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March 7, 2022

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

Dear Administrator Brooks-LaSure,

I am reaching out to personally thank you for your work to help American seniors, particularly those who rely on Medicare Part D prescription drug services, through the Centers for Medicare and Medicaid Services (CMS) *proposed rule for Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Program*. This proposed rule aims to decrease prescription drug prices for Medicare beneficiaries through reforms to the current pharmacy direct and indirect remuneration (DIR) fee process.

DIR fees present an unworkable situation for pharmacies of all sizes. I am extremely concerned about the impact on small pharmacies that contribute substantially to patients' access to care in rural areas. As you know well, many small and rural independent pharmacies are dying in America – bled dry by certain practices of contracted pharmacy benefit managers (PBMs). Pharmacists deserve to have the highest level of transparency and fairness when it comes to caring for their patients and fellow community-members. I write to ensure the problems local pharmacies are currently facing are addressed and made better by this proposed rule, not worse.

While I have shared the overarching problems DIR fees have caused Oklahoma pharmacies with you previously and in another letter you will receive from me today, I also wanted to take the opportunity to raise a number of specific points after reviewing the details of this CMS proposed rule.

In the example provided for the newly defined “lowest possible reimbursement” on page 75 of the proposed rule, a plan sponsor’s reimbursement to pharmacies, based on performance, “for a drug that the sponsor has agreed to pay the pharmacy \$100 at the point-of-sale, the pharmacy’s final reimbursement under this arrangement would be: (1) \$95 for poor performance; (2) \$100 for average performance; or (3) \$101 for high performance.” With the proposed definition of “lowest possible price,” the expectation would be that \$95.00 would be the new baseline reimbursement level for all pharmacies, essentially punishing all pharmacies despite their true performance levels. While this of course does not prevent sponsors from initiating additional bonus payments based on performance, the expectation that plans will voluntarily spend additional resources is not likely.

Also in the example used, the beneficiary, who has a 25 percent coinsurance requirement, receives a savings of \$1.25, while the pharmacy loses up to \$6.00 on the prescription in this scenario. While beneficiary savings is a primary goal of mine, access is just as important. Savings on a prescription does a rural Oklahoman no good if his local pharmacy closes due to substantial reimbursement decreases.

The primary problem caused by DIR fees in their current form that I hear the most from Oklahomans is the lack of clarity regarding the timing or amount of a clawback fee, preventing long-term financial planning. While several of these proposed changes may provide more long-term clarity, if the clarity a local pharmacy receives indicates amassed levels of reimbursement decreases, long-term sustainability may not be an option. After seeing several rural Oklahoma pharmacies close over the past few years, I raise these possibilities to you to ensure you are also focused on keeping rural pharmacies open through this proposal.

In the wake of these proposed changes, some pharmacies have also raised fears that several fees they are already charged, such as service fees and network fees, may be increased to make up for any losses a PBM may incur. I appreciate CMS’s efforts to include all such fees in the new definition of “negotiated price,” and I urge you to

ensure there are no loopholes in which certain harmful fees may be added to the backs of pharmacies after the point of sale.

Additionally, as I have raised with you previously, not all pharmacies have comparable resources. Some pharmacies dispense fewer drugs and don't have the volume or purchasing power to control underlying costs in ways that may be available to others in the marketplace. However, this does not mean they are not equally as important to the community they serve. I reiterate that this is not always taken into consideration by plan sponsors in determining adequate reimbursement levels to further emphasize the need for all pharmacies to have a level playing field.


In an example of the sometimes illogical application of DIR fees currently, pharmacy type is not always taken into consideration when determining fees. For example, a PBM could impose a fee on a specialty pharmacy regarding a drug that a specialty pharmacy may not even carry. I urge you to consider this unfair practice in the finalization of this proposed rule. Further, I urge CMS to consider the necessity of the implementation of standardized performance metrics to which pharmacies are held, which would address several of the concerns I have raised.

When we spoke a few weeks ago, I shared an example of the prescription of a diabetic statin as a part of a quality metric used by several PBMs that could infer a clawback if not prescribed, filled, and taken by a diabetic patient, despite whether the patient's physician chose to prescribe this drug or not. In this example, pharmacists are punished for a decision made by a patient and his physician. A pharmacist should not be punished for the decision of a physician and patient.

Lastly, as the rule mentions on page 70, "President Biden's Executive Order (E.O.) 14036, "Promoting Competition in the American Economy" (86 FR 36987), section 5 ("Further Agency Responsibilities"), called for agencies to consider how regulations could be used to improve and promote competition throughout the prescription drug industry." I am certainly aware of the increased level of health care consolidation in America, whether in the payer, hospital, pharmaceutical, or pharmacy industries. I cite this Executive Order to highlight that abuses of DIR practices, several of which CMS refers to in the proposed rule, have resulted in conditions that make it impossible for many pharmacies to participate in markets where they are needed most due to decreased reimbursement and unfair treatment. Absent the agency's action, the opposite of this Executive Order's intent will continue to play out.

I sincerely appreciate your willingness to move forward with DIR reforms within the CMS CY23 proposed rule. I urge CMS to consider all possible outcomes and to finalize this proposed rule in an effort to increase transparency and financial sustainability both for Medicare Part D beneficiaries in Oklahoma and for the pharmacies that serve them.

In God We Trust,

A handwritten signature in black ink, appearing to read "James Lankford". The signature is fluid and cursive, with a large initial "J" and "L".

James Lankford
United States Senator