PhRMA
RESEARCH • PROGRESS • HOPE
950 F STREET, NW, SUITE 300 • WASHINGTON, DC 20004 • 202-835-3400 • PhRMA.org

July 23, 2021

VIA ELECTRONIC FILING — *http://www.regulations.gov*

The Honorable Xavier Becerra
Secretary of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Ali Khawar
Acting Assistant Secretary, Employee Benefits Security Administration
Department of Labor
200 Constitution Ave NW Room N-5653
Washington, DC 20210

Laurie Bodenheimer
Associate Director, Healthcare and Insurance
Office of Personnel Management
Washington, DC

Rachel D. Levy
Associate Chief Counsel (Employee Benefits, Exempt Organizations, Employment Taxes)
Internal Revenue Service
Department of the Treasury
Washington, DC

Carol A. Weiser
Benefits Tax Counsel
Department of the Treasury
1500 Pennsylvania Ave NW
Washington, DC 20001

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

Dear Secretary Becerra, Acting Assistant Secretary Khawar, Ms. Bodenheimer, Ms. Levy, and Ms. Weiser:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to submit comments on the Request for Information Regarding Reporting on Pharmacy Benefits and Prescription Drug Costs (the RFI).[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives.

[1] 86 Fed. Reg. 32813 (Jun. 23, 2021).

Since 2000, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone.

The Departments of the Treasury, Labor and Health and Human Services (the Departments) and the Office of Personnel Management (OPM) have requested information from stakeholders on how they should implement division BB, section 204 of the Consolidated Appropriations Act (CAA), 2021. As discussed in further detail below keyed to specific questions from the RFI, PhRMA believes the section 204 reporting will be important in providing the Departments and OPM with significant information about health care costs across the pharmaceutical supply chain. **Importantly, the section 204 reporting should be designed to demonstrate the magnitude of discounts that manufacturers provide through rebates and other payments to pharmacy benefit managers (PBMs).** PBM practices mean these discounts are not always shared directly with patients at the point-of-sale, so plans and PBMs benefit from substantial discounts while often requiring patients to pay high deductibles and coinsurance based on a medicine's full list price. Consequently, the sickest patients may pay more for medicines than their health plans do, a perverse form of "reverse insurance," as discussed in detail below.

In addition, the reporting should reflect how all sectors of the health care system, including hospitals and physicians, influence costs. The reporting should differentiate between the net ingredient costs of medicines administered by hospitals and other providers and the substantial markups commonly applied to these medicines. Administration costs and markups should be categorized as revenue received by hospitals and other providers, not as spending attributable to medicines.

Finally, among other comments below, PhRMA emphasizes that manufacturer cost-sharing assistance provided to patients to help pay deductibles, copayments and coinsurance expenses is not a drug discount and should not be reported as remuneration to the plan or PBM.

B. Definitions

Question B.1

PhRMA, among others in the pharmaceutical supply chain,[2] believes that certain PBM business practices primarily benefit the PBMs themselves and not the patients they and the health plan sponsors purportedly serve. This is evidenced by reports published by states pursuant to PBM and insurer reporting requirements similar to those found in the CAA. For example, the Maine Health Data Organization found in its 2020 Annual Prescription Drug Pricing Transparency Report that "if rebate amounts were instead distributed between payers and consumers according

[2] *See e.g.*, National Community Pharmacists Association. Comments on 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 NPRM. April 2019. http://www.ncpa.co/pdf/ncpa-comments-proposed-rebate-rule.pdf; Alliance of Specialty Medicine. Comments on 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 NPRM. March 2019. https://specialtydocs.org/wp-content/uploads/2019/06/Alliance_-_Rebate_Rule_Letter_2019.pdf.

to the rate of initial cost sharing, consumers would have realized out of pocket cost savings of 20.89% for brand drugs...."[3] As others have noted, PBMs may favor medicines for which they can negotiate high rebates,[4] even if those discounts are not passed through to patients. PhRMA appreciates efforts to publicize the volume of rebates and other remuneration that is paid to PBMs.

We describe below certain PBM practices that should be taken into account in this rulemaking and recommend that the reporting include remuneration paid by manufacturers in connection with medicine utilization. Further, we encourage the adoption of a functional definition of PBM to reflect the evolution of that industry, and we emphasize that manufacturer cost-sharing assistance for patients is not remuneration to PBMs or plan sponsors.

PBM Remuneration Practices

The pharmaceutical supply chain and payment system has evolved over time. This evolution reflects changes in prescription drug benefit design as well as changes in the size, role, and structure of PBMs. While the current system has helped to control overall spending and allows for differential pricing, the Centers for Medicare & Medicaid Services (CMS), the Medicare Payment Advisory Commission (MedPAC), and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) have observed that the growth in rebates PBMs negotiate with pharmaceutical manufacturers may incentivize PBMs to favor medicines that carry higher rebates.[5] This may be the result of the types of historical arrangements PBMs reportedly have negotiated with their health plan and employer clients, under which the health plan or employer client allows the PBMs to retain a portion of the rebates and other price concessions the PBM negotiated on its behalf as compensation for the services the PBM is providing to the client.[6] Because certain payments retained by the PBM may be based on a percentage of a medicine's list price, PBMs may have incentives to establish formularies that favor medicines with large rebates over lower list price medicines.[7] Indeed, the Senate Finance Committee has found that PBM practices discourage access to low list price insulin and that, while net prices for insulin have decreased in recent years, PBMs and health plans, not patients, have realized those savings.[8]

The complex set of rebates and fees and PBM contractual arrangements can make it difficult for payers to assess whether they are fully benefiting from all price concessions that PBMs negotiate. One benefits consultant has observed that PBMs are increasingly changing the

[3] Maine Health Data Organization. Prescription drug transparency report. February 2021. https://mhdo.maine.gov/_pdf/MHDO%20Rx%20Transparency%20Report%20210209%20FINAL.pdf.
[4] *See*, United States Senate Finance Committee. Insulin: examining the factors driving the rising cost of a century old drug. January 2021. https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.
[5] 82 Fed. Reg. at 56336; Medicare Payment Advisory Commission. Report to the Congress: Medicare payment policy. chapter 14: The Medicare Prescription Drug Program (Part D): status report. March 2018. http://medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0; 84 Fed. Reg. at 2341.
[6] Altarum. The impact of prescription drug rebates on health plans and consumers. April 2018. https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf.
[7] Hoey D.B. STAT. Rebates to pharmacy benefit managers are a hidden contributor to high drug prices. November 2016. https://www.statnews.com/2016/11/28/rebates-pharmacy-benefit-managers-contribute-high-drug-prices/.
[8] United States Senate Finance Committee. Insulin: examining the factors driving the rising cost of a century old drug. January 2021. https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.

contractual definition of the types of payments that must be shared in their agreements with their plan sponsors to exclude certain payments, allowing the PBM to retain these payments rather than passing them back to the plan sponsor. Moreover, administrative fees can be as high as 30% of the total amount paid in rebates and fees by the manufacturer to the PBM and in some cases may not be reported to the plan sponsor by the PBM.[9] Lack of transparency over PBM-retained fees in contracts between employers and PBMs has led many plan sponsors to question how much the PBM is retaining for administrative fees and whether the PBM is disclosing and passing all price concessions, such as savings from price protection rebates.[10]

Therefore, we encourage comprehensive reporting of all ***direct*** and ***indirect*** remuneration that health plans receive, including via remuneration received and permitted by the health plan to be retained by their contracted PBMs. We also recommend that, when applicable, reporting should include the dollar amount and percentage of rebates passed through to patients at the point-of-sale. PhRMA believes the reporting of this information and its publication *in the aggregate* without disclosing medicine-specific pricing will provide important public information regarding the substantial payments that PBMs receive and the substantial reductions in net revenue realized by manufacturers. We recommend that this remuneration include *all amounts* tied to utilization that are paid by manufacturers to PBMs or health plans.

For this purpose, the rules should define PBM functionally to capture the broad range of entities that may receive or retain manufacturer remuneration tied to utilization. This accounts for complex corporate structures and ongoing vertical integration of PBMs into or with other entities and reduces the potential for abuse. The definition we propose below is similar to definitions that have been codified in various states[11] and reflects the broad range of services that PBMs currently offer while affording flexibility as the PBM business model continues to evolve over time:

> "Pharmacy Benefit Manager" means any person, business, or other entity that, pursuant to a written agreement with group health plans or health insurance issuers, either directly or through an intermediary, acts as a price negotiator for plans or issuers or manages the prescription drug benefits provided by plans or issuers, including but not limited to, the processing and payment of claims for prescription drugs, the performance of drug utilization review, the processing of drug prior authorization requests, the adjudication of appeals or grievances related to the prescription drug benefit, contracting with network pharmacies, controlling the cost of covered prescription drugs, or the provision of services related thereto. Under this definition, any person, business, or other entity that carries out one or more of the activities above or any entity that is owned, affiliated, or

[9] Mercer. Will point-of-sale rebates disrupt the PBM business? July 2017. https://www.mercer.us/our-thinking/healthcare/will-point-of-sale-rebates-disrupt-the-pbm-business.html.
[10] Midwestern Business Group on Health. Drawing a line in the sand: employers must rethink pharmacy benefit strategies. September 2017. https://higherlogicdownload.s3.amazonaws.com/MBGH/4f7f512a-e946-4060-9575-b27c65545cb8/UploadedImages/Specialty%20Pharmacy/DMJ_MBGH_Line_in_the_Sand_RV12_9617.pdf.
[11] Drug Channels Institute. Drug Channels news roundup, March 2021: Sanofi's gross-to-net bubble, Express Scripts rebates, health insurance hustle, and vertical integration illustrated. March 2021. https://www.drugchannels.net/2021/03/drug-channels-news-roundup-march-2021.html.

> related under a common ownership structure with such a person, business, or entity is a "pharmacy benefit manager."[12]

Without such a definition, PBMs could easily adjust their business practices or shift their corporate structures to avoid being considered "PBMs" for purpose of the regulation, thus undermining the important policy goals of this reporting.

Manufacturer Cost-Sharing Assistance and Accumulator Adjustment Programs

Manufacturer cost-sharing assistance programs, also known as "coupons" or "copay cards," ("manufacturer assistance") are types of assistance offered to patients to help them pay for the out-of-pocket costs charged by their health plans for prescribed medicines. Manufacturer assistance provides an important source of financial support for eligible patients and can improve patient adherence, leading to improved patient outcomes.[13]

When patients' cost-sharing obligations rise, patients are more likely to abandon their medicines. In 2017, 69% of commercially insured patients did not fill their new prescriptions when they had to pay more than $250 out of pocket, while only about 11% of patients with out-of-pocket costs of less than $30 abandoned their prescriptions at the pharmacy.[14] Thus, higher patient out-of-pocket costs frequently lead to medicines never reaching the patient, because the patient's health plan has erected a financial barrier around appropriate treatment even though the medicine has been prescribed and the health plan has agreed to cover the treatment. Additionally, the out-of-pocket burden for patients is growing because of rapidly increasing patient cost sharing for brand medicines, a result of commercial market health plans and PBMs increasing reliance on large deductibles and coinsurance.[15] For these reasons, HHS itself has recognized the importance of patient assistance, noting that it is crucial for "consumers whose drug costs would otherwise be extremely high due to a rare or costly condition."[16]

Manufacturer assistance, such as "coupons" or "copay cards," is not remuneration to "the plan or coverage or its administrators or service providers" and should not be reported as such. Manufacturers offer assistance exclusively to the patient, never to any plan or PBM.

---

[12] *See*, PhRMA. Comments on 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 NPRM. April 2019. https://www.phrma.org/policy-paper/phrma-comment-letter-on-oig-safe-harbor-proposed-rule.

[13] IQVIA analysis for PhRMA. Faced with high cost sharing for brand medicines, commercially insured patients with chronic conditions increasingly use manufacturer cost-sharing assistance. July 2020. https://phrma.org/report/Commercially-Insured-Patients-with-Chronic-Conditions-Face-High-Cost-Sharing-for-Brand-Medicines.

[14] IQVIA. Patient affordability part two: implications for patient behavior & therapy consumption. May 2018. https://www.iqvia.com/locations/united-states/library/case-studies/patient-affordability-part-two.

[15] IQVIA. Patient affordability part one: the implications of changing benefit designs and High Cost-Sharing. May 2018. https://www.iqvia.com/locations/united-states/library/case-studies/patient-affordability-part-one; Peterson-Kaiser Family Foundation. Tracking the rise in premium contributions and cost-sharing for families with large employer coverage. August 2019. https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributions-and-cost-sharing-for-families-with-large-employer-coverage/ (showing a 205% increase in commercial market enrollee spending on deductibles from 2007 to 2017, vastly outpacing wage growth); Pharmacy Benefit Management Institute. Trends in specialty drug benefits report, 2017 edition. 2017 (noting that, in 2016, coinsurance overtook copays as the preferred form of cost sharing on commercial plans for specialty drugs).

[16] 84 Fed. Reg. 17454, 17544 (Apr. 25, 2019).

Manufacturer assistance is not a reduction in price offered by a manufacturer, and it is not intended to be retained by any PBM or payer.

However, plans' accumulator adjustment programs prevent manufacturer assistance provided to patients from being counted toward the patient's deductible or annual limitation on cost sharing (i.e., out-of-pocket spending limit).[17] We reiterate that accumulator adjustment programs are contrary to the requirements of the Affordable Care Act (ACA), which requires all non-grandfathered group health plans and health insurance issuers to count cost sharing for essential health benefits – including manufacturer assistance – toward the annual limitation on cost sharing.[18]

Moreover, when such programs are implemented by health plans, they can substantially increase patients' out-of-pocket costs, increasing financial burden and health risk, especially for those with serious illnesses. Ignoring harms to patient adherence and well-being, health plans and PBMs continue to institute accumulator adjustment programs, under which patients are punished for using cost-sharing assistance and end up paying more out-of-pocket than their plans would otherwise permit. Accumulator adjustment programs can potentially leave patients with thousands of dollars in unexpected costs at the pharmacy, resulting in exactly the problems that cost-sharing assistance is designed to avoid: prescription abandonment, poor health outcomes, and unnecessary medical spending. If patients cannot pay their full cost sharing at the pharmacy, they are typically turned away and leave the pharmacy without the medicine their doctor prescribed.

Given the sustained trend toward less generous coverage for brand prescription medicines in commercial health insurance,[19] accumulator adjustment programs may undermine medication adherence, which can increase overall health care costs. Research has shown that following the implementation of an accumulator adjustment program, high-deductible health plan enrollees taking specialty medicines to treat autoimmune disorders had a 20% higher level of treatment discontinuation compared to pre-implementation.[20] As an AIDS Institute report on accumulator adjustment programs noted: "Copay accumulator programs put patients with chronic conditions in a tough position—forcing them to choose between their health and other financial obligations."[21] While HHS has not appropriately addressed these major concerns, they have

---

[17] PhRMA notes that, in addition to accumulator adjustment programs, some health plans and PBMs may be employing other methods to take advantage of manufacturer assistance intended to go solely to patients. For example, maximizer programs subject certain patients to atypically high cost sharing, just because they rely on a particular medicine.
[18] ACA § 1302(c)(3), 42 U.S.C. § 18022(c)(3).
[19] IQVIA. Patient affordability part one: the implications of changing benefit designs and High Cost-Sharing. May 2018. https://www.iqvia.com/locations/united-states/library/case-studies/patient-affordability-part-one; Peterson-Kaiser Family Foundation. Tracking the rise in premium contributions and cost-sharing for families with large employer coverage. August 2019. https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributions-and-cost-sharing-for-families-with-large-employer-coverage/ (showing a 205% increase in commercial market enrollee spending on deductibles from 2007 to 2017, vastly outpacing wage growth); Pharmacy Benefit Management Institute. Trends in specialty drug benefits report, 2017 edition. 2017 (noting that, in 2016, coinsurance overtook copays as the preferred form of cost sharing on commercial plans for specialty drugs).
[20] Bruce W. Sherman, et al., Impact of a Co-pay Accumulator Adjustment Program on Specialty Drug Adherence, 25 Am. J. Managed Care 335 (2019).
[21] The AIDS Institute. Copay accumulator adjustment programs. June 2020. http://www.theaidsinstitute.org/sites/default/files/attachments/AI_CoPay_Accumulator_Adjustment_Brochure_w%20Appendix_FINAL.pdf.

recently acknowledged them, commenting that accumulator adjustment programs harm patients by "shift[ing] costs back to the patient prematurely by not applying the full value of the manufacturer-sponsored assistance to a patient's health plan deductible."[22] Further, "[u]pon exhaustion of the value of the manufacturer's assistance …[,] the beneficiary of the manufacturer-sponsored assistance must pay the remaining amount of their deductible for the drug before the plan's benefit begins."[23] "When this happens," HHS recognized, "the patient may be forced to stop taking the drug, switch to an alternative offered by the plan, or pay the full bill for the non-formulary drug, none of which are patient-friendly, especially for those patients with rare and life threatening conditions."[24] For these reasons, we continue to urge HHS, along with the Departments of Labor and Treasury, to implement the ACA's annual limit on cost-sharing provision as Congress intended and ban the practice of accumulator adjustment programs.

To the extent that plans and PBMs continue to use accumulator adjustment programs to misappropriate manufacturer assistance, such assistance does not constitute remuneration to the plan or PBM because it does not alter the net price paid by the plan or PBM for the medicine, nor is it offered by or intended by the manufacturer to reduce the costs of the plans or PBMs. Any reduction in drug costs that the plan or PBM unilaterally achieves through accumulator adjustment programs occurs against the will of and without the consent of the manufacturer and at the expense of patients. To the extent a plan or PBM reduces its expenses for medicines or other health care services by increasing patient cost sharing, through an accumulator adjustment program or otherwise, the aggregate costs reported by the plan should be reduced accordingly.

Question B.2

PhRMA is concerned that PBM practices steer patients to PBM-owned pharmacies and, in doing so, may restrict patients' access to medicines.[25] In defining "pharmacy," the Departments and OPM should consider distinguishing between community and PBM-owned pharmacies. The PBM industry is consolidating and integrating, with major PBMs typically owning specialty, mail-order, and/or retail pharmacies. PBMs often – through health plans – require or incentivize patients to use the pharmacies that the PBMs own. At the same time, PBMs' network participation agreements with independent retail pharmacies can be burdensome and confusing for these pharmacies and can jeopardize their economic viability. PBM-imposed fees and claw-backs can appear arbitrary and create an unlevel playing field, especially when the economic incentives may be different for a PBM-controlled pharmacy. PBMs have been known to unilaterally increase fees on independent pharmacies, require drugs be dispensed through PBM-owned pharmacies, or impose below-acquisition cost reimbursement on independent pharmacies.[26]

---

[22] 85 Fed. Reg. 87000, 87049 (Dec. 31, 2020).
[23] *Id*.
[24] *Id*. at 87050.
[25] National Community Pharmacists Association. PBM business practices one pagers. December 2020. https://ncpa.org/sites/default/files/2020-12/pbm-business-practices-one-pagers.pdf.
[26] Pacific Research Institute. Economic costs of pharmacy benefit managers. May 2017. https://www.pacificresearch.org/wp-content/uploads/2017/06/PBM_Lit_Final.pdf.

The first step to addressing the detrimental impact of these practices is understanding them, so reporting on PBM-pharmacy transactions should be detailed enough to understand the differences in payment practices to PBM-owned and community pharmacies.

Questions B.3, B.4, and B.5

PhRMA recommends that for the purpose of this reporting, the term "prescription drug" should generally be defined the same way across each field. Consistency is particularly important here because the section 204 reporting will address price and utilization trends according to several different metrics (utilization, net price, rebates), and using different identifiers for the same medicines could result in misleading comparisons among the reported data.

D. Information Required to be Reported

Questions D.1, D.2, and D.5

Regarding the 50 most frequently dispensed brand medicines, the 50 medicines with the greatest expenditure increases, and the 25 medicines yielding the greatest discounts from manufacturers, as required by the CAA, it is essential to produce data that meaningfully illuminate the contribution of prescription medicines and PBMs to health care costs. Therefore, reporting requirements must be designed to collect and present data in the appropriate context. This means data on pricing and expenditures for medicines should be reported net of rebates and other remuneration. Furthermore, data on plan expenditures and rebates should reflect real-world utilization of medicines, not merely net *unit* price. The goal of section 204 is to identify elements of medicine costs that play the largest role in the health care system. A single price increase, even by a high percentage, for a medicine with very low utilization is unlikely to have a significant impact on overall expenditures. The focus instead is on the major categories of plan expenditure. Therefore, focusing on aggregate net expenditures, reflecting utilization and rebates, best achieves this goal.

Question D.6

Health plans' reporting of prescription costs must fairly and accurately compare the cost of medicines to other components of health care spending, including hospital and physician services. As discussed above, pharmaceutical manufacturers negotiate significant discounts with health plans and PBMs, typically through post-point-of-sale rebates. In order to ensure that comparisons between medicine spending and other categories of health care spending are accurate, health plans' reporting of medicine costs should be net of rebates and other price concessions.

To the extent the regulations require health plans to separately report expenditures on physician-administered drugs (instead of including this amount in total expenditures for hospital and physician services), the regulations should specify that reporting of medicine expenditures should be limited to the physician or hospital's *acquisition cost* for the medicine, not the inflated cost reimbursed by the health plan. Allowing health plans to report medicines costs as the total

amount they pay a hospital or physician would seriously overestimate spending on prescription medicines. Actuaries at Milliman have found that on average, hospitals are reimbursed 247% of their acquisition costs for medicines administered in the outpatient setting.[27] In short, hospitals may earn far more for administering a medicine than the company that discovered and manufactured the treatment. Allowing hospitals to categorize the revenues they receive from administration costs and markups as spending attributable to prescription medicines would significantly obscure the role hospitals play in driving health care spending. Finally, insofar as physician-administered drugs are reported separately from hospital and physician services, it is important that they are not double-counted as both.

Question D.7

PhRMA recommends that data be reported separately by market, state, and employer size. Market (fully insured group, self-insured group, or individual), state of licensure or plan sponsor, and employer size (small or large) are the basic parameters that govern health plan regulation and oversight, so it makes sense that this reporting should be separated according to those criteria. Permitting national reporting would preclude reasonable comparisons, as some health plans operate in only a single state or market, whereas others operate nearly nationwide. Therefore, aggregating at the level of the plan would produce results that defy easy comparison. Additionally, costs of the health care delivery system can vary significantly by region, so state-by-state reporting can illustrate the costs driven by the health care delivery system.

Questions D.8 and D.11

PhRMA has long been concerned that health plans and PBMs have consistently failed to share rebates and discounts negotiated with manufacturers with patients at the point-of-sale. On average, brand medicine net prices are 44% lower than their list prices in part due to significant rebates, discounts, and other price concessions negotiated between manufacturers and PBMs.[28] These rebates and discounts contribute to the $187 billion in total price concessions paid by manufacturers in 2020.[29]

Rebates, discounts, and other price concessions that PBMs negotiate substantially reduce the net price paid by the plan sponsor. However, plans generally structure their benefits such that patients pay cost sharing based on a medicine's undiscounted list price, rather than the discounted price paid by the PBM and health plan. Coinsurance and deductibles account for more than half of commercially insured patient spending on brand medicines across many

[27] Milliman. Analysis of 340B hospitals' outpatient department acquisition cost and commercial reimbursement for physician-administered brand medicines. December 2019. https://www.milliman.com/-/media/milliman/pdfs/articles/margin_analysis_of_hopd_rx_at_340b_hospitals.ashx.
[28] IQVIA. Use of medicines in the U.S.: spending and usage trends and outlook to 2025. May 2021. https://www.iqvia.com/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-us#:~:text=Total%20net%20spending%20on%20medicines,off%2Dinvoice%20discounts%20and%20rebates.
[29] Drug Channels Institute. The 2021 economic report on U.S. pharmacies and pharmacy benefit managers. March 2021. https://www.drugchannels.net/2021/03/new-2021-economic-report-on-us.html.

therapeutic areas and are usually based on the undiscounted list prices, forcing patients to pay cost sharing that does not reflect the cost net of rebates and discounts.[30]

This practice can result in a plan or PBM realizing a net gain when a prescription is filled. For example, imagine a patient enrolled in a high-deductible health plan who takes a medication with a list price of $400. The patient's health plan has negotiated a 55% rebate, which substantially reduces the cost to the plan. However, because the patient has not yet met his deductible, his plan does not provide any coverage for the prescription, and the patient's bill reflects the medication's full list price of $400. Despite paying nothing for this patient's medicine, the plan still collects the rebate, earning over $220.[31] In essence, plans and PBMs have historically "double dipped." Not only do they receive manufacturer rebates, but rather than allowing them to be carried forward to patients, they also generally calculate cost-sharing and deductible obligations based on a list price that does not reflect the actual cost that has been incurred by the plan or PBM for the medicine.

Manufacturer rebates are often not directly shared with patients at the point-of-sale and instead captured by others in the supply chain. In 2018, nearly half of all spending on brand medicines was received by entities other than the manufacturer that researched and developed the product, including PBMs, insurers, and others.[32] PhRMA has long advocated for sharing negotiated rebates directly with patients at the point-of-sale. This would represent an important step toward improving medicine affordability and ensuring patients can access the medicines they need.

Compounding these issues are the growth of benefit designs that impose high out-of-pocket cost-sharing and deductible obligations on enrollees. Enrollment in high-deductible health plans and use of coinsurance for medicines has grown sharply in recent years, increasingly exposing patients to high out-of-pocket costs based on medicines' undiscounted list prices.[33] Further, use of deductibles and coinsurance has increased particularly acutely for new medicines that represent the most innovative therapies and often treat the sickest patients.[34]

High cost sharing is a cause for concern, as a substantial body of research clearly demonstrates that increases in out-of-pocket costs are associated with both lower medication adherence and

---

[30] IQVIA analysis for PhRMA. Faced with high cost sharing for brand medicines, commercially insured patients with chronic conditions increasingly use manufacturer cost-sharing assistance. July 2020. https://phrma.org/report/Commercially-Insured-Patients-with-Chronic-Conditions-Face-High-Cost-Sharing-for-Brand-Medicines.

[31] *See*, PhRMA. Follow the dollar. November 2017. http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf (for illustrative examples of the flow of payment for prescription medicines across the supply chain).

[32] Berkeley Research Group. Revisiting the pharmaceutical supply chain: 2018-2018. January 2020. https://www.thinkbrg.com/insights/publications/revisiting-the-pharmaceutical-supply-chain-2013-2018/.

[33] Peterson-Kaiser Family Foundation. Tracking the rise in premium contributions and cost-sharing for families with large employer coverage. August 2019. https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributions-and-cost-sharing-for-families-with-large-employer-coverage/.

[34] IQVIA. Medicine spending and affordability in the U.S. August 2020. https://www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us; IQVIA analysis for PhRMA. Commercially insured patients with chronic conditions face high cost sharing for brand medicines. January 2021. https://phrma.org/report/Commercially-Insured-Patients-with-Chronic-Conditions-Face-High-Cost-Sharing-for-Brand-Medicines.

increased abandonment rates, putting patients' ability to stay on needed therapies at risk.[35] For beneficiaries with a serious illness or multiple chronic conditions, out-of-pocket expenses for prescription medicines can easily add up to many thousands of dollars annually, resulting in patients with chronic or life-threatening illnesses such as diabetes, schizophrenia, multiple sclerosis, and cancer walking away from the pharmacy counter without filling vital prescriptions.[36] High rates of medication nonadherence raise fundamental concerns about patient health and safety, as well as costs for the broader health care system.

Plans often use funds directly intended to discount medicines for patients to defray overall plan spending.[37] Putting aside that the fraction of retained rebates that plans use toward reducing patient premiums is not always significant or adequate, this also creates fundamental mis-incentives with respect to plan design: in effect, the sick are subsidizing the healthy. As the actuarial firm Milliman has pointed out,[38] the practice results in a system of "reverse insurance" where payers require sicker patients using brand medicines with rebates to pay more out of pocket, while rebate savings are spread out among all plan enrollees in the form of lower premiums. Having sicker patients with high medicine costs subsidize premiums for healthier enrollees is the opposite of how health insurance is intended to work. In effect, the current system has created a tax on the sick.[39]

Reporting by health plans on the amount of rebates that are used to lower the cost of premiums, instead of reducing cost sharing for patients taking rebated brand medicines, will help illuminate this problem and drive policy solutions.

Question D.9

PhRMA recommends that information collected on rebates and other remuneration be broken out into relevant categories, such as PBM-retained rebates, PBM incentive payments, and administrative services payments, consistent with the information collection for qualified health plan PBM transparency under section 1150A of the Social Security Act. This level of detail is important to understand the contributions of PBMs to health care costs.

---

[35] IMS Institute for Healthcare Informatics. Emergency and impact of pharmacy deductibles: implications for patients in commercial health plans. September 2015. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/emergence-and-impact-of-pharmacy-deductibles.pdf; Doshi JA, et al. High cost sharing and specialty drug initiation under Medicare Part D: a case study in patients with newly diagnosed chronic myeloid leukemia, 22 Am. J. Managed Care 4 Suppl. (2016):S78-S86; Brot-Goldberg ZC, et al. What does a deductible do? the impact of cost sharing on health care prices, quantities, and spending dynamics, NBER Working Paper 21632, October 2015; Eaddy MT, et al. *How patient cost sharing trends affect adherence and outcomes*, 37 Pharmacy & Therapeutics 1 (2012).

[36] IQVIA for PhRMA. Faced with high cost sharing for brand medicines, commercially insured patients with chronic conditions increasingly use manufacturer cost-sharing assistance. July 2020. https://phrma.org/report/Commercially-Insured-Patients-with-Chronic-Conditions-Face-High-Cost-Sharing-for-Brand-Medicines.

[37] Drug Channels Institute. Employers are getting more rebates than ever—but sharing little with their employees. January 2018. https://www.drugchannels.net/2018/01/employers-are-getting-more-rebates-than.html ("[M]ore than two-thirds of employers use rebate payments to offset overall spending on drug costs. Only 11% use rebates to offset member premiums, an option that spreads the benefit to all employees.").

[38] Milliman. 2017 Milliman medical index. May 2017. https://www.milliman.com/en/insight/periodicals/mmi/2017-milliman-medical-index/.

[39] *Id*.

PBMs commonly negotiate arrangements with their health plan and employer clients that allow them to retain a portion of negotiated rebates and other price concessions as compensation for their services.[40] As industry and government experts have noted, PBMs may have incentives to establish formularies that favor medicines with high list prices, and large rebates, over lower list price medicines.[41] As discussed more fully in the response to Question B.1., the complex set of rebates and fees can make it difficult for payers to assess whether they are fully benefiting from all price concessions that PBMs negotiate.

PhRMA supports policies that help patients make better health care choices and will make the health care system operate more efficiently without harming competition in the market or putting proprietary information at risk. Such policies should: (1) give meaningful information to employers and/or patients about how to use health care and health insurance; (2) apply prospectively so that the regulated industry has time to comply accurately and completely with the reporting obligations; and (3) preserve the confidentiality of proprietary information.

Consistent with the information collection under Social Security Act section 1150A, health plans should be required to disclose several data elements, including the total amount of rebates and price concessions (including incentive and administrative payments) the PBM negotiates with manufacturers and pharmacies, the dollar amount passed through to plans, and the aggregate amount of the difference between the amount a plan sponsor pays for prescription medicines and the amount paid to the pharmacy by the PBM. These data would provide meaningful information to health issuers, employers, and other plan sponsors that would allow them to effectively negotiate on behalf of enrollees to ensure they are fully benefiting from PBM-generated savings. These data would also facilitate other reporting required under this regulation regarding the amount of remuneration used to reduce premiums and out-of-pocket costs. HHS should study the reported data, publish summary findings, and propose policy changes that would permit broader access to information about PBM practices.

Question D.10

There may be limited instances where plans or PBMs make direct payments to manufacturers (e.g., in the case of value-based arrangement contracts where previously made payments may be adjusted based on outcomes). Insofar as such payments are made to manufacturers to offset or reconcile rebates owed, they should be netted against rebates and other price concessions.

---

[40] Altarum. The impact of prescription drug rebates on health plans and consumers. April 2018. https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf.

[41] *See e.g.*, Drug Channels Institute. The gross-to-net bubble hit $175 billion in 2019: why patients need rebate reform. August 2020. https://www.drugchannels.net/2020/08/the-gross-to-net-bubble-hit-175-billion.html; Medicare Payment Advisory Commission. Report to the Congress: Medicare payment policy. chapter 14: the Medicare Prescription Drug Program (Part D): status report. March 2018. http://medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0; 84 fed. reg. 2340 (Feb. 6, 2019); United States Senate Finance Committee. Insulin: examining the factors driving the rising cost of a century old drug. January 2021. https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.

Other Sections

Question A.6 and F.4

At least nine states have implemented programs that require insurers to report information similar to the requirements of the CAA.[42] Many of those states require that insurers and PBMs provide information on manufacturer discounts. As with any state program or effort, there have been varying approaches for implementation based on factors such as individual state goals and technological capabilities or limitations. While PhRMA does not believe that any state has an ideal program on which the Departments and OPM should fully base their efforts, PhRMA generally supports meaningful transparency measures that will afford patients the opportunity to make informed decisions about their health care. PhRMA believes that the Departments and OPM should aim for the standardization of common elements across transparency programs to improve the utility and accuracy of information reported. This includes standard policies to account for drug manufacturer discounts in certain reporting fields that could impact policymaking.

The value of these principles is demonstrated by recent state reports, which provide evidence that properly accounting for drug manufacturer discounts can provide clarity on cost drivers that should aid in developing policy solutions that will benefit patients the most. For example, recent reports have shown that when rebates were accounted for, pharmacy spending increased at a lower rate than other major health care service categories[43] and that spending on prescription drugs net of rebates accounts for about 11% of total health plan premiums.[44] Unfortunately, some reports by health insurers do not properly account for manufacturer discounts, which can result in findings that do not adequately reflect the complexity of the pharmaceutical supply chain. Other state reports have highlighted the impact that the activities of certain pharmaceutical supply chain entities can have on patient spending and total health care costs. For example, at least two states have reported on PBM revenue generated from manufacturer rebates and the extent to which patients could benefit if those rebates were shared with patients at the point of sale. With regards to manufacturer rebates, one state has reported that:

> "Because this cost reduction is only realized by payers, the overall consumer cost share percentage increased from 23.49% to 26.79% after rebates were applied. If rebate amounts were instead distributed between payers and consumers according to the rate of initial cost sharing, consumers would have realized out of pocket cost savings of 20.89% for brand drugs, an 11.75% cost reduction overall."[45]

PhRMA requests that the Departments and OPM continue to work with pharmaceutical supply chain stakeholders in the development of their reporting systems, especially as other federal

---

[42] CA, CT, ND, OR, TX, UT, VT, VA, WA
[43] Massachusetts Center for Health Information and Analysis. Annual report: performance of the Massachusetts health care system. March 2021. https://www.chiamass.gov/assets/2021-annual-report/2021-Annual-Report.pdf.
[44] California Department of Managed Health Care; Prescription drug cost transparency report for measurement year 2019. 2021. https://www.dmhc.ca.gov/Portals/0/Docs/DO/2019SB17PrescriptionDrugTransparencyReport.pdf.
[45] Maine Health Data Organization. Prescription drug pricing transparency report. February 2021. https://mhdo.maine.gov/_pdf/MHDO%20Rx%20Transparency%20Report%20210209%20FINAL.pdf.

transparency efforts regarding health care costs are implemented. PhRMA appreciates the agencies' efforts to use the experience of states in its development of reporting systems and the agencies' recognition that aggregated information is necessary to protect the integrity of current systems. We urge the Departments and OPM to ensure that any aggregated public information does not lead to more confusion or complication of the pharmaceutical supply chain.

Questions C.3 and C.4

The Departments and OPM should be cautious about the role of PBMs in reporting. PBMs are an important source of information for reporting, but a persistent problem has been the opacity of their disclosures to the public and even to their own clients. It is important that PBMs be subject to strong compliance measures to ensure the government receives accurate and forthright reporting.

PBMs are incentivized to keep data about their dealings with manufacturers and plan sponsors confidential because current business practices may allow PBMs to benefit at the expense of patients and plan sponsors. As a recent report by the Senate Finance Committee on the insulin market demonstrates, pharmaceutical manufacturers compete fiercely using rebates to lower list prices, but those savings are often not shared with patients with deductibles or coinsurance.[46]

Because PBM incentives may not always be aligned with those of patients or plan sponsors, the Departments and OPM should be cautious about relying on data submissions directly from PBMs. The regulations should ensure that PBMs provide complete and accurate data to plan sponsors, who should be responsible for submissions to the government.

Question F.5

International price comparisons are flawed for many reasons and therefore should not be included in the Departments' and OPM's public reports. First, most international comparisons focus solely on list prices and exclude from calculations the steep discounts and rebates negotiated by health plans and PBMs in the United States (discussed in detail above). For example, the public price of a drug in the United States is often the wholesale acquisition cost (a pre-negotiated price), despite most Americans paying a much lower price (post-negotiated price), whereas in other countries, the public price of a drug has already been negotiated on behalf of the patient and is often the price patients would actually pay. As a result, observed international price differentials based only on list prices can be significantly inflated and misleading.[47]

Secondly, international price comparisons fail to acknowledge the effect of the competitive United States market in controlling costs. High generic utilization rates, competition among brand medicines, and aggressive tactics by insurers and PBMs to negotiate prices all help to control how much the U.S. health care system spends on medicines. For example, 90% of prescription medicines dispensed in the United States are low-cost generic medicines, compared

[46] United States Senate Finance Committee. Insulin: examining the factors driving the rising cost of a century old drug. January 2021. https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.
[47] RAND. International prescription drug price comparisons. 2021. https://www.rand.org/pubs/research_reports/RR2956.html.

to 69% in France, and 67% in Australia.[48] Critically, generic medicines are, on average, cheaper in the United States than in other developed countries, producing significant system-wide savings.[49] These unique dynamics are lost when looking only at individual medicine price differentials.

It is also important to consider the effect of price-setting tactics that are used in other countries. Decreased access to medicines is a common feature of health systems with government price setting. The United States leads the world in access to new medicines as a result of our country's market-based system. Nearly 90% of new medicines launched since 2011 are available in the United States compared to just half in other developed countries like the United Kingdom and Canada.[50] Among medicines that eventually become available in these countries, patients must often wait an average of 17 months longer to access treatments than patients in the United States.[51] Additionally, 78% of new medicines launched globally since 2011 were available in the United States within one year compared to just 25% for Canada, 17% for France, and 13% for Australia.[52] Further, price controls would have a significant impact on research and development in the United States at a time when we are leading the world in innovative therapies, and price controls outside of the U.S. have already resulted in negative impacts to the development and availability of new therapies.[53]

International medicine price comparisons lack context and incorrectly imply that medicine price differentials are a major driver of increased health care spending in the United States. For example, retail medicine spending only accounts for 7% of the difference in overall health care spending between the United States and Canada.[54] And prices for many health care services are higher in the United States compared to other countries. For example, the average price of a nightly hospital stay in the United States is nearly seven times more than in Australia.[55] It is critical for policymakers to put price differentials into context rather than considering prescription medicines in a vacuum.

Similarly, comparing health care costs across different markets or payer types within the U.S. can lead to inaccurate and misleading analyses. Many differences exist in reimbursement methodologies such as fee-for-service schedules, value-based arrangements, statutorily required use of various pricing metrics, and statutorily required discounts and rebates for certain payers.

---

[48] PhRMA analysis of IQVIA Innovation Insights. Generic share of 2019 prescription medicine volume in standard units. March 2020.
[49] RAND. International prescription drug price comparisons. 2021. https://www.rand.org/pubs/research_reports/RR2956.html.
[50] PhRMA analysis of IQVIA Analytics Link and U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) data on new active substances first launched globally between January 2011 and December 2020. April 2021.
[51] *Id*.
[52] *Id*.
[53] *See*, NDP Analytics. Will US leadership in biopharmaceutical R&D continue? consequences of price controls and other anti-innovation policies. November 2020; Schwartz, T., A. Ward, X. Xu, and J. Sullivan. The Impact of lifting government price controls on global pharmaceutical innovation and population health. 21 Value in Health 1 Suppl. 2018. https://www.valueinhealthjournal.com/article/S1098-3015(18)31110-0/fulltext.
[54] PhRMA analysis of Organisation for Economic Co-operation and Development (OECD). Health resources: health spending and pharmaceutical spending indicators. https://www.oecdilibrary.org/social-issues-migration-health/health-resources/indicator-group/english_777a9575-en.
[55] International Federation of Health Plans. 2017 comparative price report: international variation in medical and hospital prices by country. 2017.

These differences in reimbursement methodologies can lead to further differentials in prescribing and utilization patterns. Thus, comparisons across commercial and public programs markets would be far from "apples-to-apples" and could yield results that are more confusing than they are informative.

Protection of Confidential Information

We appreciate that, consistent with the CAA, the Departments and OPM have acknowledged the importance of maintaining confidentiality of information aggregated to create the public report. We note that certain information reported to the Departments and OPM may contain "trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential."[56] We also note that the Trade Secrets Act makes it illegal to disclose that information[57] and the Departments and OPM would be prohibited from disclosing it, whether through a Freedom of Information Act request or otherwise.

***

PhRMA appreciates the opportunity to comment on the request for information and looks forward to working with you on the proposed regulation. We are happy to discuss these comments if it is helpful and provide any further detail that you request.

Sincerely,

Emily Donaldson
Deputy Vice President
Policy and Research

Lisa Lowenstein
Assistant General Counsel

[56] 5 U.S.C. § 552(b)(4).
[57] 18 U.S.C. § 1905. *See also Canadian Commercial Corp. v. Dep't of the Air Force*, 514 F.3d 37, 39 (D.C. Cir. 2008) ("unless another statute or a regulation authorizes disclosure of the information, the Trade Secrets Act requires each agency to withhold any information it may withhold under Exemption 4").