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October 17, 2023

The Honorable Xavier Becerra
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Julie Su
Acting Secretary of Labor
200 Constitution Avenue, N.W.
Washington, DC 20210

The Honorable Janet Yellen
Secretary of the Treasury
1500 Pennsylvania Avenue, N.W.
Washington, D.C. 20220

Submitted electronically via regulations.gov

Re: Requirements Related to the Mental Health Parity and Addiction Equity Act [CMS-9902-P]

Dear Secretaries Becerra, Su, and Yellen:

The Academy of Managed Care Pharmacy (AMCP) thanks the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury (collectively, the Departments) for the opportunity to provide comments in response to the proposed rule titled "Requirements Related to the Mental Health Parity and Addiction Equity Act [CMS-9902-P]" (Proposed Rule) published in the Federal Register on August 30, 2023.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's nearly 8,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

AMCP has several concerns with the Proposed Rule, including the administrative burden on plans to implement the new requirements and the challenges of implementation by the applicability date, the difficulty of compliance for the pharmacy benefit given the variations in prescription drugs, the potential impact on utilization management, the application of network adequacy requirements to pharmacy networks, and concerns about using a material difference standard for outcomes.

Administrative Burden

The Proposed Rule establishes three requirements for plans and issuers when imposing a nonquantitative treatment limitation (an NQTL). First, an NQTL must be no more restrictive when applied to mental health and substance use disorder (MH/SUD) benefits than when applied to medical/surgical (M/S) benefits. Second, the plan or issuer must meet certain design and applications requirements. Third, the plan or issuer must collect, evaluate, and consider the impact of relevant data on access to MH/SUD benefits as opposed to M/S and take reasonable action to address any material differences. A plan or issuer must meet all three requirements before it may impose the NQTL on MH/SUD benefits.

AMCP's members are concerned about the administrative burden of implementation and compliance as well as the short turn-around time needed to meet the scope of the requirements by the effective date. Issuers would need to undertake potentially significant IT work and expense to implement the requirements and may need to coordinate among a variety of vendors, including third-party administrators (TPAs) and pharmacy benefit managers (PBMs). Each of these entities may operate on different IT systems and may collect and store data in different ways. Incompatible data and tight resources could significantly limit a plan or issuer's ability to perform accurate parity assessments. For these reasons, AMCP requests that the Departments incorporate a transition period of at least one plan year to allow for full implementation.

Applicability to the Prescription Drug Benefit

AMCP is concerned about the applicability of the new requirements to pharmacy benefits. Demonstrating compliance with the proposed requirements is likely to be especially challenging for prescription drug benefits given the wide variations in drugs (including but not limited to dosage, strength, route of administration, and costs). Each of these variations impacts and adds to the complexity of any analysis.

Another concern raised by AMCP's members is that this Proposed Rule could significantly restrict plans' ability to engage in medication utilization management, which is a critical set of tools for ensuring quality outcomes and containing costs. Drugs subject to utilization management are typically drugs with specific safety concerns, more affordable alternatives, potential for off-label use, potential for misuse or abuse, or special handling requirements.[1] Medication utilization management tools are developed and overseen by pharmacists and other qualified health professionals and ensure that patients are receiving the appropriate medications.

Network Adequacy

In AMCP's experience, well-designed pharmacy networks encourage the use of appropriate, clinically advantageous, and cost-effective pharmacies regardless of whether the patient is seeking prescription drugs relating to M/S benefits or for the treatment of MH/SUD. Pharmacy

[1] Leaf, S. & Bates, H. Access, Affordability, and Outcomes: The Value of Managed Care Pharmacy, October 2023 Report, p. 18. Available at https://www.amcp.org/sites/default/files/2023-10/AMCP_VMCP_Report_RGB_Oct9.pdf

networks are a vital managed care pharmacy tool to promote improved health outcomes while controlling patient cost sharing and total health care system costs.

The Proposed Rule would impose network adequacy requirements that do not appear to address any substantive barrier to behavioral health care in the prescription drug classification given that pharmacy networks are not based on whether a drug carried by any given pharmacy is to be used for M/S benefits or MH/SUD benefits. AMCP urges the Departments to address how or whether these requirements are to be applied to pharmacy networks.

Outcomes Measures

The Proposed Rule requires plans and issuers to collect and evaluate relevant outcomes and operational data and then address any material differences in access between MH/SUD and M/S benefits. AMCP members have expressed concerns with moving toward this material difference standard for outcomes measures given the lack of definition of materiality and uncertainty regarding why corrective action would have to be taken prior to a finding of noncompliance. AMCP supports an ongoing evaluation of existing processes but is concerned that the outcomes measures may amount to overreach and may be unduly burdensome.

Conclusion

AMCP appreciates your consideration of the concerns outlined above and looks forward to continuing work on these issues with the Departments. If you have any questions regarding AMCP's comments or would like further information, please contact AMCP's Director of Regulatory Affairs, Geni Tunstall, at etunstall@amcp.org or (703) 705-9358.

Sincerely,

Susan A. Cantrell, MHL, RPh, CAE
Chief Executive Officer