



March 7, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4192-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (CMS-4192-P)

Dear Administrator Brooks La-Sure:

The National Home Infusion Association (NHIA) appreciates the opportunity to submit comments on the proposed rule: *Medicare and Medicaid Programs; CY 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs* (the “Proposed Rule”) issued by the Centers for Medicare & Medicaid Services (CMS) in the *Federal Register* on January 12, 2022.¹ NHIA is a trade association that represents companies that provide infusion therapy to patients in their homes, as well as companies that manufacture and supply infusion and specialty pharmacy products. As the leading voice for the home and specialty infusion community, we write to share our feedback regarding CMS’ proposed changes to pharmacy price concessions to drug prices at the point of sale.

Pharmacy Price Concessions to Drug Prices at the Point of Sale

CMS proposes to eliminate the exception for contingent pharmacy price concessions, which currently allows pharmacy price concessions that cannot reasonably be determined at the point of sale to be excluded from the definition of “negotiated prices.” In addition, CMS proposes to remove the current definition of “negotiated prices” and adopt a new definition of “negotiated price.” Under the Proposed Rule, “negotiated price” would be defined as the lowest amount a pharmacy could receive as reimbursement for a covered Part D drug under its contract with the Part D plan sponsor or intermediary. The proposed definition would include all pharmacy price concessions and any dispensing fees and exclude additional contingent amounts if those amounts would increase prices. CMS notes the policy is intended to achieve the goals of meaningful price

¹ 87 Fed. Reg. 1842 (January 12, 2022)

transparency, consistent application of all pharmacy payment concessions by all Part D sponsors and prevention of cost-shifting to beneficiaries and taxpayers.

CMS also proposes to add a definition of “price concession,” which is not currently defined in the Part D statute, regulations or sub-regulatory guidance. CMS would define “price concession” broadly and it would include all forms of discounts and direct or indirect subsidies or rebates that reduce the costs incurred by Part D sponsors under Part D plans. NHIA supports this definition and requests that CMS confirm that any fee related to a Part D prescription claim is considered a price concession, including an administrative fee, a transaction fee, or a performance-based penalty.

CMS notes that total direct and indirect remuneration (DIR) reported by Part D sponsors has significantly increased in recent years and that pharmacy price concessions have increased faster than any other category of DIR. CMS reported data that showed that pharmacy price concessions, net of all pharmacy incentive payments, increased by more than 107,400 percent from 2010 – 2020. This increase is not sustainable and is detrimental to Medicare beneficiaries. In a 2017 report, CMS stated that significant increases in DIR resulted in higher beneficiary cost-sharing obligations.² In the Proposed Rule, CMS also acknowledged that less than two percent of plans have passed through any price concessions to beneficiaries at the point of sale in recent years. CMS referenced studies that show that higher cost-sharing for prescription drugs can interfere with access to needed medications and poorer health outcomes. NHIA shares the concerns CMS outlined concerning DIR and encourages CMS to move forward with a final rule that will address these problems.

While NHIA appreciates the efforts CMS is making to address the abusive practices of PBMs surrounding DIR, NHIA believes that CMS’ proposal does not go far enough. NHIA is concerned that PBMs will continue to exploit loopholes unless CMS specifies that all pharmacy price concessions are accounted for at the point of sale at a claim level. NHIA asks that CMS clarify this to ensure that PBMs are not able to restructure pharmacy fees to circumvent CMS’ intent.

In addition, in contrast to the proposed changes to the definition of “negotiated price” discussed above, CMS proposes to allow for an “alternative negotiated price” for applicable drugs in the coverage gap. Specifically, CMS states that for applicable drugs in the coverage gap, “plans would have the flexibility to determine how much of the pharmacy price concessions to pass through at the point-of-sale.” NHIA believes that this proposal would be detrimental to Medicare beneficiaries in the coverage gap, as they would not receive the benefits of lower cost-sharing discussed above and the proposal would be operationally burdensome for pharmacies. NHIA opposes allowing for an “alternative negotiated price” for drugs in the coverage gap and

² <https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir>



requests that CMS apply the proposed revised definition of negotiated price consistently throughout the Part D benefit, which would benefit Medicare beneficiaries.

NHIA Recommendation:

NHIA supports the proposed changes to the definition of “negotiated price,” and believes the revised definition would lower negotiated prices for drugs and therefore reduce out-of-pocket prescription drug costs for Medicare beneficiaries in the Part D program. NHIA requests, however, that CMS specify that all pharmacy price concessions are attributable at the claim level to ensure that PBMs are not able to circumvent CMS’ intent. In addition, NHIA requests that CMS confirm that any fee related to a Part D prescription claim is considered a price concession, including an administrative fee, a transaction fee, or a performance-based penalty. NHIA also opposes allowing for an “alternative negotiated price” for drugs in the coverage gap and requests that CMS apply the proposed revised definition of negotiated price consistently throughout the Part D benefit, which would benefit Medicare beneficiaries.

NHIA appreciates the opportunity to provide comments on these important issues and welcomes the opportunity to work with CMS to improve the Medicare Part D benefit for all beneficiaries. For questions or additional information, please contact me at connie.sullivan@nhia.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Connie Sullivan", written in a cursive style.

Connie Sullivan, B.S. Pharm
President and Chief Executive Officer