

June 5, 2023

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

Re: Response to HPMS Solicitation

Dear Administrator Brooks-LaSure:

The National Health Council (NHC) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide you feedback on programmatic policies for the Part D redesign in CY 2025 and beyond.

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 more than 155 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.

Input from Patients

The NHC appreciates CMS exploring important parameters of the Part D program to account for impacts of the Inflation Reduction Act (IRA) Part D redesign and other policies. While we appreciate the opportunity to provide a response to this solicitation, we would like to express our concern about utilizing the Health Plan Management System (HPMS) portal to seek input on these important questions. This is not a venue that patients and their advocates have access to, as health insurance plans are the primary users of the portal.

The foundational questions posed in this request underscore that the Part D program is about to undergo the most significant changes in its history. CMS must ensure stakeholders have ample opportunity to provide input throughout the implementation and adjustment process. And CMS must create opportunities for patients to communicate challenges caused by unintended consequences throughout the rollout. We would request that you provide opportunities for patient advocacy organizations to provide input into these important questions through other avenues as you move forward, and we look forward to participating in that comment process.

Meaningful Differences: Basic vs. Enhanced Benefit Plans

Given that the IRA requires the out-of-pocket (OOP) cap to be part of the standard benefit, measuring differences between basic and enhanced plans based on out-of-pocket (OOP) spending (as is done today) is likely no longer an appropriate metric to determine the relative value of an enhanced vs. basic plan.

Despite the \$2,000 OOP cap under benefit redesign, having enhanced PDP plan options available in the market will still be valuable for beneficiaries. Maintaining beneficiary choice for prescription drug plans (PDPs) is likely particularly important for certain beneficiary patient populations, such as sicker enrollees and beneficiaries in rural areas. Additionally, in many rural areas, stand-lone PDPs are more prevalent, and MA-PD options are more limited. If CMS were to continue to use OOP costs to make this determination, the differences would need to be relatively small, which would likely not be useful or representative of actual differences in value to enrollees.

We reiterate the point that CMS should undertake further effort to collect perspectives of patient organizations beyond the HPMS portal solicitation to determine what patients' view as "meaningful" in respect to this question. With that said, CMS could consider measuring meaningful differences (or if CMS eliminates meaningful difference requirements for PDPs, determining what constitutes an "enhanced" plan) through measures such as formulary generosity [e.g., whether the plan provides coverage of more drugs, has less utilization management (UM), places drugs on lower tiers]. Measures of formulary generosity would need to be determined across all therapeutic areas such that a plan would not be considered enhanced if it only provides more generous formulary coverage for one therapeutic area but not another. Factors to consider may include:

- Total number of drugs covered by plan;
- Average number of drugs covered per class;
- Total number of drugs subject to UM;
- Average number of drugs subject to UM per class;
- Average number of drugs per class subject copay vs. coinsurance; and
- Average number of drugs per class on the non-preferred tier.

CMS could also consider other factors such as availability of preferred pharmacies and/or total number of pharmacies included in a plan's network.

Establishing alternative approaches for determining what constitutes an enhanced plan based on metrics that are important to beneficiaries make it easier for them to distinguish between basic vs. enhanced plans when selecting plans during Open Enrollment. CMS should solicit feedback from stakeholders on what factors would be helpful for beneficiaries to see when comparing plans.

Tiering and Cost Sharing

CMS seeks clarification about the extent to which plans increase cost sharing and what impact will this have on beneficiaries given the increase in plan liability under benefit redesign.

For beneficiaries with high drug spending that will reach the OOP cap, higher cost sharing on tiers will not be as impactful as it is today (as these beneficiaries will reach the OOP cap regardless of the cost sharing charged on a tier and will be able to spread the cost over the course of a calendar year). However, for enrollees that have more moderate spending that are not projected to reach the OOP cap, increased cost sharing/movement of drugs to higher tiers will increase OOP costs (particularly if more drugs are moved from copay to coinsurance tiers). And given the projected difficulty of implementing the allowance for beneficiaries to spread their costs over the year (as noted below), higher cost-sharing may have an impact on people's ability to afford their medicine early in the year if they are not aware of this opportunity.

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The NHC asks CMS to perform comprehensive formulary reviews as it relates to formulary coverage, utilization management, and tier structures/cost sharing to ensure beneficiary access under benefit redesign. CMS should carefully monitor changes in cost sharing and formulary coverage under benefit redesign (e.g., conducting studies comparing cost sharing, coverage, and utilization management pre- vs. post-redesign).

Risk Adjustment

CMS established in the PY2024 Rate Announcement that it will recalibrate the RxHCC model for PY2025. The results of this work will impact the availability of Part D plans and many of the issues in this RFI. As CMS implements the changes related to redesign of the Part D benefit, it is important for CMS to also make adjustments to the RxHCC model to bring it in line with current benefit parameters and other IRA changes. This enables risk adjustment rewards plans to enroll beneficiaries with more expensive health needs and offer them robust formularies to help manage their conditions.

Given the many adjustments that will be required of the risk adjustment model to account for IRA implementation, it will be more important than ever that CMS actively seeks and incorporates stakeholder feedback. This could be similar to the process that was conducted when the ACA Marketplace risk adjustment model was updated. A simple 30-day comment period process will likely not be sufficient.

Beneficiary Education and Protection

As with any program change of this magnitude, it is critical that CMS engage in beneficiary education as it relates to the new benefit design changes such as the OOP cap and OOP smoothing. We encourage CMS to work with patients and advocates to develop a national strategy and tools to assure that beneficiaries are aware of the coming changes and fully understand how the changes will affect them. It is also important that guardrails are put in place to ensure beneficiaries have appropriate access to the smoothing program regardless of the plan they are enrolled in.

Implementing OOP Cap and Patient "Smoothing" Provisions

Although not explicitly referenced in the HPMS request, one of the areas of IRA implementation of great importance for beneficiaries is their ability to spread payments out over a calendar year or "smoothing." It is important that any final regulations related to smoothing meet the needs of the beneficiaries, and the NHC provides the following recommendations for achieving that goal.

One of the first concerns is assuring that beneficiaries understand smoothing and their ability to utilize it. We strongly urge CMS to use every available means to educate enrollees – and/or develop materials for other stakeholders to help educate enrollees - about their option to choose a maximum monthly cap. Standardized communications materials for insurance plans, pharmacies, pharmacists, and other providers should be a priority CMS project. Materials should be codeveloped with multiple stakeholder types, including patient advocates. Information about the option to smooth costs should be available at multiple points so that beneficiaries are aware of and understand their ability to opt-in to the smoothing option.

There are also several technical aspects of smoothing that need to be addressed. The NHC looks forward to the ability of beneficiaries to opt-in to smoothing at the point-of-sale and/or at the pharmacy. However, implementation is incredibly complex and challenging. Further conversation among stakeholders and with CMS is warranted to determine if flexibility may be

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necessary during the initial years of the program, and oversight and regular regulatory adjustment will be crucial. The opt-in for smoothing should be available year-round, as reflected in the statute. Beneficiaries should have the option to smooth costs not just in January or when signing up for a Part D plan, but over the course of the plan year.

Additional conversations and dialogue are necessary to identify and address the potential unintended consequences, such as increased utilization management and other barriers to access, of the OOP cap. Implementation timelines are short, given technical, operational, and educational needs. Close collaboration between stakeholders can help facilitate the rate of implementation, as well as help develop consensus-driven input to CMS.

Conclusion

The NHC thanks CMS for the opportunity to provide input on this important issue. 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.

Sincerely,

Randall L. Rutta

Chief Executive Officer

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