December 13, 2022

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

Meena Seshamani, M.D., Ph.D.
Deputy Administrator and Director
Center for Medicare
Center for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Implementation of Section 11202 of the Inflation Reduction Act/42 USC §1395w–102(b)(2)(E)

Dear Administrator Brooks-LaSure and Deputy Administrator Seshamani,

As national organizations that represent millions of people living with severe and chronic conditions such as cancer, multiple sclerosis, arthritis, epilepsy, and cystic fibrosis, we are writing to provide our views and recommendations on the implementation of the Inflation Reduction Act (IRA), specifically Section 11202 which allows Medicare Part D enrollees to avail themselves of a new maximum monthly cap on cost-sharing payments beginning in 2025.

The patient community advocated for years for the IRA's annual Part D out-of-pocket spending cap as well as the monthly cap in Section 11202. These new patient protections work together to end the extreme cost-sharing endured by patients who rely on costly retail drugs on both an annual and monthly basis. Without these protections, Part D enrollees filling a single costly prescription can face over $10,000 in annual cost-sharing, with $3,000+ required at one time to receive just their first fill of the year. Extraordinary out-of-pocket costs like these are an incredible burden on patients who rely on one or more Part D drugs. Sadly, such high cost-sharing proves insurmountable for many patients—leading approximately four in ten patients facing these costs never to initiate their therapies.[1] We are overjoyed that President Biden signed into law protections that will end these extreme out-of-pocket costs for patients on Medicare Part D.

Our organizations look forward to working with the Center for Medicare and Medicaid Services (CMS) to ensure that these patient protections are implemented in a patient-friendly manner that best aligns with Congress' intent to protect Part D enrollees from high out-of-pocket costs. As you prepare to communicate to Part D stakeholders through guidance and other means regarding their roles and responsibilities in incorporating the patient protections established in Section 11202, we urge you to consider the following issues:

- **Patient Protections Against Lockouts:** CMS should establish a mandatory minimum grace period, during which a delayed/missed payment by a beneficiary enrolled in the maximum

[1] Doshi, J. et al. (2018). Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents. *Journal of Clinical Oncology* 36, no. 5.

monthly cap option will trigger neither the loss of their monthly cap protection for that year nor their ability to elect a monthly cap in subsequent years. Additionally, CMS should establish a hardship exception process to prevent patients experiencing significant financial challenges from triggering the loss of their monthly cap option. Further, CMS should clarify that plans' ability to preclude enrollment by any beneficiary in a year subsequent to their failure to pay an amount previously billed is both optional and limited.

- **Pre-Deductible Application and Mid-Month Timing**: CMS should ensure that plan sponsors apply a patient's smoothing election immediately, regardless of when during the month it is made.
- **CMS Patient Education and Outreach**: CMS should provide extensive, proactive consumer education and outreach ahead of and during the 2025 plan year open enrollment, including mailed notices, email notices, prominent Medicare website notices, and other mechanisms. Those efforts should then become integrated into CMS' annual open enrollment outreach plans.
- **Plan Outreach and Education**: CMS should require Part D Prescription Drug Plans (PDPs) and Medicare Advantage-affiliated Prescription Drug Plans (MAPDs) to do extensive, proactive consumer education about the maximum monthly cap option for potential, new, and existing plan enrollees via all relevant promotional materials. CMS should ensure that PDPs/MAPDs annually provide complete and correct information to plan enrollees regarding the maximum monthly cap option, with a particular focus on plan enrollees who are taking or have a history of taking drugs that would in the absence of a monthly cap lead to significant upfront out-of-pocket costs.
- **Pharmacy Responsibilities:** CMS should develop uniform procedures for PDPs/MAPDs to notify pharmacies of an enrollee's potential to benefit from electing to participate in a plan's maximum monthly cap option. Similarly, CMS should develop uniform procedures for PDPs/MAPDs to ensure pharmacies can easily and electronically enroll a patient, at the point of sale, in a plan's maximum monthly cap option, in order to facilitate streamlined enrollment during pharmacy interactions.
- **Automatic Re-Enrollment**: CMS should require PDPs/MAPDs to establish automatic re-enrollment to facilitate Part D enrollees staying in their maximum monthly cap option at the start of a new plan year.

For a full list of our recommendations with additional details, please see our accompanying document.

We look forward to partnering with CMS to support the successful implementation of Section 11202 and other policies that impact the ability of the patients we represent to access the health care they need. Our organizations would welcome the opportunity to meet and discuss our recommendations further. As you consider these recommendations and discuss further engagement on this topic with our organizations, please contact Brian Connell at brian.connell@lls.org.

Sincerely,

American Cancer Society Cancer Action Network
Arthritis Foundation
Cystic Fibrosis Foundation
Epilepsy Foundation
National Multiple Sclerosis Society
The Leukemia & Lymphoma Society

Inflation Reduction Act
Implementation of Section 11202 / 42 USC §1395w–102(b)(2)(E)
Maximum Monthly Cap (a.k.a. "smoothing)

1. **Patient Protections Against lockouts**
   a. **Grace Period**
      i. Concern: Patients enrolled in their plan's smoothing option could easily miss a bill for their monthly installment. If an enrollee is determined to have missed such payment, there are potentially severe consequences: their plan is allowed to disenroll them from the smoothing option and preclude them from accessing the smoothing option in subsequent years.
      ii. Solution summary: CMS should establish a mandatory grace period, during which a delayed/missed payment by a beneficiary enrolled in smoothing will trigger neither the loss of smoothing for that year nor the lockout provision affecting subsequent years.
      iii. Patient recommendation: CMS should require, via guidance or rulemaking, plans to establish a missed payment grace period of at least 2 calendar months before a beneficiary is considered to have failed to pay the amount billed and subject to the ramifications outlined in 42 USC §1395w–102(b)(2)(E)(v)(IV). This length of grace period would be identical to the grace period established by CMS for missed premium payments by enrollees in a PDP or MA plan.[2]
   b. **Hardship Exemption**
      i. Concern: Patients enrolled in their plan's smoothing option who experience temporary hardship due to unforeseen circumstances could miss a monthly payment, leading to potential disenrollment from the smoothing option and preventing them from accessing the option in subsequent years.
      ii. Solution summary: CMS should establish a hardship exemption, to prevent patients experiencing significant financial or health challenges from triggering the loss of smoothing or the lock out provision.
      iii. Patient recommendation: CMS should establish via guidance or rulemaking a process by which an enrollee may demonstrate "good cause" for failure to pay the amount billed within the grace period and is able to continue to elect a smoothing option upon payment of delinquency. This exemption would mirror Medicare's existing "good cause" policy allowing a beneficiary to reinstate Medicare part D coverage if they can show good reason for not paying within the grace period such as an emergency or unexpected situation.[3]
   c. **Appeals**
      i. Concern: Especially in early implementation, patients may be incorrectly deemed to have missed a monthly payment and may be disenrolled and locked out of a smoothing option unfairly with no recourse.
      ii. Solution summary: CMS should ensure that plan determinations of the amount allowed to be billed under 42 USC §1395w–102(b)(2)(E) and/or that an enrollee has triggered 42 USC §1395w–102(b)(2)(E)(v)(IV) are subject to the plan's existing internal and external appeals processes.
      iii. Patient recommendation: CMS should clarify via guidance that a Part D enrollee's appeal rights for coverage determinations set forth at 42 CFR part

[2] Part C: Sections 1851(g)(3)(B)(i) and 1856(b)(1) of the Social Security Act (42 USC 1395w-21(g)(3)(B)(i); 1395w-26(b)(1)) and 42 CFR 422.74(d)(1) https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422/subpart-B/section-422.74#p-422.74(d)(1). Part D: Section 1860D-1(b)(1)(B)(v) (42 USC 1395w-101(b)(1)(B)(v)) and 42 CFR 423.44(d)(1) https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-B#p-423.44(d)(1)

[3] 42 CFR 423.44(d)(1)(vi). https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/subpart-B#p-423.44(d)(1)(vi)

422 Subpart M and 42 CFR Part 423 Subparts M and U extend to the determination of the monthly amount allowed to be billed under 42 USC §1395w–102(b)(2)(E) as well as whether an enrollee has triggered 42 USC §1395w–102(b)(2)(E)(v)(IV).

d. Access to smoothing options in other plans following a missed payment

i. Concern: Absent clarity from CMS, patients enrolled in their plan's smoothing option could miss a monthly payment while on one plan, leading to potential disenrollment from the smoothing option that year and preventing them from accessing the option in another plan in the future.

ii. Solution summary: CMS should ensure that plans preclude enrollment in the smoothing option due to missed payment in a subsequent year *only* when patients re-enroll in the same plan they had when they missed that payment. Plans should not be allowed to preclude enrollment in years due to a patient having missed a payment to a different plan.

iii. Patient recommendation: CMS should establish, via guidance or rulemaking, limitations on plans' ability to preclude enrollment under 42 USC § 1395w–102(b)(2)(E)(v)(IV)(bb) due to missed payments in other plans in any prior year.

e. Enrollee Education

i. Concern: Enrollees are unlikely to fully grasp the implications of missing a monthly smoothing payment or their available remedies in the case of an error or emergency. Mid-year discontinuance will be a common event among cancer patients. Patients who fail to understand the need to make these payments will lose the option of smoothing in future years.

ii. Solution summary: CMS should ensure that enrollees receive initial and repeated education regarding the need to pay monthly smoothing installments in every remaining month of the plan year—regardless of whether they continue their Part D therapy.

iii. Patient recommendations: CMS should develop educational materials given to beneficiaries upon enrollment and in regular intervals explaining the consequences of missing a monthly smoothing payment, options for appeal, and resources for on-demand assistance filing appeals. CMS should solicit input from stakeholders regarding the manner and frequency with which beneficiaries must receive educational materials related to the smoothing option.

f. Clarification on Lockout Flexibility

i. Concern: Plan sponsors may not realize the operational flexibilities that exist in implementing a smoothing option and might design their systems to automatically preclude an enrollee from re-enrolling in a smoothing option in subsequent years.

ii. Solution summary: CMS should make clear that plans are not required under 42 USC §1395w–102(b)(2)(E)(v)(IV) to preclude enrollees from making subsequent smoothing elections due to any previously missed payments. CMS should only allow the lockout to apply in the next subsequent year instead of indefinitely, and only to the extent that the enrollee wishes to re-enroll in the same plan as they previously held.

iii. Patient recommendations: CMS should emphasize to plan sponsors in guidance that 42 USC §1395w–102(b)(2)(E)(v)(IV)(bb) expressly contemplates plans sponsors, at their election, to allow enrollees to re-enroll in a smoothing option after correcting delinquent payments.

2. Pre-Deductible Application and Mid-Month Timing

a. **Clarification of pre-deductible application**

i. Concern: Enrollees with high expected costs at the beginning of the year may still have to face a substantial deductible first that is larger than the monthly cap would under a smoothing option.
ii. Solution summary: CMS should ensure plan sponsors include the amount of an enrollee's deductible when determining cost-sharing associated with a smoothing option.
iii. Patient recommendations: CMS should clarify, via regulation or guidance, that the maximum monthly cap on cost-sharing payments applies throughout the benefit and as such, incurred costs include the amount of an enrollee's deductible and the maximum monthly cap applies when an enrollee has not yet reached their deductible. This is consistent with the existing statute at 42 U.S.C. 1395w-102(b)(4)(C)(i) which includes deductible in the application of incurred costs.

b. Clarification of Mid-month election

i. Concern: Enrollees that encounter high costs in the middle of a month may elect a smoothing option and could potentially face delays in applying the smoothing option.
ii. Solution summary: CMS should ensure that plans apply a patient's smoothing election immediately, regardless of when during the month it is made.
iii. Patient recommendations: CMS should clarify that an enrollee may make an election at any time during the month, and that the month shall be considered a "month in the plan year for which an enrollee . . . has made an election" under 42 USC §1395w-102(b)(2)(E)(ii).

3. Patient Education re: Smoothing Option

a. Medicare Outreach and Education

i. Concern: Beneficiaries will need extensive outreach and education from Medicare to fully understand the smoothing election and its implications.
ii. Solution summary: CMS should provide extensive, proactive consumer education ahead of and during the 2025 plan year open enrollment, including mailed notices, email notices, prominent Medicare website notices, and other mechanisms.
iii. Patient recommendations:
- CMS should invest in educational materials available to beneficiaries, distributed upon enrollment and in regular intervals, explaining the smoothing options, payment implications, appeal rights, etc. CMS should solicit input from stakeholders regarding the manner and frequency with which beneficiaries must receive educational materials related to the smoothing option.
- CMS should provide example patient scenarios of when a beneficiary would benefit from making a smoothing election prior to the beginning of a plan year, as well as scenarios demonstrating mid-year elections.

b. Plan Outreach and Education

i. Concern: Despite CMS outreach, enrollees (particularly existing enrollees) are likely to only pay attention to notices and information provided directly to them by their existing plans.
ii. Solution summary: CMS should require PDPs/MAPDs to do extensive, proactive consumer education—both to potential enrollees via all relevant promotional materials and to current enrollees. CMS should ensure that PDPs/MAPDs are providing robust and correct information to enrollees regarding smoothing.
iii. Patient recommendations:

- CMS should develop and share publicly and with PDPs/MAPDs a searchable list of drugs which may lead to enrollee cost sharing at a level above the monthly maximum smoothing payment. For example, CMS could issue ahead of 2025 open enrollment a list of drugs whose 2023 or 2024 list prices would have produced cost sharing above $167 for the first prescription under the 2025 benefit design.
- CMS should require plans, ahead of open enrollment for plan year 2025, to conduct targeted outreach via phone and mail/email to any current enrollee who has filled a prescription for one or more drugs whose 2023 or 2024 list prices would have produced cost sharing above $167 for the first prescription under the 2025 benefit design to educate them about their monthly smoothing payment option.
- CMS should develop best practices for plans to identify when an enrollee can benefit from a smoothing election mid-year. For example, CMS could develop guidance that PDP/MAPDs should send an additional notification of the smoothing option upon the enrollee incurring a minimum dollar of drug costs, e.g. $167/month cumulatively for each month the threshold is exceeded.
- CMS should require PDP/MAPD Real Time Benefit Tools to illustrate cost-sharing for enrollees under their current election (traditional benefit or smoothing benefit). If a patient is not enrolled in the smoothing benefit, the real time benefit tool should illustrate the cost-sharing for the enrollee if the patient were to chose to enroll in smoothing prior to filling the drug being considered.
- CMS should proactively monitor PDP/MAPD marketing materials as well as agent and broker conduct to ensure compliance with plan outreach requirements.

c. Pharmacy Outreach and Education

i. Concern: Enrollees that have missed notices about the smoothing option but go to fill their prescriptions may be dismayed at a high out-of-pocket cost and could choose to forgo their prescriptions, not knowing about other options.

ii. Solution summary: CMS should establish robust procedures for pharmacies to inform beneficiaries about the potential to benefit from a smoothing option.

iii. Patient recommendations:

- CMS should require PDPs/MAPDs to establish a point-of-sale enrollment mechanism to facilitate enrollment of smoothing during pharmacy interactions (both mail-order and brick-and-mortar).
- CMS should establish guidance and/or minimum transaction thresholds for pharmacies that allow pharmacists to identify when "it is likely the enrollee may benefit from making" a smoothing election, e.g., enrollees filling prescriptions for drugs whose 2023 or 2024 list prices would have produced cost sharing above $167 for the first prescription under the 2025 benefit design.
- CMS should forbid PDPs/MAPDs from including contract terms with any agents (including pharmacies, employees, brokers, etc.) that disincentivize a pharmacy or agent from enrolling beneficiaries in a plan's smoothing option.

4. Automatic Re-Enrollment

a. Automatic re-enrollment of smoothing option

i. Concern: Enrollees that have elected a smoothing option are likely to have a continued need for smoothing across plan years and should not have to re-elect every year.

ii. Solution summary: CMS should require PDPs/MAPDs to establish automatic re-enrollment in a smoothing option should all other payments be met at the start of a new plan year.
iii. Patient recommendations: CMS should establish, via guidance or regulation, a requirement that PDPs/MAPDs automatically re-enroll beneficiaries in the smoothing option at the start of each plan year unless the enrollee affirmatively opts out. This is similar to how Medicare currently handles re-enrollments in Part D, as well as how the yearly Qualified Health Plan re-enrollment is effectuated. For beneficiaries within a grace period for a missed payment, CMS should require PDPs/MAPDs to conditionally re-enroll them in the smoothing option unless and until the grace period expires.