



December 30, 2020

[Submitted electronically via www.regulations.gov and to Ken.Buerger@cms.hhs.gov]

Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
Attention: CMS-9914-P
P.O. Box 8016
Baltimore, MD 21244-8016

c/o: Center for Consumer Information and Insurance Oversight at CMS

Re: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations, Proposed Rule

Dear Mr. Buerger:

The American Pharmacists Association (APhA) is pleased to submit these comments in response to the proposed rule for the HHS Notice of Benefit and Payment Parameters (NBPP) for 2022 and Pharmacy Benefit Manager Standards.

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.

Prescription Drug Distribution and Cost Reporting by QHP Issuers (§ 156.295)

APhA urges HHS/CMS to ensure transparency by requiring disclosure of pharmaceutical benefit manager (PBM) information submitted from the plans under Section 1150A to the states and providing clear guardrails for submitted data to prevent manipulation or misleading information by PBMs.

In the proposed rule, CMS states “rather than requiring the QHP issuer to serve as a conduit between its PBM and HHS, or unnecessarily requiring both the PBM and the QHP issuer to submit duplicated data, we propose to implement section 1150A to make QHP issuers responsible for reporting this data directly to the Secretary only when the QHP issuer does not contract with a PBM to administer the prescription drug benefit for their QHPs. Where a QHP contracts with a PBM, the PBM is responsible for reporting data to the Secretary as required by § 184.50.”

Section 1150A of existing law requires qualified health benefits plans (QHPs) offered through an exchange established by a State under section 1311 of the Patient Protection and Affordable Care Act (ACA) to provide information to the HHS Secretary and, in the case of a PBM, to the plan with which the PBM is under contract with, “at such times, and in such form and manner, as the Secretary shall specify,” with respect to services provided by a health benefits plan or PBM for a contract year.

The information includes:

“(2) The aggregate amount, and the type of rebates, discounts, or price concessions (excluding bona fide service fees, which include but are not limited to distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs)) that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.

(3) The aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.”

However, the law also states the “information disclosed by a health benefits plan or PBM under this section is confidential and shall not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs,” for a few select purposes. Two of these purposes where disclosure is permitted includes: “[a]s the Secretary determines to be necessary to carry out this section,” and “[t]o States to carry out section 1311 of the Patient Protection and Affordable Care Act.” As you are likely aware, a number of states have passed statutes to eliminate PBMs’ harmful practice of “spread pricing” and retroactive primacy concessions “clawbacks,” or “true-ups,” that operate similar to destructive retroactive Direct and Indirect Remuneration (DIR) fees under Medicare. Accordingly, APhA strongly urges the HHS Secretary to require disclosure of this PBM transparency information submitted from the plans under Section 1150A to the states.

Shifting the requirement for the reporting of “spread pricing,” (e.g., the difference between the reimbursements paid to pharmacies and the rates reported back to the payer where the PBM retains the difference) under § 184.50 from the QHPs to the PBMs does not increase transparency into the opaque drug pricing practices of the PBMs. Without clear PBM guardrails, it may also inadvertently allow PBMs to further manipulate the data submitted. For example, it is known that for pharmacies, PBMs use fake “list prices,” for prescription drugs, which are wildly overinflated relative to their actual cost (for a markup of about 20% or more).¹ Brand name drugs have high average wholesale prices (AWPs) that are offset by negotiated rebates and discounts that make those net prices much lower. Generic drugs have high AWPs (derived from

¹ Thomson Reuters MicroMedex. Website. AWP Policy. Accessed October 30, 2020 at https://www.micromedexolutions.com/micromedex2/4.31.0/WebHelp/RED_BOOK/AWP_Policy/AWP_Policy.htm

brand drugs) that in no way reflect the actual prices pharmacies pay to acquire those drugs. In both regards, the “actual” prices of both brand and generic drugs are hidden by PBMs from the plan sponsor and patient. As CMS understands, certain data are unique to PBMs, such as data related to rebates, bona fide service fees, and PBM spread amounts. CMS should follow the lead of the Office of Personnel Management (OPM), which requires PBMs that serve the Federal Employee Health Benefits Program (FEHBP) to make disclosures that go above and beyond those required under the ACA.² In addition, HHS, marketplace plans, the states and the public should have access to additional information used by PBMs to manipulate drug prices.

F. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements 1. Definitions (§ 158.103)

APhA strongly supports CMS’ proposal “to amend § 158.103 to add a definition of prescription drug rebates and other price concessions that issuers must deduct from incurred claims for medical loss ratio (MLR) reporting and rebate calculation purposes pursuant to § 158.140(b)(1)(i).” We agree that codifying and clarifying the definition of prescription drug rebates and other price concessions will allow issuers to more accurately report the costs associated with enrollees’ prescription drug utilization for purposes of the MLR calculation.

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

As 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 with all other HHS regulations and definitions, such as the HHS Office of Inspector General’s (OIG) final “rebate” rule⁵—as we mentioned in our recent comments in response to HHS’ “Request for Information (RFI) on Redundant, Overlapping, or Inconsistent Regulations.”⁶

² See, OPM, Proposed Changes to Standard 2017 Fee-For-Service Health Benefits Contract. Standards for Pharmacy Benefit Management Company (PBM). <https://www.opm.gov/healthcare-insurance/healthcare/carriers/2016/2016-12c1.pdf>

⁵ 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>

⁶ HHS. Request for Information (RFI) on Redundant, Overlapping, or Inconsistent Regulations. November 27, 2020, available at: <https://www.govinfo.gov/content/pkg/FR-2020-11-27/pdf/2020-26022.pdf>

Thank you for the opportunity to provide feedback on the HHS NBPP for 2021. If you have any questions or require additional information, please contact Michael Baxter, Senior Director of Regulatory Policy, at mbaxter@aphanet.org.

Sincerely,

A handwritten signature in black ink that reads "Ilisa BG Bernstein". The signature is written in a cursive style with a horizontal line at the end.

Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice and Government Affairs