surgical benefits and family medical/surgical benefits. Because the coinsurance is applied without regard to coverage units, the predominant coinsurance that applies to substantially all medical/surgical benefits is determined without regard to coverage units.

(D) *Example 4—(1) Facts.* A plan applies the following financial requirements for prescription drug benefits. The requirements are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits. Moreover, the process for certifying a particular drug as “generic”, “preferred brand name”, “non-preferred brand name”, or “specialty” complies with the rules of paragraph (c)(4) of this section (relating to requirements for nonquantitative treatment limitations).

Table 3 to Paragraph (c)(3)(iv)(D)(1)

| | Tier 1 | Tier 2 | Tier 3 | Tier 4 |
|----------------------|---------------|----------------------------|---|-----------------|
| Tier description | Generic drugs | Preferred brand name drugs | Non-preferred brand name drugs (which may have Tier 1 or Tier 2 alternatives) | Specialty drugs |
| Percent paid by plan | 90% | 80% | 60% | 50% |

(2) *Conclusion.* In this paragraph (c)(3)(iv)(D) (*Example 4*), the financial requirements that apply to prescription drug benefits are applied without regard to whether a drug is generally prescribed with respect to medical/surgical benefits or with respect to mental health or substance use disorder benefits; the process for certifying drugs in different tiers complies with paragraph (c)(4) of this section; and the bases for establishing different levels or types of financial requirements are reasonable. The financial requirements applied to prescription drug benefits do not violate the parity requirements of this paragraph (c)(3).

(E) *Example 5—(1) Facts.* A plan has two tiers of network of providers: a preferred provider tier and a participating provider tier. Providers are placed in either the preferred tier or participating tier based on reasonable factors determined in accordance with the rules in paragraph (c)(4) of this section, such as accreditation, quality and performance measures (including customer feedback), and relative reimbursement rates. Furthermore, provider tier placement is determined without regard to whether a provider specializes in the treatment of mental health conditions or substance use disorders, or medical/surgical conditions. The plan divides the in-network classifications into two sub-classifications (in-network/preferred and in-network/participating). The plan does not impose any financial requirement or treatment limitation on mental health or substance use disorder benefits in either of these sub-

classifications that is more restrictive than the predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(E) (*Example 5*), the division of in-network benefits into sub-classifications that reflect the preferred and participating provider tiers does not violate the parity requirements of this paragraph (c)(3).

(F) *Example 6—(1) Facts.* With respect to outpatient, in-network benefits, a plan imposes a \$25 copayment for office visits and a 20 percent coinsurance requirement for outpatient surgery. The plan divides the outpatient, in-network classification into two sub-classifications (in-network office visits and all other outpatient, in-network items and services). The plan or issuer does not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in either of these sub-classifications that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in each sub-classification.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(F) (*Example 6*), the division of outpatient, in-network benefits into sub-classifications for office visits and all other outpatient, in-network items and services does not violate the parity requirements of this paragraph (c)(3).

(G) *Example 7—(1) Facts.* Same facts as in paragraph (c)(3)(iv)(F)(1) of this section (*Example 6*), but for purposes of determining parity, the plan divides the outpatient, in-network classification into outpatient, in-network generalists and outpatient, in-network specialists.

(2) *Conclusion.* In this paragraph (c)(3)(iv)(G) (*Example 7*), the division of outpatient, in-network benefits into any sub-classifications other than office visits and all other outpatient items and services violates the requirements of paragraph (c)(3)(iii)(C) of this section.

* * * * *

(4) *Nonquantitative treatment limitations.* Consistent with paragraph (a)(1) of this section, a group health plan (or health insurance coverage offered by an issuer in connection with a group health plan) may not impose any nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification that is more restrictive, as written or in operation, than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification. For this purpose, a nonquantitative treatment limitation is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification if the plan or issuer fails to meet the requirements of paragraph (c)(4)(i) or (iii) of this section. In such a case, the plan (or health insurance coverage) will be considered to violate

PHS Act section 2726 (a)(3)(A)(ii), and the nonquantitative treatment limitation may not be imposed by the plan (or health insurance coverage) with respect to mental health or substance use disorder benefits in the classification.

(i) *Requirements related to design and application of a nonquantitative treatment limitation—(A) In general.* A plan (or health insurance coverage) may not impose a nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in any classification unless, under the terms of the plan (or health insurance coverage), as written and in operation, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits in the classification.

(B) *Prohibition on discriminatory factors and evidentiary standards.* For purposes of determining comparability and stringency under paragraph (c)(4)(i)(A) of this section, a plan (or health insurance coverage) may not rely upon discriminatory factors or evidentiary standards to design a nonquantitative treatment limitation to be imposed on mental health or substance use disorder benefits. A factor or evidentiary standard is discriminatory if the information, evidence, sources, or standards on which the factor or evidentiary standard are based are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits.

(I) Information, evidence, sources, or standards are considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all the relevant facts and circumstances, the information, evidence, sources, or standards systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to

medical/surgical benefits. For this purpose, relevant facts and circumstances may include, but are not limited to, the reliability of the source of the information, evidence, sources, or standards, including any underlying data; the independence of the information, evidence, sources, and standards relied upon; the analyses and methodologies employed to select the information and the consistency of their application; and any known safeguards deployed to prevent reliance on skewed data or metrics. Information, evidence, sources, or standards are not considered biased or not objective for this purpose if the plan or issuer has taken the steps necessary to correct, cure, or supplement any information, evidence, sources, or standards that would have been biased or not objective in the absence of such steps.

(2) For purposes of paragraph (c)(4)(i)(B) of this section, historical plan data or other historical information from a time when the plan or coverage was not subject to PHS Act section 2726 or was not in compliance with PHS Act section 2726 are considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, if the historical plan data or other historical information systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits, and the plan or issuer has not taken the steps necessary to correct, cure, or supplement the data or information.

(3) For purposes of paragraph (c)(4)(i)(B) of this section, generally recognized independent professional medical or clinical standards and carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits are not information, evidence, sources, or standards that are biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits. However, plans and issuers must comply with the other

requirements in paragraph (c)(4) of this section, as applicable, with respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation.

(ii) *Illustrative, non-exhaustive list of nonquantitative treatment limitations.*

Nonquantitative treatment limitations include –

(A) Medical management standards (such as prior authorization) limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(B) Formulary design for prescription drugs;

(C) For plans with multiple network tiers (such as preferred providers and participating providers), network tier design;

(D) Standards related to network composition, including but not limited to, standards for provider and facility admission to participate in a network or for continued network participation, including methods for determining reimbursement rates, credentialing standards, and procedures for ensuring the network includes an adequate number of each category of provider and facility to provide services under the plan or coverage;

(E) Plan or issuer methods for determining out-of-network rates, such as allowed amounts; usual, customary, and reasonable charges; or application of other external benchmarks for out-of-network rates;

(F) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(G) Exclusions based on failure to complete a course of treatment; and

(H) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the plan or coverage.

(iii) *Required use of outcomes data*—(A) *In general.* To ensure that a nonquantitative treatment limitation applicable to mental health or substance use disorder benefits in a classification, in operation, is no more restrictive than the predominant nonquantitative treatment limitation applied to substantially all medical/surgical benefits in the classification, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and carefully consider the impact as part of the plan’s or issuer’s evaluation. As part of its evaluation, the plan or issuer may not disregard relevant outcomes data that it knows or reasonably should know suggest that a nonquantitative treatment limitation is associated with material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits. The Secretary, jointly with the Secretary of the Treasury and the Secretary of Labor, may specify in guidance the type, form, and manner of collection and evaluation for the data required under this paragraph (c)(4)(iii)(A).

(1) *Relevant data generally.* For purposes of this paragraph (c)(4)(iii)(A), relevant data could include, as appropriate, but are not limited to, the number and percentage of claims denials and any other data relevant to the nonquantitative treatment limitation required by State law or private accreditation standards.

(2) *Relevant data for nonquantitative treatment limitations related to network composition.* In addition to the relevant data set forth in paragraph (c)(4)(iii)(A)(1) of this section, relevant data for nonquantitative treatment limitations related to network composition could include, as appropriate, but are not limited to, in-network and out-of-network utilization rates (including data related to provider claim submissions), network adequacy metrics (including time and distance data, and data on providers accepting new patients), and provider reimbursement rates (for comparable services and as benchmarked to a reference standard).

(3) *Unavailability of data.* (i) If a plan or issuer newly imposes a nonquantitative treatment limitation for which relevant data is initially temporarily unavailable and the plan or issuer therefore cannot comply with paragraph (c)(4)(iii)(A) of this section, the plan or issuer must include in its comparative analysis, as required under § 146.137(c)(5)(i)(C), a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed. Such a plan or issuer also must comply with paragraph (c)(4)(iii)(A) of this section as soon as practicable once relevant data becomes available.

(ii) If a plan or issuer imposes a nonquantitative treatment limitation for which no data exist that can reasonably assess any relevant impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, the plan or issuer must include in its comparative analysis, as required under § 146.137(c)(5)(i)(D), a reasoned justification as to the basis for the conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, why the nature of the nonquantitative treatment limitation prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the nonquantitative treatment limitation complies with this section. If a plan or issuer becomes aware of data that can reasonably assess any relevant impact of the nonquantitative treatment limitation, the plan or issuer must comply with paragraph (c)(4)(iii)(A) of this section as soon as practicable.

(iii) Consistent with paragraph (a)(1) of this section, paragraphs (c)(4)(iii)(A)(3)(i) and (ii) of this section shall only apply in very limited circumstances and, where applicable, shall be construed narrowly.

(B) *Material differences.* To the extent the relevant data evaluated under paragraph (c)(4)(iii)(A) of this section suggest that the nonquantitative treatment limitation contributes to

material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, such differences will be considered a strong indicator that the plan or issuer violates paragraph (c)(4) of this section.

(1) Where the relevant data suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in a classification, the plan or issuer must take reasonable action, as necessary, to address the material differences to ensure compliance, in operation, with paragraph (c)(4) of this section and must document the actions that have been or are being taken by the plan or issuer to address material differences in access to mental health or substance use disorder benefits, as compared to medical/surgical benefits, as required by § 146.137(c)(5)(iv).

(2) For purposes of paragraph (c)(4)(iii)(B) of this section, relevant data are considered to suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits if, based on all relevant facts and circumstances, and taking into account the considerations outlined in this paragraph (c)(4)(iii)(B)(2), the difference in the data suggests that the nonquantitative treatment limitation is likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits.

(i) Relevant facts and circumstances, for purposes of this paragraph (c)(4)(iii)(B)(2), may include, but are not limited to, the terms of the nonquantitative treatment limitation at issue, the quality or limitations of the data, causal explanations and analyses, evidence as to the recurring or non-recurring nature of the results, and the magnitude of any disparities.

(ii) Differences in access to mental health or substance use disorder benefits attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove

fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits, which are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation, are not considered to be material for purposes of paragraph (c)(4)(iii)(B) of this section. To the extent a plan or issuer attributes any differences in access to the application of such standards or measures, the plan or issuer must explain the bases for that conclusion in the documentation prepared under § 146.137(c)(5)(iv)(A).

(C) *Nonquantitative treatment limitations related to network composition.* For purposes of applying paragraph (c)(4)(iii)(A) of this section with respect to nonquantitative treatment limitations related to network composition, a plan or issuer must collect and evaluate relevant data in a manner reasonably designed to assess the aggregate impact of all such nonquantitative treatment limitations on access to mental health and substance use disorder benefits and medical/surgical benefits. Examples of possible actions that a plan or issuer could take to comply with the requirement under paragraph (c)(4)(iii)(B)(1) of this section to take reasonable action, as necessary, to address any material differences in access with respect to nonquantitative treatment limitations related to network composition, to ensure compliance with paragraph (c)(4) of this section, include, but are not limited to:

(1) Strengthening efforts to recruit and encourage a broad range of available mental health and substance use disorder providers and facilities to join the plan's or issuer's network of providers, including taking actions to increase compensation or other inducements, streamline credentialing processes, or contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network;

(2) Expanding the availability of telehealth arrangements to mitigate any overall mental health and substance use disorder provider shortages in a geographic area;

(3) Providing additional outreach and assistance to participants and beneficiaries enrolled in the plan or coverage to assist them in finding available in-network mental health and substance use disorder providers and facilities; and

(4) Ensuring that provider directories are accurate and reliable.

(iv) *Prohibition on separate nonquantitative treatment limitations applicable only to mental health or substance use disorder benefits.* Consistent with paragraph (c)(2)(i) of this section, a group health plan (or health insurance coverage offered by an issuer in connection with such a plan) may not apply any nonquantitative treatment limitation that is applicable only with respect to mental health or substance use disorder benefits and does not apply with respect to any medical/surgical benefits in the same benefit classification.

(v) *Effect of final determination of noncompliance under § 146.137*—(A) If a group health plan (or health insurance issuer offering coverage in connection with a group health plan) receives a final determination from the Secretary or applicable State authority that the plan or issuer is not in compliance with the requirements of PHS Act section 2726(a)(8) or § 146.137 with respect to a nonquantitative treatment limitation, the nonquantitative treatment limitation violates this paragraph (c)(4) and the Secretary or applicable State authority may direct the plan or issuer not to impose the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the relevant classification, unless and until the plan or issuer demonstrates to the Secretary or applicable State authority compliance with the requirements of this section or takes appropriate action to remedy the violation.

(B) A determination by the Secretary of whether to require cessation of a nonquantitative treatment limitation under this paragraph (c)(4)(v) will be based on an evaluation of the relevant facts and circumstances involved in the specific final determination and the nature of the underlying nonquantitative treatment limitation and will take into account the interest of plan participants and beneficiaries and feedback from the plan or issuer.

(vi) *Examples.* The rules of this paragraph (c)(4) are illustrated by the following examples. In each example, the group health plan is subject to the requirements of this section and provides both medical/surgical benefits and mental health and substance use disorder benefits.

(A) *Example 1 (Not comparable and more stringent factors for reimbursement rate methodology, in operation)*—(1) *Facts.* A plan’s reimbursement rate methodology for outpatient, in-network providers is based on a variety of factors. As written, for mental health, substance use disorder, and medical/surgical benefits, all reimbursement rates for physicians and non-physician practitioners for the same Current Procedural Terminology (CPT) code are based on a combination of factors, such as the nature of the service, duration of the service, intensity and specialization of training, provider licensure and type, number of providers qualified to provide the service in a given geographic area, and market need (demand). In operation, the plan utilizes an additional strategy to further reduce reimbursement rates for mental health and substance use disorder non-physician providers from those paid to mental health and substance use disorder physicians by the same percentage for every CPT code, but does not apply the same reductions for non-physician medical/surgical providers.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(A) (*Example 1*), the plan violates the rules of paragraph (c)(4) of this section. Because the plan reimburses non-physician providers of mental health and substance use disorder services by reducing their reimbursement rate from the rate for physician providers of mental health and substance use disorder services by the same percentage for every CPT code but does not apply the same reductions to non-physician providers of medical/surgical services from the rate for physician providers of medical/surgical services, in operation, the factors used in designing and applying the nonquantitative treatment limitation to mental health and substance use disorder benefits in the outpatient, in-network classification are not comparable to, and are applied more stringently than, the factors used in designing and applying the limitation with respect to medical/surgical benefits in the same classification. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(B) *Example 2 (Strategy for exclusion for experimental or investigative treatment more stringently applied to ABA therapy in operation)*—(1) *Facts.* A plan, as written, generally excludes coverage for all treatments that are experimental or investigative for both medical/surgical benefits and mental health and substance use disorder benefits in the outpatient, in-network classification. As a result, the plan generally excludes, as experimental, a treatment or procedure when no professionally recognized treatment guidelines include the treatment or procedure as a clinically appropriate standard of care for the condition or disorder and fewer than two randomized controlled trials are available to support the treatment’s use with respect to the given condition or disorder. The plan provides benefits for the treatment of ASD, which is a mental health condition, but, in operation, the plan excludes coverage for ABA therapy to treat children with ASD, deeming it experimental. More than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD and more than two randomized controlled trials are available to support the use of ABA therapy as one intervention to treat certain children with ASD.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(B) (*Example 2*), the plan violates the rules of paragraph (c)(4) of this section. As written, the plan excludes coverage of experimental treatment of medical conditions and surgical procedures, mental health conditions, and substance use disorders when no professionally recognized treatment guidelines define clinically appropriate standards of care for the condition or disorder as including the treatment or procedure at issue, and fewer than two randomized controlled trials are available to support the treatment's use with respect to the given condition or procedure. However, in operation, the plan deviates from this strategy with respect to ABA therapy because more than one professionally recognized treatment guideline defines clinically appropriate standards of care for ASD as including ABA therapy to treat certain children with ASD and more than two randomized controlled trials are available to support the use of ABA therapy to treat certain children with ASD. Therefore, in operation, the strategy used to design the nonquantitative treatment limitation for benefits for the treatment of ASD, which is a mental health condition, in the outpatient, in-network classification is not comparable to, and is applied more stringently than, the strategy used to design the nonquantitative treatment limitation for medical/surgical benefits in the same classification. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the outpatient, in-network classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(C) *Example 3 (Step therapy protocol with exception for severe or irreversible consequences, discriminatory factor)*—(1) *Facts.* A plan's written terms include a step therapy protocol that requires participants and beneficiaries who are prescribed certain drugs to try and fail a generic or preferred brand name drug before the plan will cover the drug originally prescribed by a participant's or beneficiary's attending provider. The plan provides an exception to this protocol that was developed solely based on a methodology developed by an external third-party organization. The third-party organization's methodology, which is not based on a generally recognized independent professional medical or clinical standard, identifies instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences. However, with respect to a drug prescribed for a mental health condition or a substance use disorder, the third-party organization's methodology only identifies instances in which a delay in treatment could result in both severe and irreversible consequences, and the plan does not take any steps to correct, cure, or supplement the methodology.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(C) (*Example 3*), the plan violates the rules of paragraph (c)(4)(i)(B) of this section. The source upon which the factor used to apply the step therapy protocol is based is biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits because it addresses instances in which a delay in treatment with a drug prescribed for a medical condition or surgical procedure could result in either severe or irreversible consequences, but only addresses instances in which a delay in treatment with a drug prescribed for a mental health condition or substance use disorder could result in both severe and irreversible consequences, and the plan fails to take the steps necessary to correct, cure, or supplement the methodology so that it is not biased and is objective. Based on the relevant facts and circumstances, this source systematically disfavors access or is specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. Therefore, the factor used to apply the step therapy protocol is discriminatory for purposes of determining

comparability and stringency under paragraph (c)(4)(i)(A) of this section, and may not be relied upon by the plan.

(D) *Example 4 (Use of historical plan data and plan steps to correct, cure, or supplement)*—(1) *Facts.* A plan’s methodology for calculating provider reimbursement rates relies only on historical plan data on total plan spending for each specialty, divided between mental health and substance use disorder providers and medical/surgical providers, from a time when the plan was not subject to PHS Act section 2726. The plan has used these historical plan data for many years to establish base reimbursement rates in all provider specialties for which it provides medical/surgical, mental health, and substance use disorder benefits in the inpatient, in-network classification. In evaluating the use of these historical plan data in the design of the methodology for calculating provider reimbursement rates, the plan determined, based on all the relevant facts and circumstances, that the historical plan data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. To ensure this information about historical reimbursement rates is not biased and is objective, the plan supplements its methodology to develop the base reimbursement rates for mental health and substance use disorder providers in accordance with additional information, evidence, sources, and standards that reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification and to attract sufficient mental health and substance use disorder providers to the network, so that the relevant facts and circumstances indicate the supplemented information, evidence, sources, or standards do not systematically disfavor access and are not specifically designed to disfavor access to mental health and substance use disorder benefits as compared to medical/surgical benefits.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(D) (*Example 4*), the plan does not violate the rules of paragraph (c)(4)(i)(B) of this section with respect to the plan’s methodology for calculating provider reimbursement rates in the inpatient, in-network classification. The relevant facts and circumstances indicate that the plan’s use of only historical plan data to design its methodology for calculating provider reimbursement rates in the inpatient, in-network classification would otherwise be considered to be biased or not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits under paragraph (c)(4)(i)(B)(2) of this section, since the historical data systematically disfavor access or are specifically designed to disfavor access to mental health or substance use disorder benefits as compared to medical/surgical benefits. However, the plan took the steps necessary to supplement the information, evidence, sources, and standards to reasonably reflect the increased demand for mental health and substance use disorder benefits in the inpatient, in-network classification, and adjust the methodology to increase reimbursement rates for those benefits, thereby ensuring that the information, evidence, sources, and standards relied upon by the plan for this purpose are not biased and are objective. Therefore, the factors and evidentiary standards used to design the plan’s methodology for calculating provider reimbursement rates in the inpatient, in-network classification are not discriminatory.

(E) *Example 5 (Generally recognized independent professional medical or clinical standards and more stringent prior authorization requirement in operation)*—(1) *Facts.* The provisions of a plan state that it relies on, and does not deviate from, generally recognized independent professional medical or clinical standards to inform the factor used to design prior authorization requirements for both medical/surgical and mental health and substance use disorder benefits in the prescription drug classification. The generally recognized independent professional medical standard for treatment of opioid use disorder that the plan utilizes—in this

case, the American Society of Addiction Medicine national practice guidelines—does not support prior authorization every 30 days for buprenorphine/naloxone. However, in operation, the plan requires prior authorization for buprenorphine/naloxone combination for treatment of opioid use disorder, every 30 days, which is inconsistent with the generally recognized independent professional medical standard on which the factor used to design the limitation is based. The plan’s factor used to design prior authorization requirements for medical/surgical benefits in the prescription drug classification relies on, and does not deviate from, generally recognized independent professional medical or clinical standards.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(E) (*Example 5*), the plan violates the rules of paragraph (c)(4) of this section. The American Society of Addiction Medicine national practice guidelines on which the factor used to design prior authorization requirements for substance use disorder benefits is based are generally recognized independent professional medical or clinical standards that are not considered to be biased or not objective in a manner that discriminates against mental health and substance use disorder benefits under paragraph (c)(4)(i)(B)(3) of this section. However, the plan must comply with other requirements in paragraph (c)(4) of this section, as applicable, with respect to such standards or measures that are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation. In operation, the plan’s factor used to design and apply prior authorization requirements with respect to substance use disorder benefits is not comparable to, and is applied more stringently than, the same factor used to design and apply prior authorization requirements for medical/surgical benefits, because the factor relies on, and does not deviate from, generally recognized independent professional medical or clinical standards for medical/surgical benefits, but deviates from the relevant guidelines for substance use disorder benefits. As a result, the nonquantitative treatment limitation with respect to substance use disorder benefits in the prescription drug classification is more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(F) *Example 6 (Plan claims no data exist to reasonably assess impact of nonquantitative treatment limitation on access; medical necessity criteria)*—(1) *Facts.* A plan approves or denies claims for mental health and substance use disorder benefits and for medical/surgical benefits in the inpatient, in-network and outpatient, in-network classifications based on medical necessity criteria. The plan states in its comparative analysis that no data exist that can reasonably assess any relevant impact of the medical necessity criteria nonquantitative treatment limitation on relevant outcomes related to access to mental health or substance use disorder benefits as compared to the plan’s medical necessity criteria nonquantitative treatment limitation’s impact on relevant outcomes related to access to medical/surgical benefits in the relevant classifications, without further explanation.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(F) (*Example 6*), the plan violates paragraph (c)(4) of this section. The plan does not comply with paragraph (c)(4)(iii)(A)(3)(ii) of this section because the plan did not include in its comparative analysis, as required under § 146.137(c)(5)(i)(D), a reasoned justification as to the basis for its conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation’s impact, an explanation of why the nature of the nonquantitative treatment limitation prevents the plan from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure the nonquantitative treatment limitation complies with paragraph (c)(4) of this section. Data that could reasonably assess the medical necessity criteria nonquantitative treatment limitation’s impact might include,

for example, the number and percentage of claims denials, or the number and percentage of claims that were approved for a lower level of care than the level requested on the initial claim. Therefore, because the plan has not collected and evaluated relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits in the relevant classifications, the plan violates the requirements of paragraph (c)(4)(iii) of this section, and violates the requirements under § 146.137(c)(5)(i)(D) because it did not include sufficient information in its comparative analysis with respect to the lack of relevant data.

(G) *Example 7 (Concurrent review data collection; no material difference in access)*—
(1) *Facts.* A plan follows a written process to apply a concurrent review nonquantitative treatment limitation to all medical/surgical benefits and mental health and substance use disorder benefits within the inpatient, in-network classification. Under this process, a first-level review is conducted in every instance in which concurrent review applies and an authorization request is approved by the first-level reviewer only if the clinical information submitted by the facility meets the plan's criteria for a continued stay. If the first-level reviewer is unable to approve the authorization request because the clinical information submitted by the facility does not meet the plan's criteria for a continued stay, it is sent to a second-level reviewer who will either approve or deny the request. The plan collects relevant data, including the number of referrals to second-level review, and the number of denials of claims for medical/surgical benefits and mental health and substance use disorder benefits subject to concurrent review as compared to the total number of claims subject to concurrent review, in the inpatient, in-network classification. The plan also collects and evaluates the number of denied claims for medical/surgical benefits and mental health and substance use disorder benefits that are overturned on appeal in the inpatient, in-network classification. The plan evaluates the relevant data and determines that, based on the relevant facts and circumstances, the data do not suggest that the concurrent review nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits in the classification. Upon requesting the plan's comparative analysis for the concurrent review nonquantitative treatment limitation and reviewing the relevant data, the Secretary does not request additional data and agrees that the data do not suggest material differences in access.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(G) (*Example 7*), the plan does not violate the rules of paragraph (c)(4)(iii) of this section. The plan collected and evaluated relevant data in a manner reasonably designed to assess the impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits and considered the impact as part of its evaluation. Because the relevant data evaluated do not suggest that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits in the inpatient, in-network classification, under paragraph (c)(4)(iii)(B) of this section, there is no strong indicator that the plan violates paragraph (c)(4) of this section.

(H) *Example 8 (Material difference in access for prior authorization requirement with reasonable action)*—(1) *Facts.* A plan requires prior authorization that a treatment is medically necessary for all inpatient, in-network medical/surgical benefits and for all inpatient, in-network mental health and substance use disorder benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the prior authorization requirement on relevant outcomes related to access to mental health and substance use disorder benefits and

medical/surgical benefits in the inpatient, in-network classification. The plan's written process for prior authorization states that the plan approves inpatient, in-network benefits for medical conditions and surgical procedures and mental health and substance use disorder benefits for periods of 1, 3, and 7 days, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. Approvals for mental health and substance use disorder benefits are most commonly given only for 1 day, after which a treatment plan must be submitted by the patient's attending provider and approved by the plan. The relevant data show that approvals for 7 days are most common for medical conditions and surgical procedures under this plan. Based on all the relevant facts and circumstances, the difference in the relevant data suggests that the nonquantitative treatment limitation is likely to have a negative impact on access to mental health and substance use disorder benefits as compared to medical/surgical benefits. Therefore, the data suggest that the nonquantitative treatment limitation contributes to material differences in access. To address these material differences in access, the plan consults more recent medical guidelines to update the factors that inform its medical necessity nonquantitative treatment limitations. Based on this review, the plan modifies the limitation so that inpatient, in-network prior authorization requests for mental health or substance use disorder benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan includes documentation of this action as part of its comparative analysis.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(H) (*Example 8*), the plan does not violate the rules of paragraph (c)(4)(iii) of this section. While relevant data for the plan's prior authorization requirements suggested that the nonquantitative treatment limitation contributes to material differences in access to mental health and substance use disorder benefits as compared to inpatient, in-network medical/surgical benefits under paragraph (c)(4)(iii)(B) of this section, the plan has taken reasonable action, as necessary, to ensure compliance, in operation, with paragraph (c)(4) of this section by updating the factors that inform its prior authorization nonquantitative treatment limitation for inpatient, in-network mental health and substance use disorder benefits so that these benefits are approved for similar periods to what is approved for medical/surgical benefits. The plan also documents its action taken to address material differences in access to inpatient, in-network benefits as required by paragraph (c)(4)(iii)(B)(I) of this section.

(I) *Example 9 (Differences attributable to generally recognized independent professional medical or clinical standards)—(1) Facts.* A group health plan develops a medical management requirement for all inpatient, out-of-network benefits for both medical/surgical benefits and mental health and substance use disorder benefits to ensure treatment is medically necessary. The factors and evidentiary standards used to design and apply the medical management requirement rely on independent professional medical or clinical standards that are generally recognized by health care providers and facilities in relevant clinical specialties. The processes, strategies, evidentiary standards, and other factors used in designing and applying the medical management requirement to mental health and substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the requirement with respect to medical/surgical benefits. The plan collects and evaluates relevant data in a manner reasonably designed to assess the impact of the medical management nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, and considers the impact as part of the plan's evaluation, as required by paragraph (c)(4)(iii)(A) of this section. Within the inpatient, out-of-network classification, the application of the medical management requirement results in a higher percentage of denials for mental health and substance use disorder claims than medical/surgical claims, because the benefits were

found to be medically necessary for a lower percentage of mental health and substance use disorder claims. The plan correctly determines that these differences in access are attributable to the generally recognized independent professional medical or clinical standards used as the basis for the factors and evidentiary standards used to design or apply the limitation and adequately explains the bases for that conclusion as part of its comparative analysis.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(I) (*Example 9*), the plan does not violate the rules of this paragraph (c)(4). Generally recognized independent professional medical or clinical standards of care are not considered to be information, evidence, sources, or standards that are biased and not objective in a manner that discriminates against mental health or substance use disorder benefits as compared to medical/surgical benefits, and the plan otherwise complies with the requirements in paragraph (c)(4)(i) of this section. Additionally, the plan does not violate paragraph (c)(4)(iii) of this section because it has collected and evaluated relevant data, the differences in access are attributable to the generally recognized independent professional medical or clinical standards that are used as the basis for the factors and evidentiary standards used to design or apply the medical management nonquantitative treatment limitation, and the plan explains the bases for this conclusion in its comparative analysis. As a result, the nonquantitative treatment limitation with respect to mental health or substance use disorder benefits in the inpatient, out-of-network classification is no more restrictive than the predominant nonquantitative treatment limitation that applies to substantially all medical/surgical benefits in the same classification.

(J) *Example 10 (Material differences in access for standards for provider admission to a network with reasonable action)*—(I) *Facts.* A plan applies nonquantitative treatment limitations related to network composition in the inpatient, in-network and outpatient, in-network classifications. The plan's networks are constructed by separate service providers for medical/surgical benefits and mental health and substance use disorder benefits. The processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations related to network composition for mental health or substance use disorder benefits in the outpatient, in-network and inpatient, in-network classifications are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitations with respect to medical/surgical benefits in the classifications, as required under paragraph (c)(4)(i) of this section. In order to ensure, in operation, that the nonquantitative treatment limitations are no more restrictive than the predominant nonquantitative treatment limitations applied to substantially all medical/surgical benefits in the classification, the plan collects and evaluates relevant data in a manner reasonably designed to assess the aggregate impact of all the nonquantitative treatment limitations related to network composition on relevant outcomes related to access to mental health and substance use disorder benefits as compared with access to medical/surgical benefits and considers the impact as part of the plan's evaluation. The plan considers relevant data that is known, or reasonably should be known, including metrics relating to the time and distance from plan participants and beneficiaries to network providers in rural and urban regions; the number of network providers accepting new patients; the proportions of mental health and substance use disorder and medical/surgical providers and facilities that provide services in rural and urban regions who are in the plan's network; provider reimbursement rates (for comparable services and benchmarked to a reference standard, as appropriate); and in-network and out-of-network utilization rates (including data related to the dollar value and number of provider claims submissions). The plan determines that the relevant data suggest that the nonquantitative treatment limitations in the aggregate contribute to material differences in access to mental health and substance use disorder

benefits compared to medical/surgical benefits in the classifications because, based on all the relevant facts and circumstances, the differences in the data suggest that the nonquantitative treatment limitations related to network composition are likely to have a negative impact on access to mental health or substance use disorder benefits as compared to medical/surgical benefits. The plan takes reasonable actions, as necessary, to address the material differences in access, to ensure compliance, in operation, with paragraph (c)(4) of this section, by strengthening its efforts to recruit and encourage a broad range of available providers and facilities to join the plan's network of providers, including by taking actions to increase compensation and other inducements, streamline credentialing processes, contact providers reimbursed for items and services provided on an out-of-network basis to offer participation in the network, and develop a process to monitor the effects of such efforts; expanding the availability of telehealth arrangements to mitigate overall provider shortages in certain geographic areas; providing additional outreach and assistance to participants and beneficiaries enrolled in the plan to assist them in finding available in-network providers and facilities; and ensuring that the plan's provider directories are accurate and reliable. The plan documents the efforts that it has taken to address the material differences in access that the data revealed, and the plan includes the documentation as part of its comparative analysis submission.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(J) (*Example 10*), the plan does not violate the rules of this paragraph (c)(4). The plan's nonquantitative treatment limitations related to network composition comply with the rules of paragraph (c)(4)(i) of this section. Additionally, the plan collects and evaluates relevant data, as required under paragraph (c)(4)(iii)(A) of this section, in a manner reasonably designed to assess the aggregate impact of all such nonquantitative treatment limitations on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits, as required under paragraph (c)(4)(iii)(C) of this section. While the data suggest that the nonquantitative treatment limitations contribute to material differences in access to mental health and substance use disorder benefits as compared to medical/surgical benefits, the plan has taken reasonable action, as necessary, to ensure compliance with paragraph (c)(4) of this section. The plan also documents the actions that have been and are being taken by the plan to address material differences as required by § 146.137(c)(5)(iv). As a result, the network composition nonquantitative treatment limitations with respect to mental health or substance use disorder benefits in the inpatient, in-network and outpatient, in-network classifications are no more restrictive than the predominant nonquantitative treatment limitations that apply to substantially all medical/surgical benefits in the same classifications.

(K) *Example 11 (Separate EAP exhaustion treatment limitation applicable only to mental health or substance use disorder benefits)—(1) Facts.* An employer maintains both a major medical plan and an employee assistance program (EAP). The EAP provides, among other benefits, a limited number of mental health or substance use disorder counseling sessions, which, together with other benefits provided by the EAP, are not significant benefits in the nature of medical care. Participants are eligible for mental health or substance use disorder benefits under the major medical plan only after exhausting the counseling sessions provided by the EAP. No similar exhaustion requirement applies with respect to medical/surgical benefits provided under the major medical plan.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(K) (*Example 11*), the requirement that limits eligibility for mental health and substance use disorder benefits under the major medical plan until EAP benefits are exhausted is a nonquantitative treatment limitation subject to the parity requirements of this paragraph (c)(4). Because the limitation does not apply to medical/surgical

benefits, it is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits that violates paragraph (c)(4)(iv) of this section. Additionally, this EAP would not qualify as excepted benefits under § 146.145(b)(3)(vi)(B)(I) because participants in the major medical plan are required to use and exhaust benefits under the EAP (making the EAP a gatekeeper) before an individual is eligible for benefits under the plan.

(L) *Example 12 (Separate exclusion for treatment in a residential facility applicable only to mental health and substance use disorder benefits)*—(1) *Facts*. A plan generally covers inpatient, in-network and inpatient, out-of-network treatment without any limitations on setting, including skilled nursing facilities and rehabilitation hospitals, provided other medical necessity standards are satisfied. The plan has an exclusion for treatment at residential facilities, which the plan defines as an inpatient benefit for mental health and substance use disorder benefits. This exclusion was not generated through any broader nonquantitative treatment limitation (such as medical necessity or other clinical guideline).

(2) *Conclusion*. In this paragraph (c)(4)(vi)(L) (*Example 12*), the plan violates the rules of paragraph (c)(4)(iv) of this section. The exclusion of treatment at residential facilities is a separate nonquantitative treatment limitation applicable only to mental health and substance use disorder benefits in the inpatient, in-network and inpatient, out-of-network classifications because the plan does not apply a comparable exclusion with respect to any medical/surgical benefits in the same benefit classification.

(M) *Example 13 (Impermissible nonquantitative treatment limitation imposed following a final determination of noncompliance and direction by the Secretary)*—(1) *Facts*. Following an initial request by the Secretary for a plan's comparative analysis of the plan's exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification under § 146.137(d), the plan submits a comparative analysis for the nonquantitative treatment limitation. After review of the comparative analysis, as well as additional information submitted by the plan after the Secretary determines that the plan has not submitted sufficient information to be responsive to the request, the Secretary makes an initial determination that the comparative analysis fails to demonstrate that the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the inpatient, in-network classification are comparable to, and applied no more stringently than, those used in designing and applying the limitation to medical/surgical benefits in the classification. Under § 146.137(d)(3), the plan submits a corrective action plan and additional comparative analyses within 45 calendar days after the initial determination. However, the corrective action plan does not alter or eliminate the exclusion or alter the processes, strategies, evidentiary standards, and other factors used in designing and applying the exclusion. Moreover, the additional comparative analysis still does not include sufficient information. The Secretary then determines that the additional comparative analyses do not demonstrate compliance with the requirements of this paragraph (c)(4). Accordingly, the plan receives a final determination of noncompliance with PHS Act section 2726 (a)(8) and § 146.137 from the Secretary, which concludes that the plan did not demonstrate compliance through the comparative analysis process. After considering the relevant facts and circumstances, and considering the interests of plan participants and beneficiaries, as well as feedback from the plan, the Secretary directs the plan not to impose the nonquantitative treatment limitation by a certain date, unless and until the plan demonstrates compliance to the Secretary or takes appropriate action to remedy the violation. The plan makes no changes to its plan terms by that date and continues to impose the

exclusion of benefits for failure to complete a course of treatment in the inpatient, in-network classification.

(2) *Conclusion.* In this paragraph (c)(4)(vi)(M) (*Example 13*), by continuing to impose the exclusion of mental health and substance use disorder benefits for failure to complete a course of treatment in the inpatient, in-network classification after the Secretary directs the plan not to impose this nonquantitative treatment limitation, the plan violates the requirements of paragraph (c)(4)(v) of this section.

* * * * *

(d) * * *

(3) *Provisions of other law.* Compliance with the disclosure requirements in paragraphs (d)(1) and (2) of this section is not determinative of compliance with any other provision of applicable Federal or State law. In particular, in addition to those disclosure requirements, provisions of other applicable law require disclosure of information relevant to medical/surgical, mental health, and substance use disorder benefits. For example, § 147.136 of this subchapter sets forth rules regarding claims and appeals, including the right of claimants (or their authorized representative) who have received an adverse benefit determination (or a final internal adverse benefit determination) to be provided, upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the claimant's claim for benefits. This includes documents with information on medical necessity criteria for both medical/surgical benefits and mental health and substance use disorder benefits, as well as the processes, strategies, evidentiary standards, and other factors used to apply a nonquantitative treatment limitation with respect to medical/surgical benefits and mental health or substance use disorder benefits under the plan and the comparative analyses and other applicable information required by § 146.137.

(e) * * *

(4) *Coordination with EHB requirements.* Nothing in paragraph (f) or (g) of this section or § 146.137(g) changes the requirements of §§ 147.150 and 156.115 of this subchapter, providing that a health insurance issuer offering non-grandfathered health insurance coverage in

the individual or small group market that is required to provide mental health and substance use disorder services, including behavioral health treatment services, as part of essential health benefits required under §§ 156.110(a)(5) and 156.115(a) of this subchapter, must comply with the requirements under section 2726 of the PHS Act and its implementing regulations to satisfy the requirement to provide coverage for mental health and substance use disorder services, including behavioral health treatment, as part of essential health benefits.

* * * * *

(i) * * *

(1) *In general.* Except as provided in paragraph (i)(2) of this section—

(i) This section applies to group health plans and health insurance issuers offering group health insurance coverage on the first day of the first plan year beginning on or after January 1, 2025, except that the requirements of paragraphs (c)(2)(ii)(A), (c)(4)(i)(B), and (c)(4)(iii) of this section apply on the first day of the first plan year beginning on or after January 1, 2026.

(ii) Until the applicability date in paragraph (i)(1)(i) of this section, plans and issuers are required to continue to comply with 45 CFR 146.136, revised as of October 1, 2023.

* * * * *

(j) *Severability.* If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

9. Add § 146.137 to read as follows:

§ 146.137 Nonquantitative treatment limitation comparative analysis requirements.

(a) *Meaning of terms.* Unless otherwise stated in this section, the terms of this section have the meanings indicated in § 146.136(a)(2).

(b) *In general.* In the case of a group health plan (or health insurance issuer offering coverage in connection with a group health plan) that provides both medical/surgical benefits and mental health or substance use disorder benefits and that imposes any nonquantitative treatment limitation on mental health or substance use disorder benefits, the plan or issuer must perform and document a comparative analysis of the design and application of each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits. Each comparative analysis must comply with the content requirements of paragraph (c) of this section and be made available to the Secretary, upon request, in the manner required by paragraphs (d) and (e) of this section.

(c) *Comparative analysis content requirements.* With respect to each nonquantitative treatment limitation applicable to mental health or substance use disorder benefits under a group health plan (or health insurance coverage offered in connection with a group health plan), the comparative analysis performed by the plan or issuer must include, at minimum, the elements specified in this paragraph (c). In addition to the comparative analysis for each nonquantitative treatment limitation, each plan or issuer must prepare and make available to the Secretary, upon request, a written list of all nonquantitative treatment limitations imposed under the plan or coverage.

(1) *Description of the nonquantitative treatment limitation.* The comparative analysis must include, with respect to the nonquantitative treatment limitation that is the subject of the comparative analysis:

(i) Identification of the nonquantitative treatment limitation, including the specific terms of the plan or coverage or other relevant terms regarding the nonquantitative treatment limitation,

the policies or guidelines (internal or external) in which the nonquantitative treatment limitation appears or is described, and the applicable sections of any other relevant documents, such as provider contracts, that describe the nonquantitative treatment limitation;

(ii) Identification of all mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation applies, including a list of which benefits are considered mental health or substance use disorder benefits and which benefits are considered medical/surgical benefits; and

(iii) A description of which benefits are included in each classification set forth in § 146.136(c)(2)(ii)(A).

(2) *Identification and definition of the factors and evidentiary standards used to design or apply the nonquantitative treatment limitation.* The comparative analysis must include, with respect to every factor considered or relied upon to design the nonquantitative treatment limitation or apply the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits:

(i) Identification of every factor considered or relied upon, as well as the evidentiary standards considered or relied upon to design or apply each factor and the sources from which each evidentiary standard was derived, in determining which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation; and

(ii) A definition of each factor, including:

(A) A detailed description of the factor;

(B) A description of each evidentiary standard used to design or apply each factor (and the source of each evidentiary standard) identified under paragraph (c)(2)(i) of this section; and

(C) A description of any steps the plan or issuer has taken to correct, cure, or supplement any information, evidence, sources, or standards that would otherwise have been considered biased or not objective under § 146.136(c)(4)(i)(B)(I) in the absence of such steps.

(3) *Description of how factors are used in the design and application of the nonquantitative treatment limitation.* The comparative analysis must include a description of how each factor identified and defined under paragraph (c)(2) of this section is used in the design or application of the nonquantitative treatment limitation to mental health and substance use disorder benefits and medical/surgical benefits in a classification, including:

(i) A detailed explanation of how each factor identified and defined in paragraph (c)(2) of this section is used to determine which mental health or substance use disorder benefits and which medical/surgical benefits are subject to the nonquantitative treatment limitation;

(ii) An explanation of the evidentiary standards or other information or sources (if any) considered or relied upon in designing or applying the factors or relied upon in designing and applying the nonquantitative treatment limitation, including in the determination of whether and how mental health or substance use disorder benefits or medical/surgical benefits are subject to the nonquantitative treatment limitation;

(iii) If the application of the factor depends on specific decisions made in the administration of benefits, the nature of the decisions, the timing of the decisions, and the professional designations and qualifications of each decision maker;

(iv) If more than one factor is identified and defined in paragraph (c)(2) of this section, an explanation of:

(A) How all of the factors relate to each other;

(B) The order in which all the factors are applied, including when they are applied;

(C) Whether and how any factors are given more weight than others; and

(D) The reasons for the ordering or weighting of the factors; and

(v) Any deviations or variations from a factor, its applicability, or its definition (including the evidentiary standards used to define the factor and the information or sources from which each evidentiary standard was derived), such as how the factor is used differently to apply the nonquantitative treatment limitation to mental health or substance use disorder benefits as compared to medical/surgical benefits, and a description of how the plan or issuer establishes such deviations or variations.

(4) *Demonstration of comparability and stringency as written.* The comparative analysis must evaluate whether, in any classification, under the terms of the plan (or health insurance coverage) as written, any processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) Documentation of each factor identified and defined in paragraph (c)(2) of this section that was applied to determine whether the nonquantitative treatment limitation applies to mental health or substance use disorder benefits and medical/surgical benefits in a classification, including, as relevant:

(A) Quantitative data, calculations, or other analyses showing whether, in each classification in which the nonquantitative treatment limitation applies, mental health or substance use disorder benefits and medical/surgical benefits met or did not meet any applicable threshold identified in the relevant evidentiary standard to determine that the nonquantitative treatment limitation would or would not apply; and

(B) Records maintained by the plan or issuer documenting the consideration and application of all factors and evidentiary standards, as well as the results of their application;

(ii) In each classification in which the nonquantitative treatment limitation applies to mental health or substance use disorder benefits, a comparison of how the nonquantitative treatment limitation, as written, is designed and applied to mental health or substance use disorder benefits and to medical/surgical benefits, including the specific provisions of any forms, checklists, procedure manuals, or other documentation used in designing and applying the nonquantitative treatment limitation or that address the application of the nonquantitative treatment limitation;

(iii) Documentation demonstrating how the factors are comparably applied, as written, to mental health or substance use disorder benefits and medical/surgical benefits in each classification, to determine which benefits are subject to the nonquantitative treatment limitation; and

(iv) An explanation of the reasons for any deviations or variations in the application of a factor used to apply the nonquantitative treatment limitation, or the application of the nonquantitative treatment limitation, to mental health or substance use disorder benefits as compared to medical/surgical benefits, and how the plan or issuer establishes such deviations or variations, including:

(A) In the definition of the factors, the evidentiary standards used to define the factors, and the sources from which the evidentiary standards were derived;

(B) In the design of the factors or evidentiary standards; or

(C) In the application or design of the nonquantitative treatment limitation.

(5) *Demonstration of comparability and stringency in operation.* The comparative analysis must evaluate whether, in any classification, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative

treatment limitation to mental health or substance use disorder benefits are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the limitation with respect to medical/surgical benefits. The comparative analysis must include, with respect to the nonquantitative treatment limitation and the factors used in designing and applying the nonquantitative treatment limitation:

(i) A comprehensive explanation of how the plan or issuer evaluates whether, in operation, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in a classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in designing and applying the nonquantitative treatment limitation with respect to medical/surgical benefits, including:

(A) An explanation of any methodology and underlying data used to demonstrate the application of the nonquantitative treatment limitation, in operation;

(B) The sample period, inputs used in any calculations, definitions of terms used, and any criteria used to select the mental health or substance use disorder benefits and medical/surgical benefits to which the nonquantitative treatment limitation is applicable;

(C) With respect to a nonquantitative treatment limitation for which relevant data is temporarily unavailable as described in § 146.136(c)(4)(iii)(A)(3)(i), a detailed explanation of the lack of relevant data, the basis for the plan's or issuer's conclusion that there is a lack of relevant data, and when and how the data will become available and be collected and analyzed; and

(D) With respect to a nonquantitative treatment limitation for which no data exist that can reasonably assess any relevant impact of the nonquantitative treatment limitation on relevant outcomes related to access to mental health and substance use disorder benefits and medical/surgical benefits as described in § 146.136(c)(4)(iii)(A)(3)(ii), a reasoned justification as

to the basis for the conclusion that there are no data that can reasonably assess the nonquantitative treatment limitation's impact, an explanation of why the nature of the nonquantitative treatment limitation prevents the plan or issuer from reasonably measuring its impact, an explanation of what data was considered and rejected, and documentation of any additional safeguards or protocols used to ensure that the nonquantitative treatment limitation complies with § 146.136(c)(4);

(ii) Identification of the relevant data collected and evaluated, as required under § 146.136(c)(4)(iii)(A);

(iii) Documentation of the outcomes that resulted from the application of the nonquantitative treatment limitation to mental health or substance use disorder benefits and medical/surgical benefits, including:

(A) The evaluation of relevant data as required under § 146.136(c)(4)(iii)(A); and

(B) A reasoned justification and analysis that explains why the plan or issuer concluded that any differences in the relevant data do or do not suggest the nonquantitative treatment limitation contributes to material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, in accordance with § 146.136(c)(4)(iii)(B)(2);

(iv) A detailed explanation of any material differences in access demonstrated by the outcomes evaluated under paragraph (c)(5)(iii) of this section, including:

(A) A reasoned explanation of any material differences in access that are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation as applied to mental health or substance use disorder benefits and medical/surgical benefits (including any considerations beyond a plan's or issuer's control that contribute to the existence of material differences) and a detailed explanation of the bases for concluding that material differences are not attributable to differences in the comparability or relative stringency of the nonquantitative treatment limitation; and

(B) To the extent differences in access to mental health or substance use disorder benefits are attributable to generally recognized independent professional medical or clinical standards or carefully circumscribed measures reasonably and appropriately designed to detect or prevent and prove fraud and abuse that minimize the negative impact on access to appropriate mental health and substance use disorder benefits, and such standards or measures are used as the basis for a factor or evidentiary standard used to design or apply a nonquantitative treatment limitation, documentation explaining how any such differences are attributable to those standards or measures, as required in § 146.136(c)(4)(iii)(B)(2)(ii); and

(v) A discussion of the actions that have been or are being taken by the plan or issuer to address any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits, including the actions the plan or issuer has taken or is taking under § 146.136(c)(4)(iii)(B)(I) to address material differences to comply, in operation, with § 146.136(c)(4), including, as applicable:

(A) A reasoned explanation of any material differences in access to mental health or substance use disorder benefits as compared to medical/surgical benefits that persist despite reasonable actions that have been or are being taken; and

(B) For a plan or issuer designing and applying one or more nonquantitative treatment limitations related to network composition, a discussion of the actions that have been or are being taken to address material differences in access to in-network mental health and substance use disorder benefits as compared to in-network medical/surgical benefits, including those listed in § 146.136(c)(4)(iii)(C).

(6) *Findings and conclusions.* The comparative analysis must address the findings and conclusions as to the comparability of the processes, strategies, evidentiary standards, and other factors used in designing and applying the nonquantitative treatment limitation to mental health

or substance use disorder benefits and medical/surgical benefits within each classification, and the relative stringency of their application, both as written and in operation, and include:

(i) Any findings or conclusions indicating that the plan or coverage is or is not (or might or might not be) in compliance with the requirements of § 146.136(c)(4), including any additional actions the plan or issuer has taken or intends to take to address any potential areas of concern or noncompliance;

(ii) A reasoned and detailed discussion of the findings and conclusions described in paragraph (c)(6)(i) of this section;

(iii) Citations to any additional specific information not otherwise included in the comparative analysis that supports the findings and conclusions described in paragraph (c)(6)(i) of this section not otherwise discussed in the comparative analysis;

(iv) The date the analysis is completed and the title and credentials of all relevant persons who participated in the performance and documentation of the comparative analysis; and

(v) If the comparative analysis relies upon an evaluation by a reviewer or consultant considered by the plan or issuer to be an expert, an assessment of each expert's qualifications and the extent to which the plan or issuer ultimately relied upon each expert's evaluation in performing and documenting the comparative analysis of the design and application of the nonquantitative treatment limitation applicable to both mental health or substance use disorder benefits and medical/surgical benefits.

(d) *Requirements related to submission of comparative analyses to the Secretary upon request—(1) Initial request by the Secretary for comparative analysis.* A group health plan (or health insurance issuer offering coverage in connection with a group health plan) must make the comparative analysis required by paragraph (b) of this section available and submit it to the Secretary within 10 business days of receipt of a request from the Secretary (or an additional period of time specified by the Secretary).

(2) *Additional information required after a comparative analysis is deemed to be insufficient.* In instances in which the Secretary determines that the plan or issuer has not submitted sufficient information under paragraph (d)(1) of this section for the Secretary to determine whether the comparative analysis required in paragraph (b) of this section complies with paragraph (c) of this section or whether the plan or issuer complies with § 146.136(c)(4), the Secretary will specify to the plan or issuer the additional information the plan or issuer must submit to the Secretary to be responsive to the request under paragraph (d)(1) of this section. Any such information must be provided to the Secretary by the plan or issuer within 10 business days after the Secretary specifies the additional information to be submitted (or an additional period of time specified by the Secretary).

(3) *Initial determination of noncompliance, required action, and corrective action plan.* In instances in which the Secretary reviewed the comparative analysis submitted under paragraph (d)(1) of this section and any additional information submitted under paragraph (d)(2) of this section, and made an initial determination that the plan or issuer is not in compliance with the requirements of § 146.136(c)(4) or this section, the plan or issuer must respond to the initial determination by the Secretary and specify the actions the plan or issuer will take to bring the plan or coverage into compliance, and provide to the Secretary additional comparative analyses meeting the requirements of paragraph (c) of this section that demonstrate compliance with § 146.136(c)(4), not later than 45 calendar days after the Secretary's initial determination that the plan or issuer is not in compliance.

(4) *Requirement to notify participants and beneficiaries of final determination of noncompliance—(i) In general.* If the Secretary makes a final determination of noncompliance, the plan or issuer must notify all participants and beneficiaries enrolled in the plan or coverage that the plan or issuer has been determined to not be in compliance with the requirements of § 146.136(c)(4) or this section with respect to such plan or coverage. Such notice must be

provided within 7 business days of receipt of the final determination of noncompliance, and the plan or issuer must provide a copy of the notice to the Secretary, any service provider involved in the claims process, and any fiduciary responsible for deciding benefit claims within the same timeframe.

(ii) *Content of notice.* The notice to participants and beneficiaries required in paragraph (d)(4)(i) of this section shall be written in a manner calculated to be understood by the average plan participant and must include, in plain language, the following information in a standalone notice:

(A) The following statement prominently displayed on the first page, in no less than 14-point font: “Attention! The Department of Health and Human Services has determined that [insert the name of group health plan or health insurance issuer] is not in compliance with the Mental Health Parity and Addiction Equity Act.”;

(B) A summary of changes the plan or issuer has made as part of its corrective action plan specified to the Secretary following the initial determination of noncompliance, including an explanation of any opportunity for a participant or beneficiary to have a claim for benefits submitted or reprocessed;

(C) A summary of the Secretary’s final determination that the plan or issuer is not in compliance with § 146.136(c)(4) or this section, including any provisions or practices identified as being in violation of § 146.136(c)(4) or this section, additional corrective actions identified by the Secretary in the final determination notice, and information on how participants and beneficiaries can obtain from the plan or issuer a copy of the final determination of noncompliance;

(D) Any additional actions the plan or issuer is taking to come into compliance with § 146.136(c)(4) or this section, when the plan or issuer will take such actions, and a clear and accurate statement explaining whether the Secretary has concurred with those actions; and

(E) Contact information for questions and complaints, and a statement explaining how participants and beneficiaries can obtain more information about the notice, including:

(1) The plan's or issuer's phone number and an email or web portal address; and

(2) The Centers for Medicare & Medicaid Services' phone number and email or web portal address.

(iii) *Manner of notice.* The plan or issuer must make the notice required under paragraph (d)(4)(i) of this section available in paper form, or electronically (such as by email or an Internet posting) if:

(A) The format is readily accessible;

(B) The notice is provided in paper form free of charge upon request; and

(C) In a case in which the electronic form is an internet posting, the plan or issuer timely notifies the participant or beneficiary in paper form (such as a postcard) or email, that the documents are available on the internet, provides the internet address, includes the statement required in paragraph (d)(4)(ii)(A) of this section, and notifies the participant or beneficiary that the documents are available in paper form upon request.

(e) *Requests for a copy of a comparative analysis.* In addition to making a comparative analysis available upon request to the Secretary, a plan or issuer must make available a copy of the comparative analysis required by paragraph (b) of this section when requested by:

(1) Any applicable State authority; and

(2) A participant or beneficiary (including a provider or other person acting as a participant's or beneficiary's authorized representative) who has received an adverse benefit determination related to mental health or substance use disorder benefits.

(f) *Rule of construction.* Nothing in this section or § 146.136 shall be construed to prevent the Secretary from acting within the scope of existing authorities to address violations of § 146.136 or this section.

(g) *Applicability.* The provisions of this section apply to group health plans and health insurance issuers offering group health insurance coverage described in § 146.136(e), to the extent the plan or issuer is not exempt under § 146.136(f) or (g), on the first day of the first plan year beginning on or after January 1, 2025, except the requirements of paragraphs (c)(2)(ii)(C), (c)(5)(i)(C) and (D), and (c)(5)(ii) through (v) of this section apply on the first day of the first plan year beginning on or after January 1, 2026.

(h) *Severability.* If any provision of this section is held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, or stayed pending further agency action, the provision shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

10. Amend § 146.180 by:

- a. Revising paragraph (a)(2);
- b. Redesignating paragraphs (a)(3) through (7) as paragraphs (a)(4) through (8);
- c. Adding new paragraph (a)(3);
- d. Revising newly redesignated paragraphs (a)(5) and (a)(7)(i) and paragraph (f)(1); and
- e. Adding paragraph (f)(4)(iii).

The revisions and additions read as follows:

§ 146.180 Treatment of non-Federal governmental plans.

(a) * * *

(2) *General rule.* For plans years beginning on or after September 23, 2010, a sponsor of a non-Federal governmental plan may elect to exempt its plan, to the extent the plan is not

provided through health insurance coverage (that is self-funded), from one or more of the requirements described in paragraphs (a)(1)(iv) through (vii) of this section, except as provided in paragraphs (a)(3) and (f)(1) of this section with respect to the requirements described in paragraph (a)(1)(v) of this section.

(3) *Sunset of election option related to parity in mental health and substance use disorder benefits.* A sponsor of a non-Federal governmental plan may not newly elect to exempt its plans from the requirements described in paragraph (a)(1)(v) of this section on or after December 29, 2022.

* * * * *

(5) *Examples—* (i) *Example 1.* A non-Federal governmental employer has elected to exempt its self-funded group health plan from all of the requirements described in paragraph (a)(1) of this section. The plan year commences September 1st of each year. The plan is not subject to the provisions of paragraph (a)(2) of this section until the plan year that commences on September 1, 2011. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in paragraphs (a)(1)(iv) through (vii) of this section, subject to paragraphs (a)(3) and (f)(1) of this section with respect to the requirements described in paragraph (a)(1)(v) of this section.

(ii) *Example 2.* A non-Federal governmental employer has elected to exempt its collectively bargained self-funded plan from all of the requirements described in paragraph (a)(1) of this section. The collective bargaining agreement applies to 5 plan years, October 1, 2009, through September 30, 2014. For the plan year that begins on October 1, 2014, the plan sponsor is no longer permitted to elect to exempt its plan from the requirements described in paragraphs (a)(1)(i) through (iii) of this section. Accordingly, for that plan year and any subsequent plan years, the plan sponsor may elect to exempt its plan only from the requirements described in

paragraphs (a)(1)(iv) through (vii) of this section, subject to paragraphs (a)(3) and (f)(1) of this section with respect to the requirements described in paragraph (a)(1)(v) of this section.

* * * * *

(7) * * *

(i) Subject to paragraph (a)(7)(ii) of this section, the purchase of stop-loss or excess risk coverage by a self-funded non-Federal governmental plan does not prevent an election under this section.

* * * * *

(f) * * *

(1) *Election renewal.* A plan sponsor may renew an election under this section through subsequent elections. Notwithstanding the previous sentence and except as provided in paragraph (f)(4)(iii) of this section, an election with respect to the requirements described in paragraph (a)(1)(v) of this section expiring on or after June 27, 2023, may not be renewed. The timeliness standards described in paragraph (c) of this section apply to election renewals under paragraph (f) of this section.

* * * * *

(4) * * *

(iii) In the case of a plan that is subject to multiple collective bargaining agreements of varying lengths and that has an election with respect to the requirements described in paragraph (a)(1)(v) of this section in effect as of December 29, 2022, that expires on or after June 27, 2023, the plan may extend such election until the date on which the term of the last such agreement expires.

* * * * *

**PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP
AND INDIVIDUAL HEALTH INSURANCE MARKETS**

11. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 300gg through 300gg–63, 300gg–91, 300gg–92, and 300gg–111 through 300gg–139, as amended, and section 3203, Pub. L. 116–136, 134 Stat. 281.

12. Revise § 147.160 to read as follows:

§ 147.160 Parity in mental health and substance use disorder benefits.

(a) *In general.* The provisions of §§ 146.136 and 146.137 of this subchapter apply to individual health insurance coverage offered by a health insurance issuer in the same manner and to the same extent as such provisions apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the large group market.

(b) *Applicability date.* The provisions of this section apply for policy years beginning on or after January 1, 2026. Until the applicability date in the preceding sentence, issuers are required to continue to comply with 45 CFR 147.160, incorporating 45 CFR 146.136, each revised as of October 1, 2023. This section applies to non-grandfathered and grandfathered health plans as defined in § 147.140.