



January 16, 2018

Center for Medicare & Medicaid Services  
Department of Health and Human Services  
Attn: CMS-4182-P  
P.O. Box 8013  
Baltimore, MD 21244-8013

Re: Docket CMS -4182-P for “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program”

ASHP is pleased to submit comments regarding the proposed changes to Medicare Part D for 2019 (the “proposed rule”). ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization’s 45,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

I. Increasing the Transparency of the Point-of-Sale Price

ASHP thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the proposed rule. 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 point-of-sale price changes, which would require all pharmacy price concessions (i.e., direct and indirect remuneration or DIR) to be reflected at the point-of-sale rather than retroactively clawed back. 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, the fees themselves, which are often arbitrary in nature, have mushroomed over the past decade, to the point that pharmacies regularly see annual DIR totals in the tens of thousands of dollars. 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.<sup>1</sup> Instituting a transparent point-of-sale price would help reduce these out-of-pocket effects.

Given that retroactive DIR fees are also a growing concern in Medicare Part B, with some hospitals and health systems reporting annual DIR totals in the hundreds of thousands of dollars, we urge CMS to institute similar DIR transparency measures in Part B. As with Part D, we believe that any subsequent quality incentive payments could then be handled as “negative DIR.” This would safeguard quality efforts but dramatically decrease the uncertainty surrounding reimbursement.

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<sup>1</sup> 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>.

II. Expedited Substitutions of Certain Generics and Other Midyear Formulary Changes

ASHP supports CMS's proposal to increase plan flexibility regarding generic substitutions for therapeutically-equivalent, non-biologic medications by waiving the direct notice and approval requirements in certain instances. This change should accelerate access to generic medications, and ensure, based on CMS's statement that the "generic drug would need to be offered at the same or lower cost-sharing ... and the same or less restrictive utilization management criteria," that beneficiaries actually realize the lower cost of those medications. We caution, however, that the proposal should be implemented to provide beneficiaries with direct notice of these changes as soon as possible. Increased availability of generic medications enhances competition in the marketplace, thereby expanding treatment options and lowering costs for Medicare beneficiaries and the Medicare program overall.

III. Incentivizing Use of Follow-On Biologics

ASHP supports CMS's proposal to treat follow-on biologic medications as generics for the purposes of Part D non-Low Income Subsidy (LIS) catastrophic coverage and LIS cost-sharing only. If finalized, this proposal should effectively incentivize beneficiaries to utilize less expensive follow-on biologic products (when available and medically appropriate) rather than their more expensive reference products. Thus, this should help reduce drug costs for beneficiaries, particularly on high-cost specialty medications, while incentivizing manufacturers to invest in the development of follow-on biologic medications.

Again, ASHP appreciates this opportunity to provide CMS with feedback on the proposed rule. We look forward to continuing to work with CMS to improve care quality and outcomes. Please contact me if you have any questions on ASHP's comments. I can be reached by telephone at 301-664-8696 or by email at [jschulte@ashp.org](mailto:jschulte@ashp.org).

Sincerely,



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