



July 23, 2021

[Submitted electronically via regulations.gov]

Ms. Amber Rivers
Director
Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Avenue NW, Room N-5653
Washington, DC 20210

RE: Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs (CMS-9905-NC)

Dear Director Rivers:

The American Pharmacists Association (APhA) is pleased to submit comments on the Request for Information (RFI) regarding reporting on pharmacy benefits and prescription drug costs (CMS-9905-NC).

APhA is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including but not limited to community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care and enhance public health.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) are gathering input from the public regarding implementation considerations for the data collection required under section 204 of Title II of Division BB of the Consolidated Appropriations Act, 2021 (CAA), and the associated impact on group health plans and health insurance issuers. The Office of Personnel Management (OPM) is also seeking input regarding data collection as it pertains to Federal Employees Health Benefits (FEHB) carriers.

By December 27, 2021, and not later than June 1 of each year after, plans and issuers must report to the Departments the 50 most frequently dispensed brand prescription drugs, and the total

number of paid claims for each such drug; the 50 most costly prescription drugs by total annual spending, and the annual amount spent by the plan or coverage for each drug; and the 50 prescription drugs with the greatest increase in plan expenditures over the plan year preceding the plan year and the change in amounts expended by the plan or coverage in each such plan year. Additionally, plans and issuers must report total spending by the plan or coverage broken down by the type of health care services, including spending on prescription drugs by the plan or coverage as well as by participants, beneficiaries, and enrollees, as applicable; and the average monthly premiums paid. Plans and issuers must report rebates, fees, and any other remuneration paid by drug manufacturers to the plan or coverage or its administrators or service providers, including the amount paid with respect to each therapeutic class of drugs and for each of the 25 drugs that yielded the highest amount of rebates and other remuneration under the plan or coverage from drug manufacturers during the plan year. Finally, plans and issuers must report any reduction in premiums and out-of-pocket costs associated with these rebates, fees, or other remuneration.

Plans and issuers must issue their first reports to the Departments in 18 months and publish on the internet reports on prescription drug reimbursements under group health plans and group and individual health insurance coverage, prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decreases under such plans or coverage, aggregated so that no drug or plan specific information is made public.

General Comments:

APhA supports pharmaceutical industry adoption of a “transparent pricing” system that would eliminate hidden discounts, free goods, and other subtle economic devices.¹ However, we are concerned the “internet reports” under section 204 on prescription drug reimbursements under group health plans and group and individual health insurance coverage permits manipulation of drug pricing “rebates,” and reimbursements and drug pricing trends by pharmaceutical benefit managers (PBMs) and will not be useful to reducing prescription drug prices for the public without strict guiderails. In addition, the definition of “brand,” prescription drugs needs to be clearly defined to ensure brand name identification is not manipulated by responding PBMs/ insurers. For example, to be consistent with other Federal programs we recommend referencing the definition used in calculating the National Average Drug Acquisition Cost (NADAC):

¹ JAPhA. NS8:362; July 1968. JAPhA. NS44(5):551; September/October 2004) (Reviewed 2006) (Reviewed 2011) (Reviewed 2016) (Reviewed 2018), available at:

<https://www.pharmacist.com/Portals/0/PDFS/HOD/1948%20HOD%20Current%20Adopted%20Policy%20Web%200223%20removed%202nd%20page.pdf?ver=rPuUtWyskj1dgyPoErr-w%3d%3d>

“Drug category represents the classification of each [National Drug Code] NDC as one of the following: Single source (‘S’), Innovator multiple source (‘I’), or Non-innovator multiple source (‘N’). In general, NDCs designated as ‘S’ and ‘I’ are considered *brand drugs* [emphasis added] and NDCs designated as ‘N’ are considered *generic drugs* [emphasis added] for purposes of calculating the NADAC. Drug category designations are listed in the “Classification for Rate Setting” field in the NADAC reference file. The Drug Category is obtained from the most recent CMS covered outpatient drug product file.”²

APhA urges the Departments coordinate section 204 reporting with the final rule on price transparency (CMS-9915-F) from the Departments³ to help ensure Americans know how much prescription drugs will cost in advance and allowing them to make more informed and value-conscious decisions. Specifically, requiring health plans/carriers and PBMs to publicly release the in-network negotiated rates and “historical net prices,” or the retrospective average amount a plan or issuer paid an in-network provider, including any in-network pharmacy or other prescription drug dispenser, for a prescription drug, inclusive of any reasonably allocated rebates, discounts, chargebacks, fees, and any additional price concessions received by the plan or issuer with respect to the prescription drug or prescription drug services. The Departments could strengthen this requirement by removing or defining “reasonably.” The Departments should also provide a clear manner with which the “historical net price” is to be calculated to avoid PBMs manipulating historical net pricing data differently which would make drug pricing comparisons meaningless. Additionally, the Departments should ask for a breakdown of expenditures along, retail, mail and specialty pharmacy delivery.

To assist your efforts, APhA is providing the following information on the current state of pharmacy pricing we have previously supplied to OPM:

Current State of Pharmacy Pricing:

Net Payments: For additional context on pharmacy pricing, the current use of effective rate guarantees by PBMs obfuscate the actual net payments to pharmacies. Much of this is handled through intermediaries between PBMs and Pharmacy Services Administrative Organizations

² CMS. Methodology for Calculating the National Average Drug Acquisition Cost (NADAC) for Medicaid Covered Outpatient Drugs. January 2021, available at: <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/ful-nadac-downloads/nadacmethodology.pdf>

³ <https://www.cms.gov/newsroom/fact-sheets/transparency-coverage-final-rule-fact-sheet-cms-9915-f>

(PSAOs)⁴, making claim reconciliation extremely difficult, as the contractual terms of “true up,” (between a target reimbursement rate in a participating pharmacy agreement and the aggregated effective rate actually realized by a pharmacy) “net” cost differs from one PBM-PSAO relationship to the next.

Gap Between True Acquisition Cost: There is a growing knowledge gap within true acquisition cost information for the most expensive brand name medications. Limited distribution networks of medications between drug manufacturers and PBM-owned specialty pharmacies conceals true cost information for many payers, including cost after all manufacturer income / revenue is accounted for as the current FEHBP contract attempts to do.

Differential pricing within Pharmacy Networks: Research has detailed how limited access via closed networks to specialty drugs can result in payers incurring higher than needed costs relative to a more open network and competitive approach. Because PBMs control payment rate settings, and nothing within the existing FEHBP contract prevents them from paying their own pharmacies a higher network rate than competitor pharmacies, they can self-enrich through network arrangements which restrict drug dispensation to affiliated pharmacies, even within a pass-through arrangement, at increased costs to patients, employers and taxpayers.

Current State of the Delivery of Prescription Drugs:

Mail Order Concerns: Within the context of broken mechanisms to pay for prescription drugs, payers are subjected to a broken delivery model of drugs. Over the last 4 years, the rate of one-time mail delivery of packages has declined via the USPS (high of 89.6% on time in 2017 to 85.8% in 2020).⁵ During this same time, particularly during the pandemic, the upkeep of mail order pharmacy has increased, potentially jeopardizing the safety and efficacy of medications delivered via mail.⁶ As the PBM industry has moved to shift high dollar prescriptions (i.e., specialty) to mail, the financial risks from mail order delivery have increased. New programs designed to white bag delivery of what would otherwise be provider administered drugs from the PBM-owned pharmacy to facilities only increases this risk within the healthcare system.⁷

Impact of Cost Sharing: The goal of prescription drug benefits should be the right patient, receiving the right drug, at the right time. Unfortunately, PBM benefit design choices, which

⁴ Over 75% of independent and small chain pharmacies contract with PSAOs. PSAOs contract with pharmacies to perform many of the pharmacies’ core operations, such as negotiating reimbursement and tracking remittances.

⁵ <https://about.usps.com/what/performance/service-performance/fy2021-q1-package-services-quarterly-performance.pdf>

⁶ <https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us>

⁷ White bagging is the practice of disallowing a provider from procuring and managing the handling of a drug used in patient care. Instead, a third-party specialty pharmacy dispenses the drug and sends it to a hospital or physician office on a one-off basis.

shift more costs to patients, risk the ability to meet this metric. For example, structuring benefit design around the lowest net cost to payer, without also ensuring that those therapies are the lowest net cost for the patient, creates conflicts within the prescription delivery model. We have known for years that patients are most adherent to medications when cost share is small;⁸ however, we deliver drugs to patients without consideration of keeping their cost share low.

Impact of Cash Prices: These points are compounded when pharmacies are expected to help patients adhere to medications via benefit designs they have no say in. For example, consider a claim a pharmacy that “cashes out” for the patient because their cash price is cheaper than the patient’s copay via their prescription drug insurance (a situation which may occur in a FEHBP plan given the lack of a lower pricing guarantee). The pharmacy may later be monetarily penalized because the patient appears non-adherent with therapy because the insurance does not see a paid claim for that drug in their system (since it was paid via cash).

PBMs

The RFI asks “What role, if any, will Pharmacy Benefits Managers (PBMs) play in furnishing necessary information to plans and issuers, or to the Departments or OPM?” Most health issuers utilize a PBM in the current pharmaceutical drug distribution infrastructure and will likely have control and access to all the necessary information required by the Departments. Unfortunately, the PBM marketplace is highly concentrated, whereby roughly three-quarters of all equivalent prescription claims are processed by only three companies.⁹ This concentration has increased barriers to market entry, ballooned prescription drug expenditures, exacerbated cost inequities, and reduced choice for consumers and purchasers.

Ample and growing data analysis clearly show increasing evidence that consolidation of PBMs with pharmacies and vertical integration in the healthcare space has led to increases in purchasers’ and patients’ drug prices through use of hidden clawbacks fees, artificially inflated list prices, price discrimination, spread pricing, mounting price shifts and administrative fees, and patient steering for brand, generic and specialty drugs and to PBM-affiliated pharmacies.

A few of these harmful PBM practices include:

- **Clawbacks:** “Clawbacks,” by PBMs are designed to capture rebates and other mechanisms not included at the point-of-sale. However, they have been re-defined by PBMs and are now being used beyond their original purpose to retroactively adjust

⁸ <https://www.healthaffairs.org/doi/10.1377/hlthaff.27.1.103>

⁹ <https://www.drugchannels.net/2021/03/drug-channels-news-roundup-march-2021.html>

pharmacies' payment months after the sale, often resulting in reimbursement that is below the cost of drug acquisition by pharmacies. There is simply no connection between price concessions given by drug manufacturers to PBMs and the prices paid by pharmacies to their wholesalers. Thus, clawback fees "recovered" from pharmacies by PBMs are illogical (i.e., recovering money from pharmacies that pharmacies did not "receive" in the first place). Because current point-of-sale prices or copays paid by beneficiaries can be based on the contracted price before clawbacks are extracted, many beneficiaries pay higher out-of-pocket costs for prescription drugs. Numerous research suggests higher cost-sharing can impede beneficiary access and adherence to necessary medications, which leads to poorer health outcomes and higher overall medical care costs for enrollees.¹⁰

- **Artificially Inflated List Prices:** Within the prescription drug supply chain, "list prices" for prescription drugs are significantly overinflated relative to their actual cost (for a markup of about 20% or more).¹¹ PBMs use those list prices or average wholesale price ("AWP"), as the basis for their pricing guarantees to pharmacies and plan sponsors. AWP does not include buyer volume discounts or rebates often involved in prescription drug sales and is subject to manipulation by manufacturers or even wholesalers.¹² Brand name drugs have high AWP that are offset by negotiated rebates and discounts that make those net prices much lower. Generic drugs have high AWP (derived from brand drugs) that in no way reflect the actual prices pharmacies pay to acquire those drugs.¹³ In both regards, the "actual" prices of both brand and generic drugs are hidden by PBMs from the plan sponsor, patient, and pharmacies.
- **Price Discrimination:** This is a strategy that charges customers different prices for the same product based on what the seller thinks they can get the customer to agree to. PBMs and drug manufacturers negotiate a "net price," but the extent to which that true net price is captured by the payer (plans, etc.) depends on the payer's access to information and negotiating leverage. As a result, PBMs pass along some discounts and rebates to some clients but choose to retain those rebates from others. Or viewed from the lens of a patient, a PBM can use all their covered patient lives as a means to elicit larger rebates from drugmakers, but they can then turn around and require those same

¹⁰ <https://europepmc.org/article/med/19639897>

¹¹ Thomson Reuters MicroMedex. Website. AWP Policy. Accessed October 30, 2020 at

https://www.micromedexsolutions.com/micromedex2/4.31.0/WebHelp/RED_BOOK/AWP_Policy/AWP_Policy.htm

¹² Gecarelli GM. Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Mechanism? National Health Policy Forum. Issue Brief. No. 775. Accessed Sept. 20, 2020 at https://www.nhpf.org/library/issue-briefs/IB775_AWP_6-7-02.pdf

¹³ 46Brooklyn. Inside AWP: The arbitrary pricing benchmark used to pay for prescription drugs. November 8, 2018, available at: <https://www.46brooklyn.com/research/2018/11/7/visualizing-how-aint-whats-paid-awp-really-is>

patients to pay the full list price of their medications through use of high deductible plans. Hidden rebates are the key enabler allowing the drug supply chain to capture the benefits of drug price discrimination.

- **Spread Pricing:** This is the difference between the reimbursements paid to pharmacies and the rates reported back to the payer where the PBM retains the difference. Numerous studies and audits have found spread pricing amounts ballooning to excessive amounts, reaching more than \$8 per prescription in some instances.¹⁴ While spread pricing adds unnecessary costs for plan sponsors, it also raises anti-competitive issues, as PBMs (who often have pharmacies of their own) can directly profit off underpayments to network pharmacies.
- **Mounting Administrative Fees:** As scrutiny has mounted on costly PBM practices like clawback fees, rebate capture, and spread pricing, the industry has been able to evade cost containment efforts by recategorizing that revenue as something different or by shifting those dollars to other lesser-known layers of their vertically integrated enterprise. For example, as scrutiny grew on drug rebates, PBMs began pushing more of the drugmaker concessions to “rebate aggregators,” and in addition, relabeling many of those “rebates” instead as “fees.”¹⁵ And as controversy grows on the increasingly bloated clawback fees that PBMs assess on pharmacy practices, PBMs have begun diversifying and recategorizing their clawbacks as “effective rates.”¹⁶
- **Specialty Steering:** Utilization distortions of the prescription drug marketplace are all about getting lucrative specialty drugs into pharmacies owned by the vertically merged insurer and/or PBM.

We hope these comments assist your efforts to implement section 204 of the CAA. If you have any questions, or you would like to meet with APhA to receive additional context on the opaque business practices of the PBMs, please do not hesitate to contact Michael Baxter, Senior Director of Regulatory Policy, at mbaxter@aphanet.org

¹⁴https://static1.squarespace.com/static/5c326d5596e76f58ee234632/t/60c39d2f9f136858b18f5074/1623432498361/Mass%2BReport_April%2B2021.pdf

¹⁵ <https://www.benefitspro.com/2021/04/15/cautionary-tale-plan-sponsors-losing-manufacturer-rebate-dollars-to-pbms-through-rebate-aggregators/?slreturn=20210403162749>

¹⁶ <https://www.frierlevitt.com/articles/service/pharmacylaw/generic-effective-rate-ger-a-new-type-of-post-sale-clawback-by-pbms/>