

May 8, 2023

The Honorable Ron Wyden  
Chairman  
Committee on Finance  
United States Senate  
219 Dirksen Senate Office Building  
Washington, D.C. 20510

The Honorable Mike Crapo  
Ranking Member  
Committee on Finance  
United States Senate  
219 Dirksen Senate Office Building  
Washington, D.C. 20510

**Re: A Bipartisan Framework for Reducing Prescription Drug Costs by Modernizing the Supply Chain and Ensuring Meaningful Relief at the Pharmacy Counter**

Dear Chairman Wyden and Ranking Member Crapo:

## **I. Introduction**

The undersigned organizations, representing the collaborative informally known as the “Pharmacy DIR Coalition,” appreciate the opportunity to share our members’ views and gratitude on the “Bipartisan Framework for Reducing Prescription Drug Costs by Modernizing the Supply Chain and Ensuring Meaningful Relief at the Pharmacy Counter” (“Framework”) in advance of our scheduled listening session with Committee staff on the issues raised in the Framework and bipartisan policy proposals that the Committee should consider to help lower drug costs for patients and taxpayers.

We agree with the Committee’s statements in the Framework regarding the potential for Medicare and Medicaid to deliver higher-quality, more affordable, and more accessible care, and that reform and oversight of certain pharmacy benefit manager (PBM) practices is desperately needed to reach this potential. Specific to the Medicare Part D program, we appreciate the Committee’s recognition of ambiguities in Medicare’s “Any Willing Pharmacy” rules, significant growth in pharmacy fees (i.e., pharmacy DIR fees)—which increased to an astounding \$12.6 billion for 2021<sup>1</sup> (+33% from 2020), and inappropriate and unpredictable performance-based measures and the Committee’s understanding that these factors have contributed to pharmacies having to close their doors, face acquisition, or at a minimum reduce the type of drugs they dispense and/or hours of operation nationwide. Moreover, the Committee is correct that these implications establish access gaps for patients and consumers and limit the freedom of choice that is a pillar of the Medicare program.

For these reasons, we urge the Committee to pursue comprehensive reform of “direct and indirect remuneration” (DIR) fees in the Medicare Part D program. Legislation to achieve comprehensive DIR fee reform would ensure that PDP sponsors, MA-PD plans and their PBMs could no longer work to limit pharmacy networks by forcing reimbursement rates on

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<sup>1</sup> Medicare Payment Advisory Commission’s March 2023 *Report to the Congress: Medicare Payment Policy*, p. 399; Accessed May 4, 2023 at [https://www.medpac.gov/wp-content/uploads/2023/03/Mar23\\_MedPAC\\_Report\\_To\\_Congress\\_SEC.pdf#page=427](https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_SEC.pdf#page=427)

pharmacies that do not cover their costs or wield and abuse unstandardized pharmacy performance measures for their own financial gain, harming community and specialty pharmacies.

## II. Legislation for Comprehensive DIR Reform – Key Elements

### Safeguards to Ensure Fair Market Competition for Pharmacies in Medicare Part D

As the Committee suggests in the Framework, Medicare’s “Any Willing Pharmacy” rules, significant growth in pharmacy fees, and unpredictable performance-based measures, are interrelated and should be addressed in tandem. Our coalition is calling for legislation that, under the authority of the Medicare Part D “Any Willing Pharmacy” law, which requires plans/PBMs to offer “reasonable and relevant” terms and conditions, the Secretary of Health and Human Services (HHS) would promulgate regulations to ensure pharmacies are no longer intentionally reimbursed at levels that limit network participation or result in rapid pharmacy market consolidation and closures. This regulatory effort would help to ensure total reimbursement paid by PDP sponsors and MA-PD plans, net of any and all price concessions, fees, incentive payments, and any other form of remuneration, allows a pharmacy to acquire and dispense drugs and provide necessary pharmacy services to Medicare Part D beneficiaries.

It is notable that in the final Contract Year 2023 Medicare Part D rule issued in 2022, CMS acknowledges concerns raised by pharmacies that the lowest Part D drug price applied at the point of sale as determined by plans/PBMs could have market consequences for “already struggling pharmacies to decrease services or medication availability, and/or be unable to remain in business, which may impact pharmacy networks”<sup>2</sup>, stating that this will be considered for future rulemaking.<sup>3</sup> CMS has the authority to address standards for fair reimbursement through the “Any Willing Pharmacy” statute.

### Ensuring Fair Assessment of Pharmacy Performance and Quality

A necessary element of legislation to achieve comprehensive DIR fee reform is to ensure a fair assessment of pharmacy performance and quality. Pharmacy performance/“quality measures” are being manipulated by plans/PBMs to secure fees from pharmacies rather than to fairly assess pharmacy performance. Many measures are applied by PBMs that have nothing to do with the drugs a pharmacy dispenses to patients; this is emblematic of the plan/PBM schemes to “claw back” fees from pharmacies.

Consequently, the legislation that we are calling for would require the HHS Secretary to review and evaluate the performance measures currently used by PDP sponsors and MA-PD plans in order to consider how the measures are being applied to pharmacies, including whether the measures are applied based on the drugs a pharmacy dispenses and services a pharmacy provides; and whether measures are applied across all network pharmacies, including those pharmacies owned by or affiliated with PDP and MA-PD plans, in a uniform manner.

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<sup>2</sup> 87 Fed. Reg. 27704, at 27843 (May 2022).

<sup>3</sup> *Id.*, at 27845.

Specifically, when PDP sponsors and MA-PD plans use performance measures, they should be required to only use standardized measures established or approved by the HHS Secretary and relevant to the performance of a particular pharmacy based on the drugs a pharmacy dispenses. Moreover, plans would be incentivized to use standardized pharmacy performance measures through the star ratings system.

As the Committee is likely aware, the standardization of pharmacy performance measures to address concerns with the current measures process had been included in underlying bipartisan DIR fee reform legislation in the 116<sup>th</sup> and 117<sup>th</sup> Congresses. Since CMS has stated that they believe a statutory change is required to permit the agency to standardize measures, we believe this type of legislation is necessary.

### Transparency To Pharmacy

Comprehensive DIR fee reform must include price transparency for pharmacies. Pharmacies cannot effectively plan their business operations without understanding what they will be reimbursed for a given drug or the services they provide for dispensing a given drug to patients. To address these opaque reimbursement practices imposed on pharmacies, PDP sponsors and MA-PD plans should be required to promptly furnish all pricing components to pharmacies so that a pharmacy understands its final reimbursement and the purpose of any adjustments in reimbursement. As the Committee is likely aware, ensuring pricing transparency for pharmacies has been included in past bipartisan DIR reform legislation.

### Defining Specialty Pharmacy

To ensure the reimbursement safeguards outlined above allow network access to specialty pharmacies and that pharmacy performance measures are fairly applied toward specialty pharmacies based on the drugs they dispense, it is necessary for the Secretary to work with stakeholders to determine a definition for specialty pharmacy. No such definition exists in regulation today to outline specialty pharmacy as a type of pharmacy. Without a definition, PDPs and MA-PD plans can also attempt to circumvent the proposed legislative requirements in a manner that favors specialty pharmacies they own or are otherwise affiliated with. Addressing the definition of specialty pharmacy has been included in past bipartisan DIR reform legislation.

### III. The CMS Part D Final Rule Issued in 2022 Did Not Address Comprehensive DIR Fee Reform

The final rule for the CY 2023 Medicare Part D program that CMS finalized in 2022 did not address comprehensive DIR fee reform. Although we recognize that this final rule did provide helpful program and policy changes for Part D beneficiaries, the rule did not establish protections against pharmacy DIR fee claw backs, did not standardize or address pharmacy performance measures, nor did it increase transparency for pharmacies with respect to their reimbursement.

Specifically, the final rule did not implement the following necessary policy changes:

- Transparency in Pharmacy Payments: The rule did not clarify how a pharmacy will ever know the lowest possible reimbursement (floor) it can receive so that it can plan its operations and afford to remain in network.
- Other Pharmacy Fees/Penalties: Although the rule sought to set limits around other fees that could be applied against a pharmacy, there is no plan offered in the rule for CMS to oversee such fees. Already, pharmacies are seeing new types of fees applied that will get around the rule's requirements. All loopholes must be closed, and a mechanism put in place to modernize the supply chain and ensure plans/PBMs comply with the terms and intent of CMS' regulations.
- DIR Claw backs: As mentioned above, the rule did not eliminate pharmacy DIR claw backs that are imposed on pharmacies by plans/PBMs. These claw backs are still permitted under the rule. The rule also did not eliminate the incentives that exist through the Medicare regulatory process for plans/PBMs to collect pharmacy DIR fees through the Part D bidding process. Plans can continue to underestimate and over-collect pharmacy DIR and keep what they collect. There is no restriction in place.
- Reasonable Pharmacy Reimbursement: The rule did nothing to ensure that plans/PBMs do not undercut pharmacy reimbursement in an effort to limit pharmacy network participation. Unreasonable reimbursement limits patient access to pharmacies as pharmacies close down businesses or may be forced to determine that they are unable to remain in certain pharmacy networks.
- Fair Pharmacy Performance Assessment and Quality Incentives: The rule did not standardize or set forward a process to assess the fairness of the pharmacy performance measures that are used by plans/PBMs to evaluate how pharmacies perform or the quality of their services. For years, the measures used by plans/PBMs have been arbitrary and used to undercut and significantly penalize pharmacy payments. Under the rule, plans are permitted to continue using their unfair measures, and the rule did not offer any incentives for plans to change this behavior.

## IV. Conclusion

Again, the coalition thanks the Committee for incorporating the hurdles to pharmacy access as a core pillar of the Framework and for the opportunity to offer legislative proposals to secure comprehensive DIR fee reform. We acknowledge that the Framework does mention the need to address certain aspects of comprehensive DIR fee reform, including modernizing Any Willing Pharmacy requirements and recognizing the significant growth in pharmacy fees and unpredictable pharmacy performance-based measures. We appreciate the Committee recognizing the need for these reforms in the interest of Medicare beneficiaries. In this letter, we provide legislative recommendations in support of the Committee's outlined objectives to address pharmacy access.

We are also happy to discuss other legislative proposals to end PBMs' harmful business practices in Medicaid, Medicaid managed care programs, and commercial markets (i.e., prohibiting spread pricing, patient steering, etc.).

Please look to us as a resource on this matter and we welcome the opportunity to discuss with you the need for comprehensive DIR fee reform at our upcoming listening session with the Committee.

Best Regards,

The Pharmacy DIR Coalition is comprised of:

- American Pharmacists Association (APhA)
- FMI, The Food Industry Association (FMI)
- National Association of Chain Drug Stores (NACDS)
- National Association of Specialty Pharmacy (NASP)
- National Community Pharmacists Association (NCPA)
- National Grocers Association (NGA)