January 8, 2024

Submitted electronically via federal eRulemaking Portal: www.regulations.gov

The Honorable Xavier Becerra
HHS Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Ms. Chiquita Brooks-LaSure
CMS Administrator
U.S. Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
750 Security Boulevard
Baltimore, MD 21244

RE: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2025 (CMS-9895-P)

Dear Secretary Becerra and Administrator Brooks-LaSure:

On November 24, 2023, the U.S. Centers for Medicare & Medicaid Services (CMS) published a proposed rule titled "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2025" (hereafter referred to as the "Proposed Rule").[1] The Proposed Rule, among other provisions setting forth policies for issuers offering qualified health plans (QHPs) through the federally-facilitated and state-based Marketplaces, proposes to clarify policies around essential health benefits (EHBs) and solicits comments on potentially changing from the U.S. Pharmacopeia (USP) Medicare Model Guidelines as a benchmark formulary structure to the USP Drug Classification System.

The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 275 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and through the exchanges established by the Affordable Care Act (ACA). Our members work closely with plans and issuers to secure lower costs for prescription drugs and achieve better health outcomes.

PCMA supports CMS's ongoing efforts to stabilize the individual Marketplaces while lowering premiums and strengthening competition. We offer in this letter comments on four main areas addressed below:

[1] 88 Fed. Reg. 82,510 (November 24, 2023).

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I. CMS's Proposal that Prescription Drugs Covered by Individual and Small Group Plans in Excess of a State's Benchmark are Considered EHB is Contrary to the Statute and Will Have the Unintended Impact of Reducing Formulary Coverage for Enrollees.

In the Proposed Rule, CMS proposes a new 45 C.F.R. § 156.122(f), which provides that "[i]f a health plan covers prescription drugs in excess of the prescription drugs required to be covered under paragraph (a)(1) of this section [i.e., those covered by a state's EHB benchmark plan], the additional prescription drugs are considered an essential health benefit and subject to the cost-sharing requirements at § 156.130." Notably, CMS proposes these modifications only to its regulations governing the individual and small group insured markets. CMS also clarifies an exception to this general rule in the case of a drug that is mandated by state action and is in addition to EHB. As a basis for this policy, CMS cites evidence showing several individual and small group market plans have either developed or are offering programs that provide some drugs as "non-EHBs."

Since the inception of the EHB regime, PCMA has argued that benchmark plan formulary drug counts and the "greater of" requirement is unnecessary and adds unnecessary costs to the program. We are now in the eleventh year of the QHP market and access and coverage to prescription drugs remains robust. QHPs compete for enrollees based on provider networks, formulary breadth, and premiums. QHPs will not offer deficient formularies, otherwise few enrollees would join.

As we have described in many letters, plans and issuers employ PBMs, who operate pharmacy and therapeutics (P&T) committees to design formularies. These formularies are based upon the best clinical evidence available. Starting from the formulary, PBMs then negotiate with drug manufacturers to confer preferred drug status or add or remove other utilization management steps to control cost at the behest of their clients (QHP issuers).

PCMA opposes this proposal regarding the redesignation of non-EHB benefits as EHB on the basis that such a proposal is wholly inconsistent with both the statutory and regulatory constructs for EHBs. In enacting the ACA in 2010, Congress intended to create a minimum, benchmark level of coverage to ensure enrollee's access to at least the scope of benefits provided under a typical employer's plan.[2] Indeed, Congress anticipated QHPs may offer non-EHB benefits in excess of this minimum level of coverage and so adopted a statutory rule of construction to make clear that such additional, non-EHB benefits could be offered.[3] CMS thus lacks the statutory authority to expand the definition of EHB to include non-EHB benefits.

[2] *See* 42 U.S.C. § 18022(b)(3).
[3] *See* 42 U.S.C. § 18022(b)(5) ("Nothing in this title 1 shall be construed to prohibit a health plan from providing benefits in excess of the essential health benefits described in this subsection.)

Not only is CMS's proposed reinterpretation inconsistent with this statutory rule of construction, the proposed policy may have the negative impact of reducing overall formulary coverage for QHP enrollees. Drugs offered as non-EHB today are, by definition, offered in excess of the benchmark formulary minimums and thus not required to be covered on formulary. Under the policy in place today, a QHP issuer may choose to add additional, non-EHB drugs to formulary and cover them under maximizer programs, which increase adherence by lowering out-of-pocket patient costs. One worrisome unintended impact of CMS's proposal would be the formulary exclusion of many of these drugs.

Finally, we believe it is worth considering that the market has yet to assess the impact of the numerical limitation of four non-standardized plans adopted by U.S. Department of Health and Human Services (HHS) for plan year 2024. Additionally, the proposed rule would limit plans' and employers' benefit design choices, and impact plan affordability both for sponsors and for members. Given all these considerations, we strongly suggest that HHS should continue to allow the flexibility for benefit sponsors to choose their benchmark plans and benefit plan designs in ways that deliver access, coverage, and cost containment. If CMS does proceed with finalizing this proposal, we ask that the agency retain the proposed scope of the rule such that it impacts only the individual and small group insured markets. Limiting the scope of this rule is both consistent with the ACA (only individual and small group plans are *required* to cover EHBs) and necessary to avoid negative impacts on self-insured and large group market plans.

***PCMA recommendation*: PCMA opposes CMS's policy that, for the individual and small group market, drugs in excess of the benchmark are considered EHB. Additionally, we continue to oppose the underlying formulary drug count methodology for EHBs. CMS should propose the removal of the formulary drug count methodology in future EHB rulemaking and instead rely on a plan's PBM use of a P&T committee that follows all applicable codes of conduct and state and federal laws.**

II. While PCMA Continues to Oppose Formulary Reference Standards, if CMS Continues to Maintain Such Standards, It should not Eliminate USP MMG As a Formulary Benchmark Standard

In a December 2022 request for information (RFI) regarding EHB, [4] CMS solicited feedback on whether it may be more appropriate to replace the MMG with the USP Drug Classification system (USP DC), which covers a variety of classes of drugs not covered by Medicare Part D, such as anti-obesity agents and benzodiazepines, and is updated annually rather than every three years. In the Proposed Rule, CMS suggests (based on feedback received in response to the RFI), that it may be planning a shift to the USP DC for the benchmark formulary structure. In particular, CMS states: "we agree that using the USP DC to

[4] 87 Fed. Reg. 74,097 (December 2, 2022).

categorize the drugs provided as EHB would assist in strengthening the drug benefit due to its inclusion of additional drug categories and classes relevant to enrollees within the private insurance market." However, the agency does not propose such a change for 2025 and instead solicits comment on the below issues relevant to such a shift, including potential "risks and benefits" of such a shift and potential administrative burdens.

The current USP MMG classification system requires coverage of drugs by grouping drugs that often have completely different therapeutic uses. Plans are then forced to add drugs to formularies to meet punitive benchmark counts.[5] As suggested above, any formulary reference standard makes it difficult for PBMs to design prescription drug benefits based on medical evidence and necessity, by forcing them to cover drugs that are more expensive or have inefficient evidence on efficacy.

- As one example, a member reports three drugs that they are forced to include on all or almost all of their QHP formularies, despite the fact that its P&T committee has marked these as insufficient evidence unfavorable.[6]

- Another member reports that its formularies have to include brand-name combination therapies to formularies to satisfy the drug count methodology, when the two generic medications are widely available at significantly lower prices.[7]

- As biosimilars become more widely available, CMS's formulary drug count may also hinder competition as a biosimilar may replace each reference product, but not stand in for therapeutic substitution of other brand drug or biologics without biosimilars.

- In the case of first-in-class drugs with limited evidence for efficacy and serious safety concerns, plans may have to include them, if the benchmark plan does.[8] Listing of these drugs on formularies because of these regulations could be harmful.

[5] This adding of drugs would be compounded if CMS switched to a different reference standard, such as USP DC or AHFS, since they have more categories and classes than USP MMG.
[6] By "forced to cover," they mean that there are no other drugs in the category or class available, but the benchmark plan includes these, so any QHP in the state must also.
[7] Because the brand combination therapy is available, if a physician prescribes the brand drug, it will often be provided even under state substitution laws. However, if the brand combination therapy is not on formulary, prescribers may not select it if using a real-time formulary tool.
[8] This example is somewhat speculative, but CMS is well aware that FDA accelerated approval of aducanumab led to a National Coverage Decision requiring that any Medicare patient receiving drugs in this entire class (monoclonal antibodies directed at amyloid beta in Alzheimer's Disease) be enrolled in a registered clinical trial. FDA has recently granted accelerated approval to a second drug in this class. CMS's coverage policy does not extend to Medicaid, let alone QHPs.

In each of these cases, CMS is potentially exposing QHP enrollees to harm, and increasing costs on states, federal taxpayers, and the enrollees themselves at the same time.

In response to the December 2022 RFI, PCMA set forth its reasoning for opposing a shift from USP MMG to USP DC. While we have described above why the use of any formulary reference standard can be problematic, should CMS decline to propose the changes we seek, we reiterate here our belief that use of USP MMG to classify the prescription drugs required to be covered as EHB should be maintained. PBMs and plans are familiar with USP MMG and comfortable designing their benefits around this tool. Their internal review processes are built around it already. Plus, USP MMG has been in place for ten plan years with minor changes, and stability is particularly critical when other parts of the QHP market are changing. We would not be opposed to updating to a newer version of the USP MMG that aligns with treatment advances not otherwise covered by the Medicare program.[9]

In any future rulemaking, should CMS be inclined to name a different standard than USP MMG, it should grant plans significant sufficient time to update their systems. It should also consider, as an alternative, simply naming some other system as one of several reasonable standards plans could rely upon, rather than naming a single standard at all. The recent unveiling of the new USP DC PLUS by USP now adds a third possible standard, suggesting that a model which offers plans the flexibility to choose from one or more accredited formulary standards may more appropriately serve the needs of both QHP issuers and the enrollees they serve.

PCMA recommendation: If CMS will not streamline the prescription drug EHB, it should retain USP MMG as the framework for formulary drug counts. CMS should use the same version that is applicable to the Medicare Part D program.

III. Rather than Requiring a New Consumer Representative on Issuer's P&T Committees, CMS Should Allow Existing Members to Attest to a Consumer Interest or Identify a Particular Accreditation Standard.

Current CMS regulation at 45 C.F.R. § 156.122(a)(3)(i) provide standards that issuers must follow in forming a P&T committee to develop prescription drug formularies, including that the committee consist of a majority of individuals who are practicing physicians, practicing pharmacists, and other practicing healthcare professionals who are licensed to prescribe drugs. In the Proposed Rule, CMS proposes adding a requirement for including a consumer (patient) representative on P&T committees, noting a 2019 forum convened by the Academy of Managed Care Pharmacy that recommended such representation. The agency also proposes several standards for the potential patient participant. In particular, as proposed, the consumer

[9] As one example, the Part D statute precludes the coverage of drugs for the sole purpose of weight loss management, while QHPs are able to cover these. The newest products in this class hold much more promise than the less safe drugs Congress wanted to ensure were not widely covered in 2003.

representative must: (1) represent the consumer perspective; (2) have an affiliation with and or demonstrate active participation in consumer or community-based organizations; (3) have experience in the analysis and interpretation of complex data and be able to understand its public health significance; and (4) have no fiduciary obligation to a health facility or other health agency, and have no material financial interest in the rendering of health services.

While PCMA is supportive of the inclusion of a consumer voice on the P&T committee, we believe that the required inclusion of an additional representative on the P&T committee without the required expertise to review clinical data will not provide value to the program. We are also concerned that the criteria set forth for the consumer representative are far too stringent and will significantly limit the ability of plans and issuers to recruit a qualified individual. It is important to note that CMS's existing regulations at § 156.122 already contain a number of protections, including rules against conflicts of interest. For example, if the consumer representative is from a pharmaceutical manufacturer funded condition-specific advocacy organization, the individual would be conflicted and not be able to provide an unbiased perspective.

Rather than require an additional consumer representative to the P&T committee, CMS should instead allow existing P&T members to attest to having a consumer interest. These individuals would be able to provide valuable feedback as they retain their clinical perspective while broadening the consumer focus on the committee. Flexibility to attest that an existing P&T member can fulfill the consumer role, especially given that the skill set is limited to few individuals to meet the criteria outlined, will facilitate the overall process of convening P&T committees as well. As an additional alternative, CMS could in future rulemaking identify a particular accreditation or certification as CMS has already proposed under the Medicare Part D program.[10]

***PCMA recommendation*: CMS Should not Require a Separate, Consumer Representative on the P&T Committee. Instead, a P&T Committee member should be required to having a consumer or patient perspective.**

IV. In Future Rulemaking, CMS Should Clarify that Manufacturer Financial Assistance Provided to Patients Does Not Qualify as 'Cost Sharing' Under the Affordable Care Act.

In the Proposed Rule, CMS does not propose to take any further action on its current policies impacting the ability of plans and issuers to manage drug spending among their enrollees, preventing workarounds that ultimately drive up the cost of prescription drugs and undermine

[10] *See* 88 Fed. Reg. 78541, November 15, 2023. CMS proposes that Part C and D plan sponsors include a member who is certified in health equity on their utilization management review committees. Many MA-PDs use their P&T committees for this purpose and while the health equity requirement is a new proposal. CMS is not proposing that an additional individual be added – just that one or more members achieve this certification.

plan tools and supports. However, a recent flurry of activity in the Courts has created a degree of confusion in the marketplace with respect to CMS' current policy.

In the 2021 Payment Notice, CMS finalized a policy to allow group health plans and health insurance issuers to determine whether to count manufacturer payments of enrollee cost-sharing toward the enrollee's annual out-of-pocket (OOP) limits.[11] This policy allows group health plans and issuers to continue to operate copay accumulator adjustment programs (AAPs) for brand drugs with or without generic equivalents. Manufacturer coupons undercut pharmacy and therapeutic (P&T) committee-derived formularies and lead to higher spending on brand-name drugs.[12] CMS's policy reflects the negative impact manufacturer assistance may have on premiums, as well as the effect they can have on drug company pricing strategy.

On November 27, 2023, CMS filed a notice of appeal in *HIV and Hepatitis Policy Institute v. HHS* (Civ. No. 1:22-cv-02604), a case challenging CMS's 2021 accumulator policy. As part of a related filing, CMS filed a motion to clarify their current enforcement posture in relation to the D.C. District Court's decision striking down the 2021 accumulator policy. According to CMS: "HHS intends to address, through rulemaking, the issues left open by the court's opinion, including whether financial assistance provided to patients by drug manufacturers qualifies as 'cost sharing' under the Affordable Care Act. Pending the issuance of a new final rule, HHS does not intend to take any enforcement action against issuers or plans based on their treatment of such manufacturer assistance."

PCMA thanks CMS for continuing to understand the effect that activities such as direct manufacturers' assistance may have on premiums, as well as the effect they can have on drug companies' pricing strategy. We ask that, as part of future rulemaking, CMS make clear that financial assistance provided to patients does not qualify as 'cost sharing' under the Affordable Care Act in order to protect the integrity of the prescription drug benefit and protect enrollees' access to affordable premiums.

***PCMA recommendation*: PCMA thanks CMS for their clarification to date on current accumulator policy. In future rulemaking, CMS should clarify that manufacturer financial assistance provided to patients does not qualify as 'cost sharing' under the Affordable Care Act.**

[11] 85 Fed. Reg. 29164, 29232 (May 14, 2020).
[12] Dafny L, Ody C, and Schmitt M. "When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization." AMERICAN ECONOMIC JOURNAL: ECONOMIC POLICY VOL. 9, NO. 2 (May 2017), available at https://www.aeaweb.org/articles?id=10.1257/pol.20150588.

V. Conclusion

We thank CMS for the opportunity to provide comments on this important proposed rule and other regulatory matters. PBMs support the Administration's efforts to bring appropriate levels of transparency to prescription drug and other health care costs. If you need any additional information, please reach out to me at tdube@pcmanet.org.

Sincerely,

Tim Dube

Tim Dube,
Vice President, Regulatory Affairs

cc: Debjani Mukherjee, Senior Director, Regulatory Affairs, PCMA