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July 25, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Administrator Brooks-LaSure,

I have heard first-hand from rural and independent pharmacies in Iowa about the looming cash flow challenges created by changes to Medicare Part D post-point-of-sale compensation that begin on January 1, 2024.¹ Pharmacies will be faced with direct and indirect remuneration (DIR) clawback fees for calendar year (CY) 2023 while also accepting a lower point-of-sale reimbursement starting in CY 2024 in response to Centers for Medicare & Medicaid Services (CMS) final rule-making. I am writing you to ask how your agency is ensuring compliance with pharmacy access standards and prompt payment requirements under Medicare Part D throughout these changes to ensure our nation's seniors do not lose access to a local pharmacy, especially in rural communities. In Iowa, our independent pharmacies serve nearly as many communities as large chains and are typically located in more rural communities that are providing vital health care services.² It is critical that CMS utilize its oversight authority of Part D plan sponsors and their pharmacy benefit managers (PBMs) to ensure seniors do not lose access to their local pharmacy.

For years, I have been concerned about the growing Part D plan sponsor and PBM practice of applying DIR fees through a clawback of payments made after the point-of-sale.³ In a 2019 letter to CMS I wrote, "The retroactive extraction of such fees is straining the viability of pharmacy operations. Pharmacy closures harm our communities and have adverse health consequences for patients."⁴ This is why I was committed in a Finance Committee mark-up process on prohibiting retrospective recoupment of payments to pharmacies by Part D plan

¹ Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 42 Fed. Reg. 27843 (to be codified at C.F.R. Parts 417, 422, and 423).

² Iowa Health Professions Tracking Center, Office of Statewide Clinical Education Programs, University of Iowa Carver College of Medicine, "IOWA COMMUNITY PHARMACISTS By Activity 2022"; Chain pharmacies serve: 121 communities; Independent pharmacies serve: 114 communities.

³ Letter to Health and Human Services (HHS) Secretary Alex Azar and CMS Administrator Seema Verma from 23 Senators, September 2019, <https://www.grassley.senate.gov/news/news-releases/grassley-wyden-bipartisan-senators-push-hhs-pharmacy-dir-reforms-medicare-part-d>.

⁴ *Id.*

sponsors and PBMs.⁵ In the 116th Congress, I helped enable MedPAC to analyze Medicare prescription drug payment information including DIR fees.⁶ MedPAC has subsequently reported on their findings over three public hearings shedding light on the growth of DIR fee clawbacks, how DIR fees vary widely, and how DIR fee clawbacks impact patient and taxpayer costs.⁷

While shedding light on DIR fee clawbacks is welcomed news, we need more action. This is why I was pleased to support CMS's rule that discontinued DIR fee clawbacks.⁸ Pharmacy DIR fees have grown more than 107,400% between 2010 and 2020.⁹ This has caused increased costs for seniors at the pharmacy counter, and negatively impacted many rural and independent pharmacists.¹⁰ By ending DIR fee clawbacks, the final rule is expected to reduce seniors' net out-of-pocket prescription drug costs by \$21.3 billion over 10 years.¹¹ This is good news, but seniors should not lose access to their local pharmacy throughout these changes. In the final rule, CMS stated in response to concerns about "pharmacy cash flow during the first quarter of 2023" that "CMS will be particularly attuned to plan compliance with pharmacy access standards under §423.120 to ensure that all Medicare Part D beneficiaries have convenient access to pharmacies and medications."¹² The final rule also stated "that the prompt payment requirements for Part D, as described in §423.520, will continue to apply and that Part D sponsors must pay clean claims in accordance with the prompt pay regulation."¹³ I am interested in your agency's recent efforts on these two matters to ensure our nation's seniors do not lose access to a local pharmacy.

In order to better understand how CMS is conducting oversight over DIR fee clawback changes, including potential pharmacy cash flow challenges, I ask you respond to the following questions by August 31, 2023:

⁵ Office of Senator Chuck Grassley, "Grassley, Wyden Release Updated Prescription Drug Pricing Reduction Act, Reach Agreement On Health Extenders," press release, December 6, 2019, <https://www.grassley.senate.gov/news/news-releases/grassley-wyden-release-updated-prescription-drug-pricing-reduction-act-reach>; Office of Senator Chuck Grassley, "Grassley Introduces The Updated Prescription Drug Pricing Reduction Act Of 2020," press release, July 2, 2020, <https://www.grassley.senate.gov/news/news-releases/grassley-introduces-updated-prescription-drug-pricing-reduction-act-2020>.

⁶ Consolidated Appropriations Act, 2021, Public Law 116-260, Division CC, Title I, Subtitle B, Section 112.

⁷ MedPAC, "Initial Findings form MedPAC's analysis of Part D data on drug rebates and discounts," April 7, 2022, <https://www.medpac.gov/wp-content/uploads/2021/10/MedPAC-DIR-data-slides-April-2022.pdf>; MedPAC, "Analysis of Part D data on drug rebates and discounts," September 30, 2022, <https://www.medpac.gov/wp-content/uploads/2021/10/MedPAC-DIR-data-slides-April-2022.pdf>; MedPAC, "Assessing postsale rebates for prescription drugs in Medicare Part D," April 13, 2023, <https://www.medpac.gov/wp-content/uploads/2022/07/Tab-F-DIR-data-April-2023-SEC.pdf>.

⁸ Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 42 Fed. Reg. 27843 (to be codified at C.F.R. Parts 417, 422, and 423).

⁹ *Id.*

¹⁰ Kaiser Family Foundation, "How Rural Communities Are Losing Their Pharmacies, Markian Hawryluk, November 15, 2021, <https://khn.org/news/article/last-drugstore-how-rural-communities-lose-independent-pharmacies/>.

¹¹ Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, 42 Fed. Reg. 27843 (to be codified at C.F.R. Parts 417, 422, and 423).

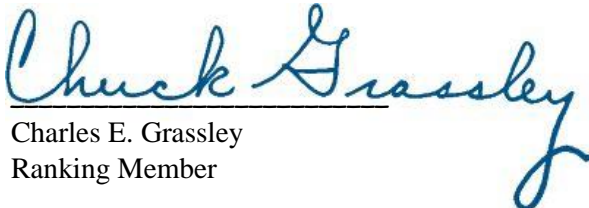
¹² *Id.*

¹³ *Id.*

1. CMS stated in the final rule it would be “particularly attuned” to pharmacy cash flow concerns and pharmacy network access.¹⁴ In preparation for CY 2024 DIR fee clawback changes, what actions has CMS taken to ensure pharmacy access standards under §423.120 are met?
2. In preparation for CY 2024 DIR fee clawback changes, what actions has CMS taken to ensure prompt pay regulations under §423.520 are met?
3. Has CMS conducted, or is prepared to conduct, additional oversight to ensure pharmacy access standards and prompt pay regulations are met in light of concerns about pharmacy cash flow issues?
4. CMS stated in the final rule that it “encourage Part D sponsors to consider options, such as payment plans or alternate payment arrangements, to minimize impacts to vulnerable pharmacies and the patients they serve.”¹⁵ Besides stating this in the final rule, has CMS taken action to encourage the use of payment plans or alternative payment arrangements to minimize the final rule’s impact on vulnerable pharmacies? Please provide a detailed list of actions.
5. CMS stated in its final rule that the DIR fee clawback changes applicability date of January 1, 2024, instead of January 1, 2023 would provide “extra implementation time” and “Part D sponsors and pharmacies will now have adequate time to implement payment plans or make other arrangements to address these cash flow concerns at the beginning of 2024.”¹⁶ Is CMS aware of the amount of DIR fee clawbacks charged to pharmacies so far in CY 2023 and if those amounts are greater than CY 2022?
6. Has CMS conducted or plan to conduct audits of Part D plan sponsors or PBMs in preparation for the CY 2024 DIR fee clawback changes? Please provide audit details.
7. Has CMS engaged with stakeholder groups, or directly with rural and independent pharmacies, in CY 2023 to better understand how DIR fee clawback changes are impacting cash flow challenges going into CY 2024? What has your agency learned?

I look forward to your update on how CMS is ensuring pharmacy network access and prompt payment policies are followed with the coming implementation of post-point-of-sale compensation changes in January 2024.

Sincerely,


Charles E. Grassley
Ranking Member

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*