National Pharmaceutical Council®

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January 8, 2024

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–9895–P
P.O. Box 8016
Baltimore, MD 21244

RE: Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO-OP) Program; and Basic Health Program [CMS-9895-P]

Dear Administrator Brooks-LaSure:

The National Pharmaceutical Council (NPC) appreciates the opportunity to submit comments regarding the Centers for Medicare & Medicaid Services (CMS) notice of proposed rulemaking, *Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO-OP) Program; and Basic Health Program.*

NPC is a health policy research organization dedicated to the advancement of good evidence and science and to fostering an environment in the United States that supports medical innovation. We have rich experience conducting research and disseminating information about the critical issues of evidence, innovation and the value of medicines for patients. Our research helps inform important healthcare policy debates and supports the achievement of best patient outcomes.

NPC's comments and recommendations, which we provide more detail on below, are as follows:

I. **Replacing the United States Pharmacopeia (USP) Medicare Model Guidelines (MMG) with the USP Drug Classification (DC) System:** NPC supports CMS transitioning from the USP MMG to USP DC in future rulemaking. While we appreciate policies that expand patient access to drugs, we request that CMS put safeguards in place to protect patient access to drugs if this policy is implemented, and that the agency establish an adequate implementation and transition timeline to prevent patient access to drugs from being interrupted if formulary changes are made.

II. **Risk Adjustment Model Recalibration:** NPC recommends that CMS regularly evaluate the HHS-HCC risk score model to ensure it fully captures the cost of conditions in the model and provides stability for issuers. We ask CMS to identify and address instances where coefficients may not adequately compensate issuers for enrollees with serious chronic conditions.

III. **Consumer Representation on Pharmacy & Therapeutics (P&T) Committees:** NPC appreciates CMS's commitment to including the patient perspective on P&T committees. We urge CMS to implement this policy in a manner that best fosters inclusion of the patient voice and consider additional opportunities for including the patient perspective.

IV. **Clarifying and Codifying Essential Health Benefits (EHB) Policy for Drugs Covered in Excess of the Benchmark**: NPC supports CMS's proposal to clarify and codify its current policy that prescription drugs in excess of those covered by a state's EHB-benchmark plan are considered EHB and asks that CMS extend this clarification to all plans, regardless of whether they are insured or self-insured, and regardless of employer size. We believe that the practice of plans classifying drugs as non-EHB is more widespread than CMS currently believes, ultimately harming patient access, raising patient out-of-pocket costs, and running counter to EHB regulations regarding cost-sharing and non-discrimination.

V. **Copay Accumulators:** CMS has not acknowledged policies related to copay accumulators in this proposed rule. NPC remains concerned that copay accumulators adversely impact patients.

VI. **Drug Tiering:** In the Proposed Rule *Notice of Benefit and Payment Parameters for 2024*[1], CMS proposed policies related to drug tiering. CMS did not finalize these policies in the final rule but stated it may consider this policy in future rulemaking. We note that CMS also does not discuss this proposal in this proposed rule and ask that CMS provide clarity on when and if this policy will be addressed.

I. Replacing the United States Pharmacopeia (USP) Medicare Model Guidelines (MMG) with the USP Drug Classification (DC) System

Under current policy, to provide EHB, a plan must cover either one drug in every USP category and class or match the State's EHB-benchmark plan's drug count, with the flexibility to exceed these minimum requirements. CMS currently uses the USP MMG and is considering transitioning to the USP DC, citing USP DC's annual updates and broader inclusion of drug classes relevant to patients receiving coverage through Exchange plans. NPC supports CMS transitioning from the USP MMG to the USP DC in future rulemaking given its broader applicability to patients covered under Exchange plans and more frequent updates. For example, there has been much innovation in the pharmaceutical treatment of obesity in recent years. Despite this, anti-obesity medicines (AOMs) do not currently need to be covered in order to meet EHB requirements as the USP MMG does not include a drug class for weight loss agents. As CMS notes, clinical guidelines have established the value of AOMs in the treatment of obesity and their exclusion from the USP MMG, among other drug classes, raises questions about its appropriateness as a drug classification standard for EHB plans.

While NPC supports policies that improve patients access to drugs, we are concerned that drugs newly added to formularies would be subject to utilization management policies that may ultimately limit patient access to drugs, for example, as plans may look to manage use of certain drugs such as AOMs given their costs. We request that CMS put safeguards in place to protect patient access to drugs if this policy is implemented, and that the agency establish an adequate implementation and transition timeline to prevent patient access to drugs from being interrupted if formulary changes are made.

[1] Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2024. Centers for Medicare & Medicaid Services, HHS. December 21, 2023. https://www.federalregister.gov/documents/2022/12/21/2022-27206/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2024

II. Risk Adjustment Model Recalibration

The Department of Health and Human Services (HHS) risk adjustment model uses hierarchical condition categories (HCCs) to predict plan liability for an average enrollee and recalibrates this model in the proposed rule. NPC recommends that CMS regularly evaluate the HHS-HCC risk score model to ensure it fully captures the cost of conditions in the model and provides stability for issuers. We ask CMS work to identify and address instances where coefficients have declined or are not sufficiently weighted to adequately compensate issuers for enrollees with serious chronic conditions as such issues could disincentivize issuers from enrolling those patients or cause them to employ adverse tiering that makes it difficult for those patients to access innovative medicines.

III. Consumer Representation on Pharmacy & Therapeutics (P&T) Committees

NPC supports the inclusion of the patient perspective into healthcare decision-making and appreciates the agency's consideration of the patient voice with its proposal to include a consumer representative on Pharmacy & Therapeutics (P&T) Committees. We thank CMS for citing the Academy of Managed Care Pharmacy (AMCP) *AMCP Partnership Forum: Principles for Sound P & T Committee Practices: What's Next Forum*[2], which NPC participated in, as a reason for proposing this policy. We ask CMS to consider forum findings when implementing this policy, if finalized, to further CMS's goal of incorporating the patient perspective. For example, the forum suggested that managed care organizations work with patient advocacy groups to help connect them with patient communities. Given the work of these groups in connecting with patients, we suggest CMS consider how P&T committees can best connect with patient advocacy groups to identify potential consumer representatives. The forum also suggested the development of educational programs for all P&T committee members, including trainings on methods, benefits, and limitations of various research approaches; clinical data interpretation skills; and value and cost-benefit assessments. We believe providing these types of trainings may strengthen the role of the consumer representative and better allow them to represent the patient voice.[3] We encourage CMS to leverage resources that have been developed by the Patient-Centered Outcomes Research Institute (PCORI) to facilitate authentic patient engagement by P&T Committees and ensure that the consumer representative adequately represents the consumer perspective because these resources are consistent with the AMCP Partnership Forum's findings and recommendations and would not require a de novo process.

IV. Clarifying and Codifying EHB Policy for Drugs Covered in Excess of the Benchmark

NPC strongly supports CMS's proposal to clarify and codify its current policy that prescription drugs in excess of those covered by a state's EHB-benchmark plan are considered EHB and asks that CMS extend this clarification to all plans, regardless of whether they are insured or self-insured, and regardless of employer size. We believe that finalizing this policy will aid in addressing the problem of copay maximizer programs, which are commonly used when drugs are designated as non-EHB in order to shift cost-sharing to patients. We encourage CMS to move forward with codifying this policy, to monitor for patient access issues, and to further develop safeguards to protect patient access.

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[2] AMCP Partnership Forum: Principles for Sound Pharmacy and Therapeutics (P&T) Committee Practices: What's Next? J Manag Care Spec Pharm. 2020 Jan;26(1):48-53. doi: 10.18553/jmcp.2020.26.1.48. PMID: 31880220; PMCID: PMC10391133.

[3] AMCP Partnership Forum: Principles for Sound Pharmacy and Therapeutics (P&T) Committee Practices: What's Next? J Manag Care Spec Pharm. 2020 Jan;26(1):48-53. doi: 10.18553/jmcp.2020.26.1.48. PMID: 31880220; PMCID: PMC10391133.

We firmly believe that the practice of plans classifying drugs as non-EHB is more widespread than CMS currently believes, ultimately harming patient access and raising patient out-of-pocket costs. As noted in the HIV + Hepatitis Policy Institute patient sign-on letters in response to the Proposed Rules *Notice of Benefit and Payment Parameters for 2023 (CMS-9911-P)*[4] and *Notice of Benefit and Payment Parameters for 2024 (CMS-9899-P)*[5], many large group plans that follow EHB designate certain medicines as "non-essential" and subsequently raise patient cost-sharing to ensure that they collect all of the patient assistance offered by the manufacturer but do not count it towards the beneficiary's cost-sharing obligation.[6, 7,8] A 2022 survey of 35 payers covering 121.5 million commercial lives found that payers covering 75 percent of these lives had implemented at least one copay maximizer or accumulator program prior to 2022.[9] These plan policies run counter to EHB regulations regarding cost-sharing and non-discrimination.

Plans are permitted to adopt their own definition of EHBs, so long as they are consistent with HHS guidelines. Under this definition, some plans are broadly categorizing specialty medications in excess of the state-EHB benchmark as non-EHBs and developing programs for non-EHB specialty medication drug lists. These programs, often referred to as specialty carve-out programs and run by alternate funding companies, require patients to enroll in the program or face high out-of-pocket costs for drugs excluded from coverages. Programs are on the rise, with 8 percent of benefits leaders stating they had an alternative funding model in place and 31 percent responding that they were exploring their use.[10] When patients enroll in programs where specialty medications have been placed on a non-EHB drug list, beneficiaries receive a $0 copay. Once the patient is enrolled, the program collects the maximum amount of copay assistance from the drug manufacturer but does not apply it towards the patient's out-of-pocket limit – a form of a copay maximizer program. These programs can expose patients to greater out-of-pocket costs as the assistance from the coupon is not counted towards the patient's out-of-pocket limit, resulting in patients not progressing through their benefits and leading to unexpected out-of-pocket costs. In turn, these unexpected expenses may reduce treatment adherence and increase patient discontinuation.[11,12] NPC urges CMS to enforce the law and essential health benefits regulations that require all cost-sharing associated with covered benefits and services to be included as part of cost-sharing. Furthermore, we ask that tri-agency guidance be issued between HHS, the Department of Labor, and the Department of the Treasury to clarify that this policy apply to all non-grandfathered health plans, regardless of whether they are insured or self-insured, and regardless of employer size, in addition to CMS applying it to individual and small group health plans. Currently, the EHB limitation

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[4] Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2023. Centers for Medicare & Medicaid Services, HHS. January 5, 2022. https://www.federalregister.gov/documents/2022/05/06/2022-09438/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2023

[5] Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2024. Centers for Medicare & Medicaid Services, HHS. December 21, 2023. https://www.federalregister.gov/documents/2022/12/21/2022-27206/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2024

[6] Aimed Alliance. Copay Accumulator 101. https://aimedalliance.org/copay-accumulator-101/

[7] HIV+HEP Policy Institute. Comments on Notice of Benefits and Payment Parameters for 2023 Proposed Rule [CMS-9911-P]. January 27, 2022. https://hivhep.org/wp-content/uploads/2022/01/Patient-Sign-On-Letter-NBPP-2023-4.pdf

[8] HIV+HEP Policy Institute. Comments on Notice of Benefits and Payment Parameters for 2024 Proposed Rule [CMS-9899-P]. January 30, 2022. https://www.regulations.gov/comment/CMS-2022-0192-0195

[9] MMIT Network. The Problem with Copay Adjustment and Alternate Funding Programs. https://www.mmitnetwork.com/thought-leadership/the-problem-with-copay-adjustment-and-alternate-funding-programs/

[10] PSG. 2022 State of Specialty Spend & Trend Report. https://www.psgconsults.com/industry-report/specialtyreport2022/?utm_campaign=2023+Thought+Leadership&utm_source=website&utm_content=psg-consults-appetite-disruption-growing

[11] Sherman B, Epstein A, Meissner B, Mittal M. Impact of a Co-pay Accumulator Adjustment Program on Specialty Drug Adherence. Am J Manag Care. 2019;25(7):500-505.

[12] Aimed Alliance. Copay Accumulator 101. https://aimedalliance.org/copay-accumulator-101/

exists only in implementing regulation, as opposed to in the statute itself, and guidance is necessary to clarify the application of this policy.

In the 2023 HHS Notice of Benefits and Payment Parameters final rule, CMS finalized its EHB nondiscrimination policy for health plan designs.[13] Under § 156.125(a), an issuer does not provide EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.[14] As such, the exclusion of certain drugs for certain health conditions discriminates against individuals with these health conditions as drugs are a EHB benefit. The use of copay maximizers has particularly grown for autoimmune therapies, multiple sclerosis therapies, and oncology therapies, meaning these programs may particularly impact patients being treated with these drugs. From 2019 to 2022, commercial patient exposure to maximizers for autoimmune therapies and multiple sclerosis therapies tripled, going from 4 percent to 14 percent and 4 percent to 15 percent, respectively. Maximizer exposure more than doubled for oncology patients during the same time period, increasing from 5 percent to 13 percent.[15] NPC encourages HHS to prohibit the development or administration of benefit design or coverage that run counter to EHB nondiscrimination policies.

V. Copay Accumulators Policy

The policy finalized in the Final Rule *Notice of Benefit and Payment Parameters for 2021*[16] made it easier for plans to adopt "copay accumulator" programs, despite concerns raised by patient groups that these programs prevent manufacturer cost-sharing assistance from counting towards patient deductibles and annual limits on cost sharing, making it harder for patients to meet their cost-sharing obligations, and leading to unexpected costs which can result in non-adherence. An October 2023 federal district court ruling set aside the 2021 rule, however, HHS has noted that they do not plan to take enforcement action against issuers or plans based on their treatment of manufacturer assistance and has sought additional clarification of the court's decision and appealed that decision.[17] On December 22, 2023, the court granted the agency's motion and, in doing so: (1) clarified that, on account of the vacatur of the 2021 NBPP policy, the 2020 NBPP policy is now in effect, and (2) declined to express any view regarding the agency's intended non-enforcement policy.[18]

NPC is deeply concerned with the impacts of HHS's appeal and lack of enforcement on patients. We call on HHS to drop its appeal of the court's decision and abandon its stated intent to engage in further rulemaking, to the extent that it intends to adopt any policy comparable to the 2021 NBPP policy. We also ask HHS to abandon its stated intent to adopt a non-enforcement policy pending the completion of

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[13] Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2023. Centers for Medicare & Medicaid Services, HHS. January 5, 2022. https://www.federalregister.gov/documents/2022/05/06/2022-09438/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2023

[14] 45 CFR 156.125(a)

[15] IQVIA. Five Years and Counting: Deductible Accumulators and Copay Maximizers in 2022. December 25, 2022. https://www.iqvia.com/locations/united-states/library/white-papers/five-years-and-counting-deductible-accumulators-and-copay-maximizers-in-2022

[16] Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2021. Centers for Medicare & Medicaid Services, HHS. February 6, 2020. https://www.federalregister.gov/documents/2020/02/06/2020-02021/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2021

[17] United States Department of Health and Human Services. Motion to Clarify. November 27, 2023. https://hivhep.org/wp-content/uploads/2023/11/govt-clarification-request.pdf

[18] United States District Court for the District of Columbia. Memorandum Opinion & Order. December 22, 2023. https://hivhep.org/wp-content/uploads/2023/12/Clarification-decision.pdf

rulemaking.[19] Furthermore, we ask CMS to issue guidance reflecting the court's decision to clarify that plans must count manufacturer cost-sharing assistance toward the annual cost-sharing limit as outlined in the 2020 NBPP. This policy is absent in this year's proposed rule. As we outline below, we believe the use of copay accumulator programs adversely impacts patients, and encourage CMS to consider this impact on patients in shaping copay accumulator policies.

Multiple studies have demonstrated that higher copayments and out-of-pocket costs can lead to reduced medication adherence, worse disease control, and increased hospitalizations.[20,21,22,23] To minimize these outcomes against rising deductibles, copay assistance funds in the form of coupons or copay cards are often offered. However, health plans and pharmacy benefit managers have increasingly implemented copay accumulator programs to prevent assistance from counting towards a patient's deductible or annual limit on cost-sharing. These programs prevent manufacturer cost-sharing assistance from counting towards patient deductibles and annual limits on cost sharing which makes it harder for patients to meet their cost-sharing obligations to progress through their benefits and can lead to unexpected costs. In turn, these greater expenses may lead to reduced treatment adherence and increased patient discontinuation – both of which can harm patient health, and conflict with the Administration's goal of reducing out-of-pocket costs.[24] In addition, a recent study has shown that copay accumulator exposure was significantly higher among non-White patients. This increased exposure suggests a disproportionate effect due to a reduction in copay assistance benefits, which has the potential to exacerbate racial and ethnic disparities in access to medications.[25] Nineteen states, the District of Columbia, and Puerto Rico have recognized the negative impacts of copay accumulator programs on patients and have enacted prohibitions against them.[26]

These policies jeopardize patient access to care. Additionally, the use of copay accumulator programs is not disclosed at an appropriate level of detail and clarity in the patient's Summary of Benefits and Coverage, nor elsewhere on the Marketplace. We recommend CMS require plan issuers to disclose which Marketplace plans include copay accumulator programs and how they are applied. In copay accumulator programs, the copay card is applied until its maximum value is reached, at which point the patient's out-of-pocket costs begin counting toward their annual deductible and out-of-pocket maximum.[27] As there is limited transparency into how copay accumulator programs are applied, patients may face greater out-of-pocket costs unexpectedly, which may lower treatment adherence if higher cost sharing prevents patients from accessing medication. Requiring greater transparency will

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[19] Ibid.

[20] Goldman DP, Joyce GF, Zheng Y. Prescription Drug Cost Sharing: Associations with Medication and Medical Utilization and Spending and Health. JAMA. 2007;298(1):61-69. doi:10.1001/jama.298.1.61.

[21] Gourzoulidis G, Kourlaba G, Stafylas P, Giamouzis G, Parissis J, Maniadakis N. Association between copayment, medication adherence and outcomes in the management of patients with diabetes and heart failure. Health Policy. 2017;121(4):363-377.

[22] Trivedi AN, Moloo H, Mor V. Increased Ambulatory Care Copayments and Hospitalizations Among the Elderly. N Engl J Med. 2010;362(4):320-328.

[23] Fusco N, Sils B, Graff J, Kistler K, Ruiz K. (in press). Cost-Sharing and Adherence, Clinical Outcomes, Healthcare Utilization, and Costs: A Systematic Literature Review. Journal of Managed Care & Specialty Pharmacy.

[24] Sherman B, Epstein A, Meissner B, Mittal M. Impact of a Co-pay Accumulator Adjustment Program on Specialty Drug Adherence. Am J Manag Care. 2019;25(7):500-505.

[25] Ingram M, Sadik K, Zhao X, Song J, Fendrick A. Assessment of Racial and Ethnic Inequities in Copay Card Utilization and Enrollment in Copay Adjustment Programs. J Manag Care Spec Pharm. 2023 Sep;29(9):1084-1092. doi: 10.18553/jmcp.2023.23021.

[26] All Copays Count Coalition. State Legislation Against Copay Accumulators. https://allcopayscount.wpengine.com/state-legislation-against-copay-accumulators/

[27] American Society of Clinical Oncology. Copay Accumulators and Maximizers Policy Brief. January 2021. https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2021-AccumulatorsPolicyBrief.pdf

safeguard patients by helping them understand how manufacturer assistance will be applied and allow Marketplace consumers to make informed choices about care before enrolling in a plan.

VI. Drug Tiering

In the Proposed Rule *Notice of Benefit and Payment Parameters for 2024*[28], CMS proposed the following requirements for issuers of standardized plan options:

1. Place all covered generic drugs in the standardized plan options' generic drug cost-sharing tier, or the specialty drug tier if there is an appropriate and non-discriminatory basis; and,
2. Place brand name drugs in either the standardized plan options' preferred brand or non-preferred brand tiers, or specialty drug tier if there is an appropriate and non-discriminatory basis in accordance with §156.125 Prohibition on Discrimination.[29]

CMS did not finalize this policy in the final rule but stated it may consider this policy in future rulemaking. We note that CMS also does not discuss this proposal in this proposed rule and ask that CMS provide clarity on when and if this policy will be addressed.

Conclusion

The National Pharmaceutical Council appreciates the opportunity to provide comments in response to the proposed rule and would be happy to meet to expand upon our comments and share our research. Please contact me at john.obrien@npcnow.org or (202) 827-2080 if we may provide any additional information.

Sincerely,

John M. O'Brien, PharmD, MPH
President and Chief Executive Officer

[28] Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2024. Centers for Medicare & Medicaid Services, HHS. December 21, 2023. https://www.federalregister.gov/documents/2022/12/21/2022-27206/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2024

[29] §156.125 Prohibition on Discrimination