

Via electronic submission

June 5, 2023

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

Re: CY2025 Part D Redesign

Dear Administrator LaSure:

On behalf of organizations representing patients with serious and chronic illnesses who rely on the Medicare Part D benefit, we write to share thoughts and recommendations to CMS as it prepares to implement section 11202 of the Inflation Reduction Act,¹ which provides a maximum monthly cap on Part D out-of-pocket costs.

Research has demonstrated that high out-of-pocket costs associated with prescription drugs can decrease medication adherence.² As Congress debated the *Inflation Reduction Act* our groups strongly advocated for both an annual cap on total Part D out-of-pocket costs and a mechanism that would allow an enrollee the option to pay the required cost-sharing in capped monthly installments. While much attention has been paid to the annual Part D cap, we believe the provisions that would establish an optional maximum monthly cap are crucial to ensure that enrollees can better afford their out-of-pocket costs.

We welcome the opportunity to work with CMS to not only shape the policy 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.

Program design: We offer the following thoughts on provisions that should be included in the regulations CMS develops related to the maximum monthly cap to ensure the program meets the needs of the enrollees:

Election: Our groups strongly believe 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. However, it also means that enrollees should be able to elect the option at the point of sale, regardless of whether an enrollee chooses to fill their prescription via mail order or a brick-and-mortar pharmacy. We also 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.

¹ 42 U.S.C. § 102(b)(2)(E).

² Dusetzina SB, Winn AN, Abel GA, Huskamp HA, Keating NL. Cost sharing and adherence to tyrosine kinase inhibitors for patients with chronic myeloid leukemia. *K Clin Oncol*. 2014; 32:302-311; Nekhlyudov L, Madden J, Graves A, Zhang F, Soumerai S, Ross-Degnan D. Cost-related medication nonadherence and cost-saving strategies used by elderly Medicare cancer survivors. *J Cancer Surviv*. 2011;5:395-404.

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.

No threshold amount: Enrollees have different financial situations and we would urge CMS to refrain from setting a minimum out-of-pocket threshold amount (other than a *de minimus* amount) needed to trigger the enrollee's election. We 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 plan may terminate the enrollee's election and require the enrollee to pay the applicable cost-sharing. In developing regulations to implement this provision, we urge 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,³ 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;⁴
- 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: 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: We recognize 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

³ 45 CFR§ 423.44.3.

⁴ CMS should track grievance response times and ensure that beneficiaries are receiving feedback in a timeline fashion.

must be consistent messaging and phrasing from CMS, plans, providers, and pharmacies. In order 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 out-of-pocket 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 out-of-pocket cap with their initial prescription drug(s)⁵ 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 organizations: Our organizations have extensive knowledge of how best to communicate with our members, many of whom will benefit from the option to elect a maximum monthly cap. As CMS is developing enrollee educational materials, we strongly urge CMS to work with our groups 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.

⁵ 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.

Conclusion

We have been pleased that CMS staff have reached out to our groups 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 patient groups as we get closer to implementation.

If you have any questions about the issues raised, please contact Anna Howard at anna.howard@cancer.org.

Sincerely,

American Cancer Society Cancer Action Network

Alliance for Aging Research

Lupus Foundation of America

Patient Access Network (PAN) Foundation