



Administrator
Washington, DC 20201

December 14, 2023

The Honorable Charles E. Grassley
Ranking Member
Committee on the Budget
United States Senate
Washington, DC 20510

Dear Ranking Member Grassley:

Thank you for your letter regarding Part D plan sponsors' compliance with pharmacy access standards and prompt payment requirements, and your recommendation about alternate payment arrangements when the Centers for Medicare & Medicaid Services' (CMS) new definition of "negotiated price" at 42 CFR §§ 423.100 and 423.2305 becomes applicable on January 1, 2024. I continue to share your concerns regarding beneficiaries' continued access to rural pharmacies and the need for mitigation of the potential impact on cash flow for pharmacies.

Our meeting with the Iowa Pharmacy Association was informative, and I understand the concerns regarding pharmacy cash flow for rural pharmacies and contracting challenges ahead of the 2024 effective date. Since then, we have reviewed CMS's ability to encourage payment plans between rural pharmacies and plan sponsors or their pharmacy benefit managers (PBMs). While section 1860D-11(i) of the Social Security Act generally prohibits CMS from interfering in negotiations between drug manufacturers, pharmacies, and prescription drug plan sponsors, or from instituting a price structure for the reimbursement of covered Part D drugs, we published a memo to all Part D plan sponsors via CMS's Health Plan Management System on November 6, 2023, titled, "Application of Pharmacy Price Concessions to the Negotiated Price at the Point of Sale Beginning January 1, 2024,"¹ which reiterates and emphasizes several key points related to this issue that CMS also stated in the Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs final rule (CMS-4192-F, CMS-1744-F, and CMS- 3401-F). In the most recent memo, CMS:

- Strongly encourages Part D plan sponsors to consider options such as payment plans or alternate payment arrangements in advance of the January 1, 2024, effective date and provide a straightforward means of requesting such an arrangement.
- Emphasizes that CMS will use our existing processes for monitoring and enforcement to ensure Part D plan sponsors' compliance with prompt payment requirements at § 423.520 and pharmacy access standards at § 423.120.

In addition, CMS conducts quarterly pharmacy network assessments to determine compliance with CMS's network requirements and also routinely monitors the status of complaints Part D sponsors receive from beneficiaries and providers, such as pharmacies, regarding access and

¹ <https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-2-november-6-10>.

payment. Adverse findings from these monitoring activities can result in compliance actions (as described in § 423.505(n)), or an enforcement action, such as civil monetary penalties and suspension of enrollment (as described in § 423.750, et. seq.). CMS has discretionary authority under §§ 422.504(e)(2) and 423.505(e)(2), to audit, evaluate, or inspect records or other evidence of Part D sponsors' accounting procedures, including records of all price concessions (as described in § 423.505(d)(2)(xii)), which CMS will utilize when necessary to ensure compliance with CMS regulations and guidance. Pharmacies and stakeholders can contact the local CMS regional office to report concerns with particular Medicare Advantage organizations and prescription drug plans. In addition, we meet with the National Community Pharmacists Association several times per year, and most recently met with them about their concerns with this particular issue in May 2023.

Most recently, CMS sent a letter to plans and issuers, including Part D plan sponsors and Medicare Advantage plans, to raise the increasing number of concerns we are hearing about certain practices by some plans and PBMs that threaten the sustainability of many pharmacies and impede access to care. In the letter, CMS urges plans and issuers to work with providers and pharmacies to alleviate these issues and safeguard access to care. For example, CMS calls on plans and PBMs to engage in sustainable and fair practices with all pharmacies – not just pharmacies owned by PBMs. Further, in the letter, CMS strongly encourages Part D plan sponsors and their PBMs to make necessary cash flow arrangements with network pharmacies in preparation for the pharmacy price concessions provision in the Contract Year 2023 Medicare Advantage and Part D final rule that is expected to lower total beneficiary out-of-pocket costs, provide meaningful price transparency, better reflect pharmacy payment arrangements, and enable CMS to assess the payment practices of Part D plan sponsors and PBMs with respect to pharmacies under the Medicare Part D program. The letter also reminds Part D plan sponsors that CMS will closely monitor plan compliance with pharmacy access and prompt payment standards to ensure that all people with Medicare Part D continue to have access to pharmacies and medications.

I am committed to ensuring beneficiaries have access to necessary health services. I value the critical role pharmacies play in healthcare delivery and recognize that we must address the needs of rural pharmacies in order to serve our beneficiaries effectively. I will continue to engage with stakeholders and consider policies for inclusion in future rulemaking that would lower prescription drug costs for beneficiaries, address challenges that rural pharmacies face, and improve the quality of pharmacy care. If you have additional questions or concerns, please have your staff contact the CMS Office of Legislation.

Sincerely,



Chiquita Brooks-LaSure