December 22, 2016

Submitted via email: marketreform@cms.hhs.gov and e-ohpsca-mhpaea-disclosure@dol.gov

U.S. Department of Labor
U.S. Department of Health and Human Services
U.S. Treasury Department

RE: FAQs About Affordable Care Act Implementation (Part 34) and Mental Health and Substance Use Disorder Parity Implementation

To Whom It May Concern:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments to the "Frequently Asked Questions about Affordable Care Act Implementation Part 34 and Mental Health and Substance Use Disorder Parity Implementation" (the "FAQs") issued on October 27, 2016 by the U.S. Department of Labor, U.S. Department of Health and Human Services, and U.S. Treasury Department (collectively, the "Departments"). PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, and the Federal Employees Health Benefits Program (FEHBP) and administer drug plans for many individuals who obtain health insurance through the Exchanges established by the Affordable Care Act (ACA).

Executive Summary

PCMA supports the coverage of preventive services and helping individuals with mental health and substance use disorders. To ensure access to affordable and high quality care, PCMA members work closely with their customers to structure effective yet affordable benefits through the use of pharmacy and therapeutics (P&T) committees and innovative benefit designs. Despite clear regulation allowing the use of reasonable medical management techniques, we are concerned that the FAQs addressing coverage of tobacco cessation pose questions around the ability of issuers and PBMs to utilize such tools in developing pharmacy benefits. Additionally, PCMA has significant concerns with the Departments' suggestion to evaluate the composition of the P&T committee for compliance with the Mental Health Parity and Addiction Equity Act. As we note in more detail below, robust standards already exist with respect to the composition of P&T committees, which are also evaluated by accrediting bodies, such as URAC and the National Committee for Quality Assurance (NCQA).

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PCMA

Comments

PCMA's comments and suggestions regarding the FAQs on tobacco cessation and mental health parity are summarized below.

1. Coverage of Tobacco Cessation Interventions

The Departments are seeking comments on whether issuers may use reasonable medical management techniques to determine which specific categories of FDA-approved pharmacotherapy interventions will be covered without cost sharing and whether issuers may use reasonable medical management techniques to manage the categories of FDA-approved pharmacotherapy interventions.

a. Law is Clear

PCMA is very concerned that the Departments are seeking comments on whether issuers may use medical management techniques when they have already acknowledged in the ACA and final regulations relating to coverage of preventive services the ability of issuers to use reasonable medical management techniques when determining appropriate preventive services coverage.[1] In the preamble and the regulations, the Departments explain that issuers can use reasonable medical management techniques to determine coverage limitations if recommendations or guidelines for a recommended service does not specify the frequency, method, treatment or setting for the provision of that service.[2] Specifically, the final rule clarified that "Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant recommendation or guideline. 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 health service."

It is not clear to us why the Departments have released FAQs seeking comments on this when the law and implementing regulations are clear on the ability of issuers and PBMs ability to use medical management techniques. Preventing the use of medical management tools would conflict with established guidance already put forth by the Departments.

We also want to point out that guidelines developed by entities such as the United States Preventive Services Task Force (USPSTF) are designed for clinicians to guide clinical practice. Interpreting the preventive services recommendations designed for clinical practices into coverage policies requires appropriate medical management techniques. Therefore we urge

[1] Patient Protection and Affordable Care Act of 2010 (P.L. 111-148) §1563 and 80 FR 41317 (July 14, 2015).
[2] 29 CFR 2590.715-2713(a)(4) and 45 CFR 147.130(a)(4).

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the Departments to continue to allow enough flexibility for the use of medical management of the recommended preventive services.

b. Affordability

Issuers and PBMs are focused on providing the most affordable, highest quality coverage to consumers and to achieve this, they need the ability to use innovative care management tools that focus on improved quality and greater value. Issuers and PBMs rely on medical management techniques to encourage enrollees to use therapeutically equivalent drugs, when appropriate, to enhance safety, reduce drug misuse or overuse, improve quality, and control costs. Moreover, medical management tools help to ensure patients receive the right care at the right time. Innovations in benefit design—as provided for under the final rules—play a critical role for issuers and PBMs to encourage high-quality care that may promote greater value throughout the entire health care system.

Furthermore, mandating coverage of all drugs removes competition among drug companies, resulting in higher drug prices and raising costs for taxpayers and patients. The use of medical management tools in prescription drug benefit design is largely responsible for the decline in the share of drug expenses paid for by consumers out of pocket while also preserving the value of drug coverage and quality of care. Unless coverage is affordable, younger and healthier people may choose to forgo purchasing insurance until they are sick or injured, which will cause costs to increase for everyone. This is why it is crucial that issuers and PBMs continue to use medical management tools to help ensure broad participation in the system.

PCMA Recommendation: We believe that the existing law and implementing guidance are clear regarding the ability to use medical management techniques. We recommend the Departments do nothing to undermine the use medical management tools.

c. Pharmacotherapy

Finally, the pharmacotherapies for tobacco dependence are therapies used to treat tobacco dependence rather than prevent tobacco dependence. We note that final regulations clarifies that treatments are not considered part of the recommended preventive services. Specifically, the preamble states "a plan or issuer may impose cost-sharing requirements for a treatment that is not a recommended preventive service, even if the treatment results from a recommended preventive service."[3] We believe that because the pharmacotherapies for tobacco cessation are treatment interventions, they should not be included as part of the covered preventive benefit.

PCMA Recommendation: The Departments should exclude from the scope of covered preventive services, pharmacotherapies that are used to treat rather than prevent a condition.

[3] 80 FR 41317

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2. Mental Health Parity and Addiction Equity Act of 2008

In the FAQs, the Departments acknowledge that many issuers use P&T committees in deciding how to cover prescription drugs. The Departments note that while the use of P&T committees to inform prior authorization requirements for prescription drugs in this manner may not violate MHPAEA per se, these processes must also comply with MHPAEA's non-quantitative treatment limits (NQTL) standard in operation. For example, if the plan deviates from nationally recognized treatment guidelines based on P&T committee reports, then use of the P&T committee would be evaluated for compliance with MHPAEA's NQTL requirements (for example, by evaluating whether the P&T committee is comprised of comparable experts for MH/SUD conditions, as compared to the experts for medical/surgical conditions, and how such experts evaluated nationally-recognized treatment guidelines in setting prior authorization for medications for both MH/SUD and medical/surgical conditions).

a. P&T Committee Standards

PCMA has several significant concerns with the Departments suggestion to evaluate the composition of the P&T committee and how appointees of the committee evaluate medical treatment guidelines. By delineating specific composition requirements, the Departments are interfering in the internal management of an issuer or its PBM. We also believe evaluating the composition of the P&T committee is unnecessary, because independent accrediting bodies, such as URAC and the National Committee for Quality Assurance (NCQA), employ dozens of experts who have worked for many years to set accrediting standards for formularies and many other health services. These accrediting bodies set standards for P&T committees, including their composition.

b. Processes for External Feedback

P&T committees already include appointees that represent a sufficient number of clinical specialties to adequately meet the needs of consumers. These physicians and other providers are representative of the types of conditions impacting enrollees. Because it is not possible to include a representative of every specialty on a committee, most committee appointees have a process for obtaining input from specialties that are not represented. For example, P&T committees utilize outside staff, including expert panels, sub-committees, or consultants as needed to ensure inclusion of relevant expertise for any formulary recommendation. Additionally, all PBMs have processes in place for authorized prescribers to request and receive medical exceptions when there is a clinically valid reason for prescribing a specific drug. It is unclear what problem the Departments are trying to solve for by issuing these FAQs.

c. Affordability

Furthermore, mandating P&T committees to cover certain medical specialists could lead to many other interest groups seeking representation of their specific medical discipline. Prescriptive requirements on the composition of P&T committees could ultimately become a vehicle for disgruntled prescription drug manufacturers to broaden formularies, which could in

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turn lead to increases in premiums at a time when HHS is seeking to ensure that consumers have access to affordable coverage.

d. Operational Challenges

Finally, given the considerable time commitment to prepare and participate on a P&T committee and the extensive infrastructure of the health insurance system and the possibilities for conflicts of interests, we are concerned that mandating specific medical specialists could pose significant challenges for issuers and PBMs to recruit specific medical specialists.

PCMA Recommendation: The Departments should not dictate the composition of the P&T committee. PCMA strongly believes that the current P&T committee standards around composition are sufficient and is not aware that the Departments have determined otherwise.

We appreciate your consideration of our comments on the FAQs. We look forward to continuing to work with the Departments on implementation issues related to the ACA. If you have any questions, please contact Mona Mahmoud at mmahmoud@pcmanet.org.

Sincerely,

Wendy Krasner

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