



NATIONAL HEALTH COUNCIL

March 1, 2024

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

**RE: Draft CY 2025 Part D Redesign Program Instructions**

Submitted electronically to [PartDRedesignPI@cms.hhs.gov](mailto:PartDRedesignPI@cms.hhs.gov)

Dear Administrator Brooks-LaSure:

The National Health Council (NHC) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services' (CMS') *Draft CY 2025 Part D Redesign Program Instructions*.

Created by and for patient organizations over 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. We promote increased access to affordable, high-value, equitable, and sustainable health care. Made up of 170 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses and organizations representing biopharmaceuticals, devices, diagnostics, generics, and payers.

**Monitoring Unintended Consequences and Patient Access**

The NHC shares CMS' commitment to implementing the Inflation Reduction Act (IRA) of 2022 Part D benefit redesign provisions, which introduces significant changes to the Medicare Part D benefit structure, effective in 2025, with the primary aim of reducing out-of-pocket (OOP) expenses for enrollees. These reforms include introducing an annual OOP cap of \$2,000, the Medicare Prescription Payment Program (MPPP) to allow beneficiaries to pay their OOP expenses over the course of a calendar year, the creation of the Manufacturer Discount Program, and the redefinition of financial responsibilities among enrollees, plan sponsors, manufacturers, and CMS. However, despite the potential benefits in reducing OOP expenses for enrollees, the operational complexities of this program, shifting incentives, and possible unintended consequences on medication access and affordability demand close attention.

The NHC has previously expressed concerns regarding the potential unintended consequences that may arise from the Part D redesign, particularly as they pertain to

formulary decisions affecting patient access to essential medications.<sup>1</sup> Under the IRA, plans will take on increased financial liability, which could lead to incentives to narrow formulary access, particularly in areas where plan liability is expected to increase most, such as for drugs with spending that primarily falls in the catastrophic phase and for low-income subsidy (LIS) enrollees, which could potentially impede access for the most vulnerable patient populations. To address these concerns, the NHC proposes the following recommendations:

1. **Intensify Oversight and Enhance Formulary Inclusiveness:** The NHC urges CMS to implement and intensify oversight mechanisms to ensure that plan formularies remain inclusive of necessary medications without imposing undue restrictions or high OOP costs on patients.
2. **Ensure Comprehensive Transparency in Formulary Management:** Provide clear, comprehensive guidelines to Part D plans to ensure transparency in plan coverage, tiering, and utilization management (UM) policies, offering safeguards against practices that could restrict access to necessary treatments. These guidelines should encompass rigorous scrutiny of the impact of the Manufacturer Discount Program on formulary decisions and UM practices, ensuring they support broad access to essential medications within the newly defined standard Part D benefit structure as outlined in the *Draft CY 2025 Part D Redesign Program Instructions*.
3. **Address Unintended Consequences of Liability Changes:** Carefully consider the impact of plan liability changes on patient access to medications, especially for vulnerable populations, and implement measures to mitigate any negative effects. Specifically, the NHC urges CMS to proactively consider modifications to its formulary review process to ensure Part D plans are providing appropriate beneficiary access to needed medications in 2025 and beyond. Additionally, CMS should consider further agency actions to provide more predictability and stability to Part D plans and the Part D market more broadly.
4. **Streamline Beneficiary Communications:** Detailed information should be provided to beneficiaries to ensure a comprehensive understanding of how these changes will influence their coverage and OOP costs. Effective communication is essential to mitigate confusion and empower beneficiaries to make informed health care decisions.
5. **Operational Transparency:** The operational aspects of the Manufacturer Discount Program, particularly regarding the application of discounts at the point

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<sup>1</sup> National Health Council. (2023). NHC comments on HPMS solicitation. Retrieved from <https://nationalhealthcouncil.org/letters-comments/nhc-comments-on-hpms-solicitation/>

of sale and the reconciliation processes, must be transparent and streamlined to avoid any delays or denials in access to discounted medications.

In addition to these recommendations, the NHC emphasizes the critical importance of incorporating patient and caregiver perspectives into the ongoing dialogue and decision-making processes related to Medicare Part D. Their firsthand experiences and insights are invaluable in understanding the real-world implications of these policy changes and ensuring that the redesigned Part D program remains patient-centered and equitable.<sup>2,3,4,5</sup> To facilitate this, the NHC suggests that CMS establish a formal mechanism for patients and patient organizations to share their challenges and experiences directly with CMS. This could include regular forums, dedicated communication channels, or advisory panels that allow for the direct engagement of patients and caregivers in the policy development and implementation process, ensuring their voices are heard and considered in shaping a Part D program that truly meets their needs.

By addressing these areas and establishing a mechanism for direct patient and caregiver input, CMS can ensure that the Part D redesign not only achieves its intended goals of reducing beneficiaries' OOP costs but also maintains equitable access to necessary medications without introducing new barriers.

### **PDP Meaningful Difference**

In response to the changes outlined in the *Draft CY 2025 Part D Redesign Program Instructions* regarding Prescription Drug Plan (PDP) Meaningful Difference, the NHC

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<sup>2</sup> Perfetto, E., Kennedy, A., and Bright, J. (2021). A vision for patient-centered core impact sets – a unifying approach to patient centricity. *The American Journal of Managed Care*. Retrieved from <https://www.ajmc.com/view/contributor-a-vision-for-patient-centered-core-impact-sets-a-unifying-approach-to-patient-centricity>

<sup>3</sup> Bennett, W., Pitts, S., Aboutmatar, H., Sharma, R., Smith, B., Das, A., Day, J., Holzhauser, K., and Bass, E. (2020). Strategies for patient, family, and caregiver engagement. Agency for Healthcare Research and Quality

<sup>4</sup> Chachoua, L., Dabbous, M., François, C., Dussart, C., Aballéa, S., and Toumi, M. (2020). Use of patient preference information in benefit-risk assessment, health technology assessment, and pricing and reimbursement decisions: a systematic literature review of attempts and initiatives. *Frontiers in Medicine*, 26(7). doi: 10.3389/fmed.2020.543046

<sup>5</sup> Wong, E., Mavondo, F., and Fisher, J. (2020). Patient feedback to improve quality of patient-centered care in public hospitals: a systematic review of the evidence. *BMC Health Services Research*, 20(1). doi: 10.1186/s12913-020-05383-3. PMID: 32527314; PMCID: PMC7291559.

acknowledges the efforts by CMS to refine the evaluation process for ensuring meaningful differences between enhanced alternative (EA) plans and basic plans. The shift towards an absolute percent threshold approach for evaluating PDP meaningful difference, alongside considerations for formulary robustness and benefit design/tier placement, represents a significant change aimed at enhancing transparency and ensuring beneficiaries can make informed choices.

However, the NHC is concerned that the current approach, while aimed at improving plan value discernment for beneficiaries, may not fully capture the nuances that significantly impact patient access to necessary medications. Particularly, the exclusion of UM practices from the evaluation of meaningful difference might overlook a critical aspect of patient care, as UM can affect access to prescribed treatments. Given CMS's acknowledgment of the increasing burden of UM practices, it is imperative that the impact of UM on patient access is considered in the meaningful difference evaluation.<sup>6</sup>

Furthermore, the NHC suggests that the evaluation of meaningful difference should extend beyond financial metrics and include patient access metrics such as the comprehensiveness of formularies and the ease of access to innovative treatments. This would ensure that plans are not only financially advantageous but also cater to the diverse medical needs of beneficiaries, particularly those with chronic, rare, or complex conditions.

The NHC also recommends that CMS undertake a more transparent and inclusive approach in evaluating plans by incorporating feedback from patients, caregivers, and patient advocacy groups. This feedback can provide invaluable insights into the real-world impacts of plan offerings on patient care and access to medications.

The NHC urges CMS to:

1. Reevaluate the exclusion of UM practices from the meaningful difference evaluation and consider their impact on patient access to care.
2. Broaden the scope for assessing meaningful difference by incorporating metrics related to patient access. This should take into account the breadth of coverage offered by formularies, the accessibility of innovative treatments, and whether UM practices are in harmony with clinical guidelines and patient needs. By implementing these measures, evaluations of plans would extend beyond

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<sup>6</sup> Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program, 89 Fed. Reg. 8758 (finalized January 17, 2024).

financial considerations to also encompass their effectiveness in addressing the broad spectrum of beneficiaries' health care needs.

3. Engage with patients, caregivers, and patient advocacy groups to gather insights that can inform a more patient-centered approach to evaluating plan differences.

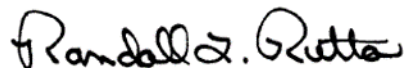
Additionally, the NHC recommends CMS evaluate the impacts of the PDP meaningful difference requirements on Part D market offerings, particularly given the absence of such requirements for MA-PDs. Specifically, CMS should monitor the impacts of these disparate requirements on the Part D plan offerings available to enrollees to ensure beneficiaries have a range of available plan choices among both PDPs and MA-PDs.

The NHC appreciates the opportunity to provide input on this critical aspect of the Part D redesign and is committed to working with CMS to ensure that the program continues to meet the needs of all beneficiaries, particularly those with the greatest health burdens.

## **Conclusion**

The NHC appreciates the opportunity to comment on the *Draft CY 2025 Part D Redesign Program Instructions*. We look forward to continued collaboration with CMS to ensure that the Part D redesign fully aligns with the needs and well-being of all Medicare beneficiaries. Please do not hesitate to contact Eric Gascho, Senior Vice President of Policy and Government Affairs, if you or your staff would like to discuss these comments in greater detail. He is reachable via e-mail at [egascho@nhcouncil.org](mailto:egascho@nhcouncil.org).

Sincerely,



Randall L. Rutta  
Chief Executive Officer