

June 5, 2023

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Re: Response to HPMS Solicitation on Medicare Part D Redesign

Dear Administrator Brooks-LaSure:

On behalf of The Patient Access Network (PAN) Foundation, one of the nation's largest charities, I write to provide comment on the Centers for Medicare & Medicaid Services' (CMS) implementation of the *Inflation Reduction Act's* (IRA) provisions related to Medicare Part D redesign.

PAN is an independent, national 501(c)(3) organization dedicated to helping federally and commercially insured people living with life-threatening, chronic, and rare diseases with the out-of-pocket (OOP) costs for their prescribed medications. PAN provides patients with direct assistance through more than 70 disease-specific programs and collaborates with national patient advocacy organizations to provide patients with education and additional support. Since 2004, we have helped more than 1 million underinsured patients.

PAN welcomes the opportunity to work with CMS to not only shape IRA implementation policies to ensure that it meets the needs of enrollees, but we also look forward to working with CMS to better educate enrollees, their families, and other stakeholders about the maximum monthly cap option for enrollees.

PAN provides the following comments:

#### **Part D OOP Cap and Smoothing Mechanism**

Although not explicitly referenced in the HPMS request, one of the areas of IRA implementation of great importance for beneficiaries is the ability of beneficiaries to spread payments out over a calendar year or "smoothing." PAN offers the following thoughts on provisions that should be included in the regulations or guidance CMS develops related to the maximum monthly cap to ensure the program meets the needs of the enrollees:

#### ***Election***

PAN strongly believes that enrollees should be able to elect to take advantage of the maximum monthly cap throughout the plan year. This means that enrollees who anticipate high drug costs could elect this option during the plan selection process. We recognize that the statute provides no deadline by which enrollees can choose to elect to take advantage of the maximum monthly cap and would urge CMS to ensure that enrollees could do so as late as November of a given plan year. Splitting up a financial liability over two months rather than one may be immensely beneficial to some enrollees, especially those newly prescribed an expensive therapeutic.

PAN acknowledges the technical complexities facing insurers and providers as they implement the cost smoothing flexibility. However, it is clear in the statute: beneficiaries are expected to be notified at the point of sale if they are likely to benefit from opting in to smoothing.<sup>1</sup> In order for smoothing to operate as intended and for this notification to be meaningful in combating medication abandonment, beneficiaries must be able to decide to activate the flexibility at the time they are facing substantial costs for Part D-covered items. This should also be the case regardless of whether an enrollee chooses to fill their prescription via mail order or a brick-and-mortar pharmacy. In discussions with stakeholders, concerns around the pharmacists' ability to provide education in a time-effective manner at the point of sale, especially given demands and the current lack of a billing code for the time associated with education, have been raised as a concern. Similarly, ensuring consistent technical standards and informational exchange capability to provide real-time information on smoothing liability at the point-of-sale are paramount.

### **No Threshold Amount**

Enrollees have different financial situations and we would urge CMS to refrain from setting a minimum OOP threshold amount (other than a *de minimus* amount) needed to trigger the enrollee's election. PAN also believe that enrollees should be able to opt to elect the maximum monthly cap prior to meeting their Part D deductible and not be forced to wait until the deductible has been met.

### **Lockout**

The statute provides that when an enrollee fails to pay their maximum monthly cap amount a prescription drug plan (PDP) may terminate the enrollee's election and require the enrollee to pay the applicable cost-sharing. In developing regulations to implement this provision, PAN urges CMS to recognize that there may be many reasons (major medical event, computer error, natural disaster, etc.) why an enrollee may miss a payment related to their maximum monthly cap and to enact provisions limiting a plan's ability to disenroll the enrollee for non-payment. CMS should model those protections on the existing regulations regarding non-payment of premiums,<sup>2</sup> including:

- Allowing plans to have a longer grace period than the statutorily required one month, but requiring that plans apply the grace rule period the same to all enrollees;
- Requiring the disenrollment and grace period policies to be disclosed in the annual notice of coverage (ANOC) and evidence of coverage (EOC);
- Require that plans provide "timely notice" to enrollees prior to disenrollment and requiring them to provide an explanation of the enrollee's right to file a grievance;<sup>3</sup>
- Prohibiting plans from disenrolling an individual who elects to have their maximum monthly cap deducted from their Social Security check;
- Clarifying that if an enrollee is disenrolled from a plan's maximum monthly cap option, the plan can refuse to enroll them in future years until past payments are made, but that this requirement is only applicable to an issuer. An enrollee is not prohibited from enrolling in a plan offered by a different issuer.

### **Methods of payment**

<sup>1</sup> Inflation Reduction Act of 2022 (Sec. 11202(a)(1)(B))s

<sup>2</sup> 45 CFR§ 423.44.3

<sup>3</sup> CMS should track grievance response times and ensure that beneficiaries are receiving feedback in a timeline fashion.

Part D enrollees have vastly different preferences when it comes to paying their maximum monthly cap amount. Some enrollees may wish to have their maximum monthly cap amount deducted from their Social Security checks (which is also an option for Part D premiums). Others may wish to have their cost-sharing automatically paid (whether that's through an automatic deduction or through EFT payments). Others may wish to pay via check. We urge CMS to ensure that Part D enrollees have a range of payment options from which to choose and to allow enrollees the option to switch payment methods. For example, an enrollee who chooses to pay via credit card at the point-of-sale when initially choosing the maximum monthly cap option, should later be able to choose a different option for payment.

**Enrollee education:**

PAN recognizes that the option to elect a maximum monthly cap has never been implemented in the Medicare program. Enrollees will need clear and concise information educating them about their option to elect a maximum monthly cap. To minimize confusion by enrollees, there must be consistent messaging and phrasing from CMS, plans, providers, and pharmacies. To ensure the success of this program, we urge CMS to engage in significant enrollee education and offer the following suggestions:

***Multiple forms of communication***

We strongly urge CMS to use every available means to educate enrollees about their option to choose a maximum monthly cap. This includes the annual Medicare & You Handbook, the Medicare plan finder, CMS social media accounts, and other means. We welcome the opportunity to work with CMS to offer suggestions on specific language to be included in these materials.

***Development of materials***

We strongly urge CMS to develop materials that provide enrollees with clear and concise information. Enrollees will need to be educated about when and where they can make an election. They will also need to be educated about their financial responsibilities for the rest of the plan year – particularly in cases where the enrollee is no longer taking the prescription drug but still has financial obligations. We urge CMS to develop examples to illustrate why someone may elect a maximum monthly cap and instances where someone may not want to make the election. These materials should be standardized and provided to enrollees at the time they opt for the maximum monthly cap.

***Plan materials***

The statute requires Part D plans to educate enrollees about the maximum monthly cap option. We urge CMS to require plans to provide information in the Annual Notice of Coverage (ANOC) and Evidence of Coverage (EOC) documents. In addition, plans should be required to provide personalized notice to enrollees when they opt for the maximum monthly cap. This notice is important for several reasons: (1) it serves as confirmation that the enrollee made the election (and provides information to the enrollee on how to opt out of the election if it was made erroneously); (2) it informs the enrollee of their option to change the manner in which the remaining financial payments are to be made (e.g., from credit card to deduction from Social Security checks); and (3) it provides the enrollee with information regarding their specific cost obligations for the remainder of the plan year.

Enrollees who elect the maximum monthly cap but who are under the annual OOP cap will need a notice to remind them of their cost sharing obligations and provide notice these costs could increase if the enrollee fills subsequent prescriptions. Enrollees who meet their annual OOP cap with their initial

prescription drug(s)<sup>4</sup> should receive a notice regarding their remaining cost sharing obligations for the remainder of the year with specific information that their cost sharing obligations will not increase over the course of the year.

### ***Partnering with patient serving organizations***

As CMS is developing enrollee educational materials, we strongly urge CMS to work with patient serving organizations to develop materials that will help to educate enrollees about the option to elect a maximum monthly cap and what the enrollees' responsibilities are when they elect that option. This could include CMS convening expert groups to provide feedback to the agency on enrollee facing materials or to convene multistakeholder efforts and coordinate with CMS.

### **Meaningful Differences: Basic vs. Enhanced Benefit Plans**

PAN supports the continuation of the meaningful differences policy. A key reason for implementing the policy initially was to minimize the confusion among prospective enrollees given the vast, if sometimes overwhelming, number of PDP options in a given region. Prospective enrollees would get confused over the differences (e.g., deductible, drug coverage, tiering) among the various plan options offered by a plan sponsor. While we support beneficiaries having access to a robust number of plans, PAN believes in maintaining a policy that will prevent the re-saturation of PDPs in the market and therefore, exacerbating confusion among beneficiaries.

Given that the IRA requires the OOP cap to be part of the standard benefit, measuring differences between basic and enhanced plans based on OOP spending (as is done today) is likely no longer an appropriate metric to determine the relative value of an enhanced vs. basic plan. 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. CMS could also consider other factors such as availability of preferred pharmacies and/or total number of pharmacies included in a plan's network.

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 PDPs is likely particularly important for certain beneficiary patient populations, such as sicker enrollees and beneficiaries in rural areas. Research has found that sicker enrollees are more likely to switch out of Medicare Advantage and enroll back in fee-for-service Medicare. Additionally, in many rural areas, standalone 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.

Establishing alternative approaches for determining what constitutes an enhanced plan based on metrics that are important to beneficiaries make it easier for beneficiaries to distinguish between basic vs. enhanced plans when selecting plans during Open Enrollment.

### **Tiering and Cost Sharing**

<sup>4</sup> Enrollees may hit the annual out-of-pocket cap with one prescription drug, or they may hit the cap as a result of multiple prescription drugs filled at the same time.

CMS seeks clarification about the extent to which plans increase cost sharing and what impact this will 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, 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.

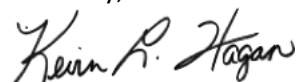
PAN urges CMS to consider more intensive formulary reviews as it relates to formulary coverage, utilization management, and tier structures/cost sharing to ensure beneficiary access under benefit redesign. CMS should carefully monitor changes in cost sharing and formulary coverage under benefit redesign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

#### **Conclusion**

PAN lauds CMS for continuing to solicit feedback, which we believe reflects a willingness on the part of CMS to ensure that the patient and consumers voices are included in the drafting of these provisions. We urge CMS staff to continue to work with stakeholders, particularly groups working directly with patients, as we get closer to implementation.

The PAN Foundation appreciates your leadership to increase equitable access to and affordability of health care for more Americans. Thank you for your consideration of our comments. If you have questions about the issues raised, please contact Amy Niles, Chief Advocacy and Engagement Officer at [aniles@panfoundation.org](mailto:aniles@panfoundation.org).

Sincerely,



Kevin L. Hagan  
President and Chief Executive Officer