FAQS ABOUT AFFORDABLE CARE ACT AND WOMEN'S HEALTH AND CANCER RIGHTS ACT IMPLEMENTATION PART 68

October 21, 2024

Set out below are Frequently Asked Questions (FAQs) regarding implementation of certain provisions of the Affordable Care Act (ACA) and the Women's Health and Cancer Rights Act (WHCRA). These FAQs have been prepared jointly by the Departments of Labor, Health and Human Services, and the Treasury (collectively, the Departments). Like previously issued FAQs (available at https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/aca-implementation-faqs and http://www.cms.gov/cciio/resources/fact-sheets-and-faqs/index.html), these FAQs answer questions from stakeholders to help people understand the law and promote compliance.

Coverage of Preventive Services

Public Health Service (PHS) Act section 2713 and its implementing regulations relating to coverage of preventive services[1] require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to cover, without the imposition of any cost-sharing requirements, the following items or services:

- Evidence-based items or services that have in effect a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved, except for the recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention issued in or around November 2009;[2,3]

[1] *See* 26 CFR 54.9815-2713; 29 CFR 2590.715-2713; 45 CFR 147.130.

[2] The USPSTF published updated breast cancer screening recommendations in April 2024. However, section 223 of Division D, Title II of the Further Consolidated Appropriations Act, 2024 (Pub. L. 118–47) requires that for purposes of PHS Act section 2713, USPSTF recommendations relating to breast cancer screening, mammography, and prevention issued before 2009 remain in effect until January 1, 2026.

[3] On March 30, 2023, the United States District Court for the Northern District of Texas issued a final judgment in the case *Braidwood Management Inc. v. Becerra*, Civil Action No. 4:20-cv-00283-O (N.D. Tex. Mar. 30, 2023) holding that the USPSTF's recommendations operating in conjunction with PHS Act section 2713(a)(1) violate the Appointments Clause of Article II of the United States Constitution. The district court decision in *Braidwood* vacated any and all actions taken by the Departments to implement or enforce PHS Act section 2713(a)(1)'s preventive service coverage requirements in response to an "A" or "B" recommendation by the USPSTF on or after March 23, 2010, and enjoined the Departments from implementing or enforcing PHS Act section 2713(a)(1)'s preventive service coverage requirements in response to an "A" or "B" rating from the USPSTF in the future. The district court also concluded that the requirement under PHS Act section 2713(a)(1) to cover pre-exposure prophylaxis (PrEP) with effective antiretroviral therapy for persons who are at high risk of HIV acquisition, consistent with the applicable USPSTF recommendation, violated the rights of some of the plaintiffs before the court under the Religious Freedom Restoration Act. On appeal, the U.S. Court of Appeals for the Fifth Circuit affirmed the district court's judgment to the extent that it enjoined the Departments from enforcing the USPSTF's

- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) with respect to the individual involved;[4]
- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA); and
- With respect to women, such additional preventive care and screenings not described in PHS Act section 2713(a)(1) as provided for in comprehensive guidelines supported by HRSA.[5]

If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service, then the plan or issuer[6] may use reasonable medical management techniques to determine any such coverage limitations. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive item or service.[7] Additionally, plans and issuers subject to PHS Act section 2713 must cover, without cost sharing, items and services that are integral to the furnishing of a recommended preventive service, regardless of whether the item or service is billed separately.[8]

Coverage of Pre-Exposure Prophylaxis (PrEP)

On June 11, 2019, the USPSTF released a recommendation[9] with an "A" rating that clinicians offer PrEP with "effective antiretroviral therapy to persons who are at high risk of HIV

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recommendations under PHS Act section 2713(a)(1) with respect to the named plaintiffs; reversed the district court's judgment to the extent it imposed a nationwide injunction; and remanded to the district court for further proceedings. *See* 104 F.4th 930 (5th Cir. 2024), *petition for cert. filed*, (U.S. Sept. 19, 2024) (No. 24-316). On August 28, 2024, the district court entered a stay pending proceedings in the Supreme Court.

[4] In addition, under section 3203 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), plans and issuers must cover, without cost-sharing requirements, any qualifying coronavirus preventive service pursuant to section 2713(a) of the PHS Act and its implementing regulations (or any successor regulations). The term "qualifying coronavirus preventive service" means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID-19) and that is, with respect to the individual involved (1) an evidence-based item or service that has in effect a rating of "A" or "B" in the current USPSTF recommendations; or (2) an immunization that has in effect a recommendation from ACIP.

[5] For accommodations and exemptions with respect to coverage of recommended contraceptive services, see 26 CFR 54.9815-2713A; 29 CFR 2590.715-2713A; 45 CFR 147.131 through 147.133.

[6] References to plans and issuers throughout these FAQs on coverage of preventive services refer to plans and issuers that are subject to PHS Act section 2713.

[7] *See* 26 CFR 54.9815-2713(a)(4); 29 CFR 2590.715-2713(a)(4); 45 CFR 147.130(a)(4).

[8] *See* 85 FR 71142, 71174 (Nov. 6, 2020) (discussing examples provided in Coverage of Certain Preventive Services Under the Affordable Care Act, 80 FR 41318 (July 14, 2015), and stating "plans and issuers subject to section 2713 of the PHS Act must cover, without cost sharing, items and services that are integral to the furnishing of the recommended preventive service, regardless of whether the item or service is billed separately."). *See also* 80 FR 41318, 41319 (July 14, 2015) (discussing previous guidance).

[9] USPSTF, Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis (June 11, 2019), available at https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis-june-2019.

acquisition," resulting in a requirement that plans and issuers cover PrEP according to the recommendation for plan years (in the individual market, policy years) beginning on or after June 30, 2020, under section 2713 of the PHS Act.[10] The Departments subsequently issued an FAQ clarifying that, consistent with CDC guidelines, the 2019 USPSTF recommendation for PrEP encompasses FDA-approved PrEP antiretroviral medications as well as specified baseline and monitoring services that are essential to the efficacy of PrEP.[11]

In June 2019, the only formulation of PrEP approved by the FDA for use in the United States in persons at risk of sexual acquisition of HIV infection was once-daily oral treatment with combined tenofovir disoproxil fumarate and emtricitabine (TDF/FTC; brand name Truvada®). On August 22, 2023, the USPSTF updated its recommendation with respect to PrEP.[12] The USPSTF reviewed additional evidence on new formulations of PrEP and, in its 2023 recommendation, the USPSTF identified two additional FDA-approved formulations of PrEP:

- Emtricitabine/tenofovir alafenamide (TAF/FTC; brand name Descovy®), the second daily oral medication approved by the FDA for PrEP in October 2019; and
- Cabotegravir (brand name Apretude®), the first long-acting injectable PrEP medication approved by the FDA in December 2021.

The 2023 USPSTF recommendation also clarified that the recommendation for PrEP applies to sexually active adults and adolescents weighing at least 35 kg (77 lb.) who do not have HIV and are at increased risk of HIV acquisition. The 2023 USPSTF recommendation continues to recommend TDF/FTC, as well as baseline and monitoring services, consistent with the CDC guidelines.

Q1: What changes must plans and issuers make to comply with the 2023 USPSTF recommendation for PrEP?

Plans and issuers must cover, without cost sharing, specified oral and injectable formulations of PrEP, as well as specified baseline and monitoring services,[13] consistent with the 2023 USPSTF recommendation, for plan years (in the individual market, policy years) beginning on or after one year from the issue date of the recommendation (in this case, plan or policy years beginning on or after August 31, 2024).

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[10] 26 CFR 54.9815-2713(b); 29 CFR 2590.715-2713(b); 45 CFR 147.130(b). Generally, for purposes of section 2713 of the PHS Act, USPSTF recommendations are considered to be issued on the last day of the month in which the USPSTF publishes or otherwise releases the recommendation. 75 FR 41726, 41729 (July 19, 2010).
[11] *See* FAQs about Affordable Care Act Implementation Part 47 (July 19, 2021), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf and https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-47.pdf (FAQs Part 47).
[12] USPSTF, Prevention of Acquisition of HIV: Preexposure Prophylaxis (Aug. 22, 2023), available at https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.
[13] *See* FAQs Part 47, Q1, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf and https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-47.pdf.

As stated in FAQs Part 47, consistent with PHS Act section 2713 and its implementing regulations, plans and issuers may use reasonable medical management techniques to encourage individuals prescribed PrEP to use specific items and services, to the extent the frequency, method, treatment, or setting is not specified in the relevant USPSTF recommendation.[14] The 2023 USPSTF recommendation for PrEP specifies three formulations of medications approved by the FDA for use as PrEP. Therefore, plans and issuers must cover, without cost sharing, the three FDA-approved PrEP formulations (two oral and one injectable) and are not permitted to use medical management techniques to direct individuals prescribed PrEP to utilize one formulation over another.

Coding for Recommended Preventive Items and Services

To ensure that individuals receive coverage consistent with PHS Act section 2713 and its implementing regulations, it is critical that appropriate medical service codes identify when items and services are furnished as preventive items or services, and that plans and issuers correctly process such claims as claims for recommended preventive items and services. When claims denote that a furnished item or service is a recommended preventive item or service under PHS Act section 2713 (or that such item or service is integral to the furnishing of a recommended preventive item or service), plans and issuers should cover such items or services without imposing cost-sharing requirements, unless the plan or issuer has individualized information that establishes that the furnished item or service is not subject to the requirements of PHS Act section 2713, as discussed in more detail in these FAQs.

There are industry-standard coding practices that are intended to identify when items and services are furnished as a recommended preventive item or service, and not for diagnostic, therapeutic, or other non-preventive purposes. For example, the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) is a standardized coding system maintained and updated by the CDC's National Center for Health Statistics (NCHS) twice a year and used to code diseases and medical conditions data.[15,16] Under ICD-10-CM, many codes with the prefix "Z" indicate the preventive nature of an encounter, such as code Z23 [*Encounter for Immunizations*] and code Z00.129 [*Encounter for routine child health examination without abnormal findings*].

As another example, the American Medical Association (AMA) maintains the Current Procedural Terminology (CPT®) coding system[17] and established modifier 33 in 2010 to provide

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[14] *See* FAQs Part 47, Q3, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf and https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-47.pdf.

[15] *See* https://www.cdc.gov/nchs/icd/icd-10-cm/index.html. Note that the World Health Organization, which owns and publishes ICD-10, authorized NCHS to develop the ICD-10-CM code set.

[16] ICD-10-CM is one of the standard medical data coding sets under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations regarding electronic transaction standards. *See* 45 CFR 162.1002(c)(2).

[17] CPT® is copyrighted by the AMA and as such must be licensed to be used in electronic products or other forms. The CPT® coding system is a uniform, alphanumeric coding system consisting of descriptive terms and identifying codes used primarily to identify medical services and procedures furnished by physicians and other health care

a standardized means to communicate that an item or service was furnished as a recommended preventive item or service under PHS Act section 2713(a).[18,19] According to AMA guidance, "[m]odifier 33 should be used when the primary purpose of the service is the delivery of an evidence-based service in accordance with the guidelines provided by one of the ACA-designated organizations, including an A or B recommendation from the USPSTF."[20] Providers[21] may also use modifier 33 to communicate that an item or service was integral to the furnishing of a recommended preventive item or service.[22]

Many recommended preventive items and services, including those that are integral to the furnishing of a recommended preventive item or service, can also be furnished to individuals for other purposes not subject to the requirements of PHS Act section 2713. Modifier 33 may be particularly helpful to signal when such items and services are preventive in nature. When providers follow AMA's coding standards and append modifier 33, they can communicate to plans and issuers that services were furnished as, or integral to the furnishing of, recommended preventive items or services and should be covered without cost sharing.

For example, several tests that are utilized to estimate an individual's creatinine levels in order to assess kidney function (as well as the function of other organ systems) can be furnished for non-preventive purposes or preventive purposes subject to the requirements of PHS Act 2713, such as in accordance with the USPSTF's recommendation for PrEP. One such test is a serum creatinine test, CPT® code 82565 [*Creatinine; blood*]. When a serum creatinine test is furnished consistent with the USPSTF's recommendation for PrEP, the test is a preventive service that must be covered without cost sharing. In that circumstance, adding modifier 33 to the claim can help communicate that the test was furnished as part of a recommended preventive service and must be covered without cost sharing. Similarly, for anesthesia furnished for a sterilization surgery for a woman or for a screening colonoscopy, adding modifier 33 to appropriate codes for those specific items and services related to the sterilization surgery or screening colonoscopy generally

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professionals for which they bill public or private health insurance programs. (*See* https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system.) The CPT® code set is regularly updated by a CPT® Editorial Panel, whose membership is composed of an independent group of experts appointed by the AMA Board of Trustees. The CPT® Editorial Panel meets three times a year to review applications for new codes and revisions to existing codes. (*See* https://www.ama-assn.org/practice-management/cpt/cpt-overview-and-code-approval.)

[18] This guidance discusses and references modifier 33 in the AMA's current CPT® coding system because it is a widely used and current standard for denoting the furnishing of preventive services on a claim. If updates are made to the CPT® coding system to replace the use of modifier 33 with alternate codes or modifiers that denote the furnishing of preventive services, the guidance included in these FAQs should still be considered to apply to any such alternate codes or modifiers.

[19] Like ICD-10-CM, the current iteration of the code set, Current Procedural Terminology, Fourth Edition (CPT-4), is also a HIPAA standard medical coding set. 45 CFR 162.1002(c)(1).

[20] *See* https://www.ama-assn.org/delivering-care/patient-support-advocacy/preventive-services-coding-guides.

[21] The term "provider" as used in 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, and 45 CFR 147.130 refers to both health care practitioners and facilities.

[22] *See* FAQs about Affordable Care Act Implementation Part 54 (July 28, 2022), Q1, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf and https://www.cms.gov/files/document/faqs-part-54.pdf (FAQs Part 54). *See also* 85 FR 71142, 71174 (Nov. 6, 2020).

denotes that the anesthesia was integral to the furnishing of a recommended preventive service.[23,24]

In certain cases, if an item or service is commonly understood to be furnished for preventive purposes, the Departments understand that providers generally do not, as a matter of standard industry practice, append modifier 33 to the coding for the item or service to denote it as preventive.[25] For example, CPT® code 77067 [*Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed*] is described as "screening" and is thus generally furnished as and understood to be a preventive service. In contrast, CPT® code 77066 [*Diagnostic mammography, including computer-aided detection (CAD) when performed; bilateral*] is described as a "diagnostic" service and is generally not furnished as, or considered to be, a preventive service subject to PHS Act section 2713.

There are also certain codes, such as the recently added ICD-10-CM code Z29.81 [*Encounter for HIV pre-exposure prophylaxis*], that can be used both to denote that an item or service was billed as part of a recommended preventive item or service and to identify the furnishing of the recommended preventive item or service itself.[26] This information can be especially helpful for preventive service recommendations that encompass a range of discrete items and services, like PrEP.[27] The USPSTF recommendation for PrEP encompasses several screenings for certain at-risk populations at PrEP initiation and on a regular basis including HIV testing, pregnancy testing, sexually transmitted infection (STI) testing (e.g., for syphilis, gonorrhea, and chlamydia), hepatitis B serology, and hepatitis C serology.[28] However, such tests can also be furnished for diagnostic purposes outside of the scope of the USPSTF recommendation for PrEP, and the USPSTF recommendation does not recommend all of those screenings for every individual taking PrEP (e.g., hepatitis C serology is recommended only for men who have sex with men, transgender women, and persons who inject drugs). Accordingly, linking ICD-10-CM code

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[23] Women's Preventive Services Guidelines, available at https://www.hrsa.gov/womens-guidelines.

[24] *See* fn. 8. *See also* FAQs about Affordable Care Act Implementation (Part XXVI) (May 11, 2015), Q7, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf; and FAQs Part 54, Q1, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-54.pdf and https://www.cms.gov/files/document/faqs-part-54.pdf.

[25] CPT® codes and modifiers are regularly updated by the AMA, and the appropriate codes and modifiers for denoting that an item or service was furnished in relation to a recommended preventive item or service might depend on the specific item or service and the circumstances under which the item or service was furnished. The Departments' guidance applies to other modifiers that are available (or will be made available in the future), and the Departments defer to the recommendations and standards for coding preventive services that the AMA may publish.

[26] *See also*, CMS, Fact Sheet: Medicare Part B Coverage of Pre-exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention (Sept. 30, 2024), available at https://www.cms.gov/files/document/fact-sheet-potential-medicare-part-b-coverage-preexposure-prophylaxis-prep-using-antiretroviral.pdf, which lists several common billing codes associated with PrEP and its related services.

[27] *See* FAQs Part 47, Q1, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-47.pdf and https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/faqs-part-47.pdf.

[28] USPSTF, Prevention of Acquisition of HIV: Preexposure Prophylaxis (Aug. 22, 2023), available at https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis. *See also* CDC: US Public Health Service: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update: A Clinical Practice Guideline, available at https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf.

Z29.81 (and/or appending CPT® modifier 33) to service codes related to such screenings encompassed under the USPSTF's recommendation for PrEP can help accurately communicate that all of the items or services were furnished in accordance with a recommendation or guideline for a preventive item or service that is required to be covered without cost sharing under PHS Act section 2713.

The Departments continue to receive reports of individuals experiencing difficulty obtaining coverage without cost sharing for recommended preventive items and services. In some cases, including where plans and issuers have not provided clear coding guidance to network providers, plans and issuers are denying claims or imposing cost sharing for recommended preventive items and services because of issues related to how a provider codes for those services.[29] In response to these reports of continued barriers to coverage, the Departments are issuing the following FAQs, with illustrative examples in Q6, to provide guidance on how plans and issuers, working with their network providers, can ensure that they cover recommended preventive items and services without cost sharing, as required by PHS Act section 2713. The Departments remain committed to ensuring that individuals receive the coverage they are entitled to under PHS Act section 2713 and will take enforcement action as warranted.

Q2: If a plan or issuer receives a claim from an in-network provider that identifies an item or service as a recommended preventive item or service using industry-standard coding practices, should the plan or issuer cover the item or service without cost sharing, consistent with PHS Act section 2713 and its implementing regulations?

Generally, yes. When an in-network provider[30] submits claims for items or services following industry-standard coding practices to denote the furnished items or services as recommended preventive items or services, plans and issuers should cover those items and services consistent with the requirements under PHS Act section 2713, unless the plan or issuer has individualized information to establish that the items or services are not recommended preventive items and services with respect to the participant, beneficiary, or enrollee, consistent with Q3 and Q4 below.

This is also true where the industry-standard coding description identifies the item or service as one that generally meets the definition of a recommended preventive item or service, even where no modifier is appended to the code. For example, CPT® code 77067 [*Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when*

[29] *See* State of Vermont Department of Financial Regulation, "Contraceptive Services Claims Restitution Information" (Nov. 13, 2023), available at https://dfr.vermont.gov/contraceptive-services-claims-restitution-information. *See also* NAIC "Preventive Services Coverage and Cost-Sharing Protections Are Inconsistently and Inequitably Implemented" (Aug. 2023), available at https://healthyfuturega.org/wp-content/uploads/2023/08/NAIC-Letter.pdf.

[30] Nothing in section 2713 of the PHS Act or its implementing regulations requires a plan or issuer that has a network of providers to provide benefits for recommended preventive items and services that are delivered by an out-of-network provider, or to do so without imposing cost-sharing requirements. However, if a plan or issuer does not have in its network a provider who can provide a recommended preventive item or service, then the plan or issuer must cover the item or service when furnished by an out-of-network provider and may not impose cost sharing with respect to the item or service. *See* 26 CFR 54.9815-2713(a)(3); 29 CFR 2590.715-2713(a)(3); 45 CFR 147.130(a)(3).

performed] is generally considered a recommended preventive service even without a modifier and should be covered without cost sharing as long as the service was furnished with respect to an individual for whom the screening recommendation applied.

Q3: If a plan or issuer receives a claim from an in-network provider that identifies an item or service as a recommended preventive item or service using industry-standard coding practices, but has individualized information that allows the plan or issuer to establish that the item or service is not a recommended preventive item or service with respect to the participant, beneficiary, or enrollee, is the plan or issuer expected to cover the item or service without cost sharing (consistent with PHS Act section 2713 and its implementing regulations)?

No. In some instances, a plan or issuer will be able to establish, based on other individualized information received with the claim or maintained by the plan or issuer, that an item or service was not furnished as a recommended preventive item or service (or was not integral to the furnishing of a recommended preventive item or service) for the participant, beneficiary, or enrollee who received the item or service, even when the provider identified it as such using industry-standard coding practices. In such cases, the plan or issuer is not required to cover the item or service without cost sharing under PHS Act section 2713, even if the claim identifies the item or service as a recommended preventive item or service.

In the event of an adverse benefit determination, participants, beneficiaries, or enrollees (or their authorized representatives) have the right to appeal under the internal appeals and external review provisions of ERISA section 503 and PHS Act section 2719, as applicable.[31]

Q4: Should a plan or issuer cover an item or service without cost sharing (consistent with PHS Act section 2713 and its implementing regulations) if, using industry-standard coding practices, the claim identifies the item or service as a recommended preventive item or service, but the plan or issuer has separate information that suggests (but does not establish) that the item or service may not have been furnished as a recommended preventive item or service with respect to the participant, beneficiary, or enrollee?

For claims for items or services that have been identified as recommended preventive items or services using industry-standing coding practices, plans and issuers should not impose cost-sharing requirements on a participant, beneficiary, or enrollee (or deny their claim as not covered), unless and until the plan or issuer has individualized information to establish that the furnished items or services are not recommended preventive items or services with respect to the participant, beneficiary, or enrollee after verifying relevant information with their provider(s).

Generally, the ERISA claims procedure regulation and the ACA internal claims and appeals regulations require plans and issuers to communicate with claimants and their authorized representatives (which may include a provider), so as to facilitate full and fair review of benefit

[31] 26 CFR 54.9815-2719; 29 CFR 2560.503-1 and 2590.715-2719; 45 CFR 147.136.

claims and provide a reasonable claims procedure, as required under ERISA section 503.[32] The ERISA claims procedure regulation at 29 CFR 2560.503-1 generally provides that if a plan or issuer did not receive sufficient information to make a claim determination, it may notify the claimant of the specific information necessary to complete the claim. Accordingly, before imposing cost-sharing requirements (or, if applicable under the terms of the plan or coverage, denying a claim) for a recommended preventive item or service because the claimant or provider did not submit sufficient information, plans and issuers should communicate with claimants and providers, as appropriate, to obtain the information the plan or issuer needs to provide a full and fair review within the otherwise applicable timeframes under the ERISA claims procedure regulation and the terms of the plan or coverage.[33]

In cases where a plan or issuer has information separate from a claim that suggests (but does not establish) that the item or service may not have been furnished as (or integral to the furnishing of) a recommended preventive item or service with respect to a participant, beneficiary, or enrollee, the Departments generally will not consider a plan or issuer to be in violation of the requirements of PHS Act section 2713 if such plan or issuer has made reasonable and unsuccessful efforts (in line with additional steps discussed in Q5 below) to obtain the information necessary from the provider to determine whether the item or service was furnished as (or integral to the furnishing of) a recommended preventive item or service, prior to imposing cost sharing on (or denying coverage for) the item or service. However, the Departments would consider a plan or issuer to be in violation of the requirements of PHS Act section 2713 if such plan or issuer does not promptly reverse the cost-sharing requirements (or coverage denial) upon being made aware that the item or service was furnished as (or integral to the furnishing of) a recommended preventive item or service.

The Departments have previously noted that with respect to preventive service recommendations for "high-risk" or "increased risk" patient populations,[34] the identification of an individual's risk is determined by clinical expertise, and decisions regarding the applicability of specific preventive service recommendations based on risk should be made by the individual's attending provider.[35] The Departments reiterate that if a provider determines that an individual belongs to a

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[32] With respect to internal claims and appeals processes for group health coverage, PHS Act section 2719 provides that plans and issuers must initially incorporate the internal claims and appeals processes set forth in 29 CFR 2560.503–1 and update such processes in accordance with standards established by the Secretary of Labor.

[33] In the event of an adverse benefit determination, participants, beneficiaries, or enrollees (or their authorized representatives) have the right to appeal under the internal appeals and external review provisions of ERISA section 503 and PHS Act section 2719, as applicable. 26 CFR 54.9815-2719; 29 CFR 2560.503-1 and 2590.715-2719; 45 CFR 147.136.

[34] Such as certain USPSTF recommendations including, but not limited to, for aspirin use to prevent preeclampsia in pregnant persons and for falls prevention in community-dwelling older adults. *See* USPSTF, Aspirin Use to Prevent Preeclampsia and Related Morbidity and Mortality: Preventive Medication (Sept. 28, 2021), available at https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/low-dose-aspirin-use-for-the-prevention-of-morbidity-and-mortality-from-preeclampsia-preventive-medication; and USPSTF, Falls Prevention in Community-Dwelling Older Adults: Interventions (June 4, 2024), available at https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/falls-prevention-community-dwelling-older-adults-interventions.

[35] *See* FAQs about Affordable Care Act Implementation (Part XII) (Feb. 20, 2013), Q7, available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xii.pdf and https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/aca_implementation_faqs12.

high-risk population and a preventive service recommendation under PHS Act section 2713 applies to that high-risk population, plans and issuers are required to cover that service without cost sharing. These FAQs do not change the Departments' prior guidance that plans and issuers must defer to the determination of the attending provider regarding the applicability of specific preventive service recommendations based on risk.

To the extent consistent with the requirements under PHS Act section 2713 regarding the use of reasonable medical management techniques, plans and issuers may employ programs designed to detect and address fraud, waste, and abuse when evaluating claims. However, if a plan's or issuer's fraud, waste, and abuse protocols identify an issue with a claim for a recommended preventive item or service, plans and issuers should not impose cost sharing (or deny the claim) without individualized information to establish fraud, waste, and abuse concerns.

Q5: What steps are plans and issuers expected to take to ensure that participants, beneficiaries, and enrollees are not improperly denied coverage or charged cost sharing for recommended preventive items and services furnished by in-network providers?

Plans and issuers should review their coding guidelines, claims processing systems, and other relevant internal protocols and make any necessary modifications to ensure that claims for recommended preventive items or services (including items and services that are integral to the furnishing of a recommended preventive item or service) are covered without cost sharing consistent with PHS Act section 2713 and its implementing regulations.

The Departments are aware that some plans and issuers use claims processing systems that determine whether all items and services that are part of the same claim are treated as preventive based on the coding of the first item or service listed on the claim. The use of this type of system may result in the imposition of cost-sharing requirements with respect to recommended preventive items and services in a manner that is inconsistent with PHS Act section 2713 and its implementing regulations. In such a case, the plan or issuer should update its claims processing system and ensure the appropriate internal controls and procedures are in place so that recommended preventive items and services (including items and services that are integral to the furnishing of a recommended preventive item or service) are covered without cost sharing consistent with PHS Act section 2713 and its implementing regulations.

The Departments expect plans and issuers to educate their network providers and provide clear guidance on the availability and proper usage of service codes and modifiers to denote when an item or service is furnished as, or integral to the furnishing of, a recommended preventive item or service. The Departments also encourage providers to take steps to ensure that all recommended preventive items or services, including items and services that are integral to the furnishing of a recommended preventive item or service, are appropriately identified as recommended preventive items or services on claims.

The AMA, American Hospital Association (AHA), and other professional associations publish standards to guide health care providers on how to consistently code for recommended preventive items or services using the appropriate procedure codes (e.g., CPT® codes) and diagnosis codes (e.g., ICD-10-CM codes). For example, the Women's Preventive Services

Initiative (WPSI) publishes the WPSI Coding Guide, which the Departments consider a reliable resource to describe industry-coding standards given that WPSI is the coalition of experts that reviews and puts forth recommendations for HRSA to adopt into the HRSA-supported Guidelines.[36] Plans and issuers should regularly review such standards to ensure individuals are not charged cost sharing or denied coverage for recommended preventive items and services or items and services that are integral to the furnishing of them, and ensure that their network providers are similarly aware of such standards. Reviewing published industry standards can be particularly helpful for correctly identifying, in claims, recommended preventive items and services for which individuals frequently report challenges accessing coverage without cost sharing, such as items and services for PrEP.

Q6: Can the Departments provide examples to illustrate the guidance in Q2-Q4 above?

Example 1: Cost sharing improperly imposed on claim for service coded as a recommended preventive service using industry-standing coding practices.

Facts

A 50-year-old patient who is considered by their provider to be at average risk for colorectal cancer undergoes a routine preventive colonoscopy to screen for colorectal cancer. During the screening, the in-network provider furnishing the colonoscopy discovers a neoplastic polyp in the patient's colon and removes the polyp. Polyp removal is an integral part of a colonoscopy.

The in-network provider subsequently submits to the plan a claim for a colonoscopy with polyp removal (CPT® code 45385 [*Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique*]) and lists both CPT® modifier 33 and ICD-10-CM diagnosis code Z12.11 [*Encounter for screening for malignant neoplasm of colon*] in accordance with industry-standard coding practices to communicate that a preventive screening colonoscopy included a polypectomy upon discovery of a polyp. Upon receipt of the claim, the plan's claim processing system treats the colonoscopy code as a therapeutic service despite the inclusion of CPT® modifier 33 and ICD-10-CM diagnosis code Z12.11. As a result, the plan imposes cost-sharing requirements for the service, treating the preventive screening colonoscopy as a therapeutic colonoscopy. The plan had no individualized information to suggest or establish that the colonoscopy was not performed as a screening procedure pursuant to the USPSTF recommendation.

Conclusion

The plan violates the requirements under PHS Act section 2713 and its implementing regulations by imposing cost-sharing requirements on a recommended preventive service. In this scenario, the provider used industry-standard coding practices on the claim to identify the service as a recommended preventive service and the plan does not have individualized information to establish that the service was not a recommended preventive service. Therefore, the plan should process the claim for the service as a recommended preventive service and cover it without imposing cost sharing.

[36] *See* American College of Obstetricians and Gynecologists (ACOG), Women's Preventive Services Initiative (WPSI) 2023-2024 Coding Guide, available at https://www.womenspreventivehealth.org/wpsi-coding-guide/.

The Departments are aware that some plans' and issuers' claims processing systems require a certain diagnosis code(s) to process some services such as a polypectomy as a preventive service. If, in an alternate scenario, the provider furnished the same services under the same circumstances but submitted a claim using only the CPT® code 45385 and CPT® modifier 33 without the ICD-10-CM diagnosis code that communicates that a polyp was discovered during a screening colonoscopy, the Departments would expect the plan to either cover the service without cost sharing, or make reasonable efforts to obtain additional information (from the provider) to determine applicability of PHS Act section 2713 requirements prior to imposing cost sharing (or denying coverage).

Example 2: Cost sharing improperly imposed on claim for a recommended preventive service not coded in a manner consistent with the issuer's specific coding standards.

Facts

An in-network provider submits a claim to an issuer for furnishing an injectable contraceptive using ICD-10-CM code Z30.013 [*Encounter for initial prescription of injectable contraceptive*] and CPT® code 96372 [*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*], in accordance with the WPSI 2023-2024 Coding Guide's standard for coding for a contraceptive shot or injection.[37] The issuer's claim processing system classifies the CPT® code as a therapeutic service and therefore imposes cost sharing for the service.

Conclusion

The issuer violates the requirements under PHS Act section 2713 and its implementing regulations by imposing cost-sharing requirements on a recommended preventive service. This is true even if the claim is coded in a manner that is not consistent with the issuer's specific coding standards for the service. The issuer may instruct the provider to revise and resubmit the claim according to the issuer's coding standards but should not impose cost sharing on (or deny coverage for) the service, unless and until the issuer has individualized information to establish that coverage of the injectable contraceptive is not subject to the requirements of PHS Act section 2713.[38]

Example 3: Plan has individualized information to establish that a service was not a recommended preventive service with respect to the individual.

Facts

An in-network provider submits a claim to a plan for furnishing a screening mammography, CPT® code 77067 [*Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed*], to a 39-year-old woman. The currently applicable USPSTF recommendation for breast cancer screening recommends that women aged 40 and older receive a screening mammography, with or without clinical breast

[37] *See* WPSI 2023-2024 Coding Guide, available at https://www.womenspreventivehealth.org/wpsi-coding-guide/.
[38] In addition, the absence of CPT® modifier 33 on the claim does not provide a basis for the issuer in this example to impose cost sharing on (or deny coverage for) the service because the provider has used another industry-standard coding practice to identify the service as a recommended preventive service.

examination (CBE), every 1-2 years.[39] Because the recommendation applies only to women aged 40 years and older, the plan covers the mammography claim but imposes cost sharing for the service.

Conclusion
The plan is not in violation of PHS Act section 2713 and its implementing regulations. Based on information maintained by the plan—the individual's date of birth—the plan has sufficient individualized information to establish that the service was not furnished consistent with the applicable USPSTF recommendation for breast cancer screening. Accordingly, imposing cost-sharing requirements for the mammography would not constitute a violation of PHS Act section 2713 and its implementing regulations.

Example 4: Plan has information that suggests, but does not establish, that a service was not a recommended preventive service with respect to the individual.

Facts
The USPSTF recommendation for PrEP recommends that individuals initiating PrEP containing tenofovir (i.e., oral PrEP) have kidney function assessed prior to initiation and cites the CDC PrEP Clinical Practice Guideline for further implementation considerations regarding follow-up testing and monitoring.[40] The CDC PrEP Clinical Practice Guideline recommends that individuals using oral PrEP have their estimated creatinine clearance rate (ml/min) (eCrCL) assessed (for example, via a serum creatinine test) every six months if individuals generally meet one of two conditions: (1) they are aged 50 or older, or (2) they had an eCrCL less than 90 ml/min at PrEP initiation.[41]

An in-network provider orders a serum creatinine test for a 45-year-old individual to assess the individual's kidney function six months after the individual was screened for HIV and initiated PrEP. The serum creatinine test is conducted at an in-network laboratory. The laboratory then submits a claim to the plan that coded the services according to industry standards, using CPT® code 82565 [*Creatinine; blood*] with the CPT® modifier 33 and ICD-10-CM code Z29.81 [*Encounter for HIV pre-exposure prophylaxis*]. The individual had an eCrCL less than 90 ml/min at PrEP initiation, but the plan does not have this information. The plan does not take any steps to seek additional information with respect to whether the individual's baseline testing results indicated an eCrCL of less than 90 ml/min. The plan proceeds to process the claim for the serum test as not a recommended preventive service and imposes cost sharing for the test.

Conclusion
The plan violates the requirements under PHS Act section 2713 and its implementing

[39] USPSTF, Breast Cancer: Screening, 2022 (Sept. 3, 2002), available at https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/breast-cancer-screening-2002.
[40] USPSTF, Prevention of Acquisition of HIV: Preexposure Prophylaxis (Aug. 22, 2023), available at https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.
[41] *See* CDC: US Public Health Service: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update: A Clinical Practice Guideline, p13, available at https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf.

regulations by imposing cost-sharing requirements on a recommended preventive service for which, using industry-standard coding practices, the claim identifies the service as a recommended preventive service and the plan does not have individualized information to establish that the service was not a recommended preventive service. Because the laboratory coded the claim according to industry-standard coding practices that denote the furnished service as a recommended preventive service, the plan should cover the service without cost sharing.

If the plan has questions regarding whether the serum creatinine test was furnished in accordance with the USPSTF recommendation for PrEP and the CDC PrEP Clinical Practice Guideline, the plan should make reasonable efforts to obtain the information necessary (e.g., eCrCL results from PrEP initiation) from the provider to make a determination of whether the service was appropriately coded as a recommended preventive service. The plan should not impose cost sharing on (or deny coverage for) the service until reasonable efforts have been made to obtain the necessary information to assess whether the service was appropriately coded as a recommended preventive service. If the plan's reasonable efforts to seek additional information are unsuccessful, the Departments would generally not consider the plan to be in violation of PHS Act section 2713 for imposing cost sharing on (or denying coverage for) the service, as long as the plan promptly reverses the cost-sharing requirements (or coverage denial) upon being made aware that the service was furnished as a recommended preventive service.

The Women's Health and Cancer Rights Act (WHCRA)

WHCRA provides protections for individuals who elect breast reconstruction in connection with a mastectomy. Under WHCRA, if a group health plan[42] or health insurance issuer offering group or individual health insurance coverage covers mastectomies, the plan or issuer must provide coverage for certain services, in a manner determined in consultation with the attending physician and the patient. Required coverage includes all stages of reconstruction of the breast on which the mastectomy was performed, surgery and reconstruction of the other breast to produce a symmetrical appearance, prostheses, and treatment of physical complications of the mastectomy, including lymphedema.[43]

Q7: Are group health plans and issuers offering group or individual health insurance coverage that cover mastectomies required to provide coverage for chest wall reconstruction with aesthetic flat closure as a type of breast reconstruction under WHCRA?

Yes. If a plan or issuer subject to WHCRA provides medical and surgical benefits with respect to a mastectomy, the plan or issuer is required to provide coverage for, among other services, in the

[42] Sponsors of self-funded, non-Federal governmental plans may elect to exempt those plans from (opt out of) certain PHS Act requirements, including WHCRA. *See* PHS Act section 2722(a)(2) and 45 CFR 146.180.
[43] WHCRA includes other requirements, including requirements on out-of-pocket costs, and notice requirements. *See* ERISA section 713, PHS Act sections 2727 (incorporating ERISA section 713) and 2752, and Internal Revenue Code (Code) section 9815 (incorporating PHS Act section 2727).

case of a participant, beneficiary, or enrollee who is receiving benefits in connection with a mastectomy and who elects breast reconstruction in connection with such mastectomy, all stages of reconstruction of the breast on which the mastectomy was performed and surgery and reconstruction of the other breast to produce a symmetrical appearance, in a manner determined in consultation with the attending physician and the patient.[44] This includes coverage for chest wall reconstruction with aesthetic flat closure, if elected by the patient in consultation with the attending physician in connection with a mastectomy, as a required type of reconstruction.[45]

Under WHCRA, plans and issuers may impose deductibles and coinsurance for these benefits only if such cost-sharing requirements are deemed appropriate and are consistent with those established for other benefits under the plan or coverage.

[44] ERISA section 713; PHS Act sections 2727 (incorporating ERISA section 713) and 2752; Code section 9815 (incorporating PHS Act section 2727).

[45] The National Cancer Institute (NCI) of the National Institutes of Health defines "aesthetic flat closure" as "a type of surgery that is done to rebuild the shape of the chest wall after one or both breasts are removed. An aesthetic flat closure may also be done after removal of a breast implant that was used to restore breast shape. During an aesthetic flat closure, extra skin, fat, and other tissues in the breast area are removed. The remaining tissue is then tightened and smoothed out so that the chest wall appears flat." *See* NCI Dictionary of Cancer Terms, available at https://www.cancer.gov/publications/dictionaries/cancer-terms/def/aesthetic-flat-closure.