U.S. SMALL BUSINESS ADMINISTRATION
OFFICE OF ADVOCACY
REGULATION • RESEARCH • OUTREACH

March 7, 2022

VIA ELECTRONIC SUBMISSION

The Honorable Xavier Becerra
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Re: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, (87 Fed Reg. 1842; January 12, 2022).

Dear Secretary Becerra:

On January 12, 2022, the U.S. Department of Health and Human Services' Centers for Medicare and Medicaid Services (CMS) published a proposed rule revising the Medicare Advantage (Part C) program, and the Medicare Prescription Drug Benefit (Part D) program.[1] The Office of Advocacy of the U.S. Small Business Administration respectfully submits the following comments on the proposed rule. Advocacy and small businesses are supportive of CMS' proposed rule. However, additional modifications are needed to ensure that small businesses do not incur substantial costs or potentially become insolvent due to disruptions to cash flow.

I. Background

A. The Office of Advocacy

Congress established the Office of Advocacy under Pub. L. 94-305 to represent the views of small entities before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA). As such the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The Regulatory Flexibility

[1] Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 87 Fed Reg. 1842 (January 12, 2022).

Act (RFA),[2] as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),[3] gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.[4] The agency must include a response to these written comments in any explanation or discussion accompanying the final rule's publication in the *Federal Register*, unless the agency certifies that the public interest is not served by doing so.[5]

Advocacy's comments are consistent with Congressional intent underlying the RFA, that "[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public."[6]

B. Background on the Proposed Rule

On January 12, 2022, CMS published a proposed rule revising the Medicare Advantage (Part C) and Medicare Prescription Drug Benefit (Part D) programs. Advocacy is concerned about certain revisions to the Prescription Drug Part D program. CMS stated that it was taking actions to update these provisions in part due to Executive Order 14036 that calls for agencies to consider how regulations can be used to improve competition within the prescription drug industry.[7] The agency explained that the current variation in pharmacy price concessions may have a negative effect on competition. CMS is therefore proposing modifications to the program.[8]

Under Medicare Part D, small pharmacies contract with a pharmacy benefit manager (PBM). These PBMs manage contracts between both the pharmacy and the prescription drug manufacturers, and process and pay prescription drug claims.[9] One way that these PBMs generate revenue is by charging fees to the small pharmacies, known as Direct and Indirect Remuneration (DIR).[10] DIR fees include administrative fees, price concessions, performance adjustments, and more.[11] Price concession fees, paid by the pharmacy to the PBM after the point-

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[2] 5 U.S.C. §601 et seq.
[3] Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. §601 et seq.).
[4] Small Business Jobs Act of 2010 (PL. 111-240) §1601.
[5] *Id*.
[6] *Id.*
[7] "Promoting Competition in the American Economy" Exec. Order 14036, 86 Fed. Reg. 36987, (July 14, 2021).
[8] 87 Fed. Reg. 1842 at 1910.
[9] *Id.* at 1909-1910.
[10] *Id.* at 1909.
[11] *Id.*

of-sale, have increased at a rapid rate in the last ten years, growing at a rate of 107,400 percent between 2010 and 2020.[12]

Currently the "negotiated price" of a prescription drug event does not include these price concession fees incurred after the point-of-sale, rendering the transaction less representative of the actual cost of the prescription drug.[13] CMS is therefore proposing to revise the term "negotiated prices" which is currently defined as the amount that PBMs will receive from small pharmacies for a particular prescription drug. The definition is inclusive of price concessions that are determinable at the point-of-sale but excludes contingent fees that cannot be determined at the point-of-sale.[14] CMS is proposing to instead change "negotiated prices" plural, to "negotiated price" singular. The term is to be defined as the lowest possible reimbursement for a particular drug including price concession fees at the point-of-sale.[15] Lowest possible reimbursement would mean the price of the prescription drug based on a pharmacy's lowest performance score.[16] If a pharmacy is given a smaller assessment or a bonus for high performance, this would be reported as negative DIR.[17] CMS states that this change is meant to eliminate any unknowns by the PBM at the point-of-sale so that the transaction is inclusive of all price concessions.[18]

II. Advocacy's Small Business Concerns

Small pharmacies are supportive of this rulemaking as it provides necessary policy updates to help consumers and businesses alike. Modifications are needed, however, to ensure that small pharmacies do not incur additional costs. Advocacy encourages CMS to consider the comments and suggestions of small businesses and implement suggested modifications to ensure that there is no remaining regulatory uncertainty. This will eliminate potential burdens to small pharmacies.

Small pharmacies make up an overwhelming percentage of the industry yet have substantially smaller revenues than large pharmacies. Over 98 percent of pharmacies in the United States have less than 100 employees, and over 88 percent have less than 20 employees.[19] However, the revenue distribution between small and large businesses in the industry are quite different. While the average revenue for pharmacies with less than 500 employees is $3.7 million, pharmacies with over 500 employees have an average revenue of more than $1.1 billion.[20] Therefore, Advocacy would advise CMS to take into consideration the significantly different financial circumstances for small pharmacies relative to their much larger competitors. Advocacy has

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[12] *Id.* at 1910.
[13] *Id*. at 1911.
[14] 42 U.S.C. § 1395a-114a (g) (6) citing 42 CFR§ 423.100.
[15] 87 Fed. Reg. 1842 at 1912.
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] U.S. Census Bureau Statistics of U.S. Businesses: 2017 Annual Data Tables by Establishment Industry (Washington, DC, March 2022), 2017 SUSB Annual Data Tables by Establishment Industry (census.gov)
[20] *Id.*

summarized actions CMS should take to ensure that small businesses are not overly burdened by the rule below.

A. CMS should take measures to ensure the proposed definition of "negotiated price" does not result in additional retroactive fees.

Under the current system, PBMs recover high sums from small pharmacies after the point-of-sale in the form of price concessions.[21] Small pharmacies noted that these price concessions have increased more than 100 percent since 2010. One small community pharmacy stated that he pays upwards of $300,000 in pharmacy price concessions. CMS' own data shows an increase of 107,400 percent.[22]

Advocacy and small pharmacies are supportive of CMS' proposal to define "negotiated price" at the point-of-sale to include price concessions. However, without additional modifications, small pharmacies are concerned that PBMs will shift price concession fees to some other category and apply them retroactively after the point-of-sale. Instead, PBMs should treat all deductions as price concessions and should fully disclose them in the negotiated price. CMS should make clarifications to the definition that close this loophole so that small pharmacies are not overly burdened by additional hidden fees from the PBMs after the fact.

B. CMS should standardize pharmacy performance measures so that PBMs cannot assess fees that penalize high-performing pharmacies.

In the proposed rule, CMS conducts a Regulatory Flexibility Act analysis in which it estimates that pharmacies will retain 2 percent of the existing price concessions that they negotiated with PBMs.[23] However, according to a study commissioned by the National Community Pharmacists Association, high-performing pharmacies may see a reduction in reimbursement of nearly 5.3 percent.[24] The current system thus penalizes high-performing pharmacies and creates perverse incentives.

To ensure that high-performing pharmacies are incentivized, and that they do not incur significant economic impacts from this rule, CMS should standardize performance measures so that these pharmacies are not losing money, and so that there is a true incentive for high-performing pharmacies.

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[21] 87 Fed. Reg.1842. at 1914.
[22] *Id*. at 1910.
[23] *Id.* at 1944.
[24] This figure has not been independently verified by Advocacy. *See* Comments of the National Community Pharmacists Association, 87 Fed. Reg. 1842, filed on March 7, 2022.

C. CMS should ensure that small pharmacies do not incur cash-flow issues by offering payment plans or other alternatives.

Based on the timing of this proposed rule, it is possible that small pharmacies may end up paying retroactive fees for claims adjudicated prior to rule finalization, at the same time as point-of-sale fees under the new rule. The proposed rule would require a pass-through of price concessions at the point-of-sale. However, PBMs may still attempt to collect retroactive DIR fees for the transition period of CY2022 to CY2023. Due to the sensitive financial conditions of small pharmacies, Advocacy is concerned that these changes to pharmacy reimbursements could financially impact smaller pharmacies. Advocacy has discovered that there is some concern that the rule could alter pharmacy cashflow from modifications to the Part D program. This may result in insolvency for small pharmacies if they are forced to pay retroactive and current fees at the same time. CMS should therefore require PMBs to offer payment plans, or other alternatives to ensure that small pharmacies do not incur cash flow problems that are detrimental to their operations.

III. Conclusion

Advocacy and small businesses are supportive of CMS' proposed rule. However, these additional modifications are needed to ensure that small businesses do not ultimately suffer negative consequences from the revised program. Advocacy is prepared to assist CMS in any way it can. If you have any questions or require additional information, please contact me or Assistant Chief Counsel Linwood Rayford at (202) 401-6880 or by email at Linwood.Rayford@sba.gov.

Sincerely,

/s/
Major L. Clark, III
Deputy Chief Counsel
Office of Advocacy
U.S. Small Business Administration

/s/
Prianka Sharma
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Copy to: Dominic Mancini, Deputy Administrator
Office of Information and Regulatory Affairs
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