



December 21, 2020

[Submitted electronically via Brian.Harrison@hhs.gov and DuplicativeRegulations@hhs.gov]

Brian Harrison
Chief of Staff
The Immediate Office of the Secretary (OIS)
U.S. Department of Health and Human Services (HHS)
Room 607G.2
200 Independence Ave, SW
Washington, DC 20024

Re: Request for Information (RFI) on Redundant, Overlapping, or Inconsistent Regulations

Dear Mr. Harrison:

The American Pharmacists Association (APhA) is pleased to submit these comments in response to the RFI on Redundant, Overlapping, or Inconsistent Regulations.

APhA is the largest association of pharmacists in the United States and the only organization advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including community pharmacies, hospitals, long-term care facilities, physician offices, clinics, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

Specifically, the RFI asks for feedback on “2. Any HHS regulations that are inconsistent with other HHS regulations, and how HHS could best resolve any inconsistencies.” In addition, “3. Any HHS regulations that overlap with federal regulation issued by another HHS office or agency in a manner that creates confusion or uncertainty, and how HHS could best address potential problems caused by such overlapping HHS regulations.”

APhA notes the following inconsistency in HHS-issued regulations that impacts pharmacists and pharmacies, detailed below:

Inconsistencies in the Applicability of CMS' Definition of "Rebates" to the Part D Program in the Office of Inspector General (OIG) Final Rule

On November 23, 2020 in response to President Trump's July 24, 2020 Executive Order on "Lowering Prices for Patients by Eliminating Kickbacks to Middlemen,"¹ HHS Secretary Alex Azar and the HHS OIG finalized a regulation to eliminate the current system of drug rebates in Medicare Part D, in order to create incentives to lower list prices and reduce out-of-pocket spending on prescription drugs by delivering discounts directly at the pharmacy counter.² Medicare Part D, also called the Medicare prescription drug benefit, is an optional United States federal-government program to help Medicare beneficiaries pay for self-administered prescription drugs, administered by the Centers for Medicare and Medicaid Services (CMS). Noting that it is outside the scope of the rule, OIG's definition in the final rule of "reductions in price" and "rebates" did not address pharmacy benefit managers' (PBMs) use of harmful retroactive pharmacy direct and indirect remuneration (DIR) fees.

In contrast, CMS' proposed rule, the "HHS Notice of Benefit and Payment Parameters for 2021," would "amend § 158.103 to add a definition of *prescription drug rebates and other price concessions* [emphasis added] that issuers must deduct from incurred claims for MLR reporting and rebate calculation purposes pursuant to § 158.140(b)(1)(i)," to "promote consistency in reporting across issuers." Per CMS regulations, and underlying statute, the Affordable Care Act's (ACA) medical loss ratio (MLR) has applied to Medicare Part D in every contract year, since 2014.

CMS' proposed definition states:

"Prescription drug rebates and other price concessions means ***all direct and indirect remuneration received or receivable by an issuer and entities providing pharmacy benefit management services to the issuer, related to the provision of a prescription drug covered by the issuer, regardless from whom the remuneration is received (for example, pharmaceutical manufacturer, wholesaler, retail pharmacy, vendor)*** [emphasis added]. Direct and indirect remuneration includes discounts, charge backs or ***rebates*** [emphasis added], cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or ***reduced-price services***,

¹ White House. Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen. July 24, 2020, available at: <https://www.whitehouse.gov/presidential-actions/executive-order-lowering-prices-patients-eliminating-kickbacks-middlemen/>

² OIG. Fraud and abuse; removal of safe harbor protection for rebates involving prescription pharmaceuticals and creation of new safe harbor protection for certain point-of-sale reductions in price on prescription pharmaceuticals and certain pharmacy benefit manager service fees. Final Rule. November 23, 2020, available at: <https://www.hhs.gov/sites/default/files/rebate-rule-discount-and-pbm-service-fee-final-rule.pdf>

[emphasis added], grants, or *other price concessions* [emphasis added] or similar benefits offered to some or all purchasers, and excluding bona fide service fees.”³

Undisputedly, as the OIG final rule applies to the Medicare Part D program, which is administered by CMS, and CMS’ preferred definition of “reduced price services,” and “rebates,” for the ACA’s MLR provision, which applies to Medicare Part D, includes **all DIR**, for consistency, we believe this should be reconciled.

Thank you for the opportunity to provide feedback on the RFI and consideration of our comments to assist your efforts to fully and accurately implement the “Avoiding Duplicative Regulation,” memorandum to best resolve these inconsistencies in HHS regulations. If you have any questions or require additional information, please contact Michael Baxter, Senior Director of Regulatory Policy, at mbaxter@aphanet.org.

CC: The Honorable Alex Azar II, Secretary, HHS

³ CMS/Department of Treasury. Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards. December 4, 2020, available at: <https://www.federalregister.gov/documents/2020/12/04/2020-26534/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2022-and#sectno-reference-184.50>