March 7, 2022

[Submitted electronically at www.regulations.gov]
Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4192-P
P.O. Box 8013
7500 Security Blvd.
Baltimore, MD 21244-1850

Re: Docket CMS-4192-P for "Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs"

Dear Administrator Brooks-LaSure:

ASHP is pleased to submit comments regarding the proposed changes to the Medicare Part D and Medicare Advantage programs (the "proposed rule") for 2023. ASHP is the collective voice of pharmacists who serve as patient care providers in hospitals, health systems, ambulatory clinics, and other healthcare settings spanning the full spectrum of medication use. The organization's over 60,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 80 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.[1]

ASHP thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the proposed rule. We are generally supportive of provisions in the proposed rule that benefit patients and increase transparency, including the proposed revisions to the network adequacy standards and the changes to negotiated price and pharmacy price concession requirements. Our comments focus on the latter issue, with feedback designed to maximize the benefit of CMS's proposed changes for patients and our healthcare system.

I. CMS Should Finalize Proposed Changes to Direct and Indirect (DIR) Remuneration Fees

ASHP shares and supports CMS's commitment to improving transparency and reducing drug costs for Part D beneficiaries. Thus, we were very pleased to see the proposed changes, which would require that a drug's negotiated price reflect all pharmacy price concessions (i.e., direct and indirect remuneration or DIR) at the point of sale, rather than allowing concessions to be clawed back retroactively. We also support the requirement that each Part D drug have a single negotiated price (per contract) in order to create a clear reimbursement floor for pharmacies. Not only will this approach increase transparency, it will help stabilize pharmacy operations and safeguard patient access, while, as CMS notes, saving beneficiaries money.

The current process of assessing retroactive DIR fees weeks or months after a prescription has been filled makes it exceedingly difficult for pharmacies to manage their budgets. Moreover, as CMS states in the proposed rule, these arbitrary fees have mushroomed over the past decade, to the point that pharmacies regularly see annual DIR totals reaching into the six figures. Many pharmacies also have limited ability to meaningfully negotiate

[1] For more information about the wide array of ASHP activities and the many ways in which pharmacists advance healthcare, visit ASHP's website, www.ashp.org, or its consumer website, www.SafeMedication.com.

these fees, as PBM contracts are often presented as "take it or leave it" adhesion contracts, opening up pharmacies to the imposition of opaque and unfair fees. DIR also extracts costs from beneficiaries in the form of increased cost-sharing. As CMS has noted in previous reports on DIR, these payments can increase out-of-pocket costs and push patients into the Medicare coverage gap sooner.[2] Instituting a transparent point-of-sale price would help reduce these problems.

To further counteract negative impacts of DIR on patient cost-sharing and our healthcare system generally, we urge CMS to consider options for extending its definition of negotiated price across all drug coverage phases, including the coverage gap during a plan year. Instituting a different definition of negotiated price solely for the coverage gap will not benefit patients and, in fact, seems likely to incentivize PBMs and plans to apply draconian fee structures to that phase.

Finally, we urge CMS to continue to take action to reduce abusive DIR fees. Specifically, we suggest that the agency examine how DIR fees are tied to quality metrics (e.g., in many cases, the DIR fees are assessed as a block, making it impossible to determine which claims resulted in a lower performance score justifying the DIR fee) and how they are infiltrating Medicare Part B. Given that retroactive DIR fees are a growing concern in Part B, with some hospitals and health systems reporting annual DIR totals in the hundreds of thousands of dollars, we urge CMS to institute DIR transparency measures in Part B similar to those outlined in the Part D proposed rule.

Again, ASHP appreciates this opportunity to provide CMS with feedback on the proposed rule. Please contact me at jschulte@ashp.org or at 301-664-8698 if you have any questions or if we can provide any additional assistance.

Sincerely,

Jillanne Schulte Wall, J.D.
Senior Director, Health & Regulatory Policy

[2] *See, e.g.,* CMS, "Medicare Part D – Direct and Indirect Remuneration (DIR)" (January 19, 2017), *available at* https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html.