Memorandum

April 8, 2022

Overview of the Pharmacy Benefit Manager Regulatory and Legislative Landscape

I. Executive Summary

While legislative momentum for drug pricing reform has waned since the Build Back Better (BBB) Act stalled, regulators and legislators have continued to focus on pharmacy benefit managers (PBMs) and their role in the pharmaceutical supply chain. As this recent attention has been spread across different agencies and between the federal and state legislatures, the Wynne Health Group has compiled recent actions involving PBMs to provide the current landscape regarding PBM oversight.

Looking forward, we can expect significant PBM activity at the state level, as states continue to enact legislation to impose licensure requirements and prohibit certain actions. If a second attempt at reconciliation is pursued this year, the new package could feature similar PBM transparency provisions as the BBB Act, but such a proposal is unlikely to be a significant cost saver. Elsewhere, with new access to direct and indirect remuneration (DIR) data, we could also expect the Medicare Payment and Access Commission (MedPAC) to explore recommendations targeted at PBM practices this fall, as well as the Federal Trade Commission pursuing a PBM study as a result of their request for comments.

II. High-Level Summary of Recent Federal Regulatory Actions

The chart below encapsulates the recent regulatory actions from the Centers for Medicare and Medicaid Services (CMS), the Departments of Health and Human Services (HHS), Labor, and Treasury (Tri-Agency) and the Office of Personal Management (OPM), and the FTC . Most actions focused on increased transparency and reporting requirements. Additional details of each regulatory development follow.

Agency	Action	Implementation or Issue Date
HHS and CMS	The 2021 Notice of Benefit and Payment Parameters Final Rule allows commercial plans to implement copayment adjustment programs for all drugs (i.e., exclude coupon value from OOP limit).[1]	Applies to ACA plans beginning in the 2021 benefit year.
	The Medicaid Valued-Based Payment final rule allowed the exclusion of PBM copay accumulators from the calculation of best price.[2]	Takes effect Jan. 1, 2023.
	The CY 2023 Medicare Advantage and Part D Policy and Technical Changes proposed rule proposes to amend the definition of	If finalized, the proposal would take Jan. 1, 2023.

[1] https://www.federalregister.gov/documents/2020/05/14/2020-10045/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2021

[2] https://www.federalregister.gov/documents/2021/05/28/2021-11160/medicaid-program-establishing-minimum-standards-in-medicaid-state-drug-utilization-review-dur-and

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	"negotiated price" to ensure that all price concessions are reflected at the point of sale.[3]	
Tri-agency and OPM	As required by the year-end omnibus, the Prescription Drug and Health Care Spending Interim Final Rule requires plans and issuers in the group and individual markets to submit information on prescription drug spending, including rebates and other remuneration.[4]	Plans must report by December 27, 2022.
FTC	The Report to Congress on Rebate Walls examines how such a practice impacts competition in pharmaceutical markets and may lead to increased pharmaceutical spending [5]	May 28, 2021
	The FTC voted against a study to examine PBM contracting practices with a 2-2 deadlock from Commissioners.[6]	Feb. 17, 2022.
	After the deadlock vote on the PBM study, the FTC subsequently issued a Request for Information (RFI) on how PBMs are affecting drug affordability and access.[7] The FTC indicated this RFI would inform future work the agency may take on the PBM industry.	Issued Feb. 24, 2022. Comments are due April 25

In the following sections, we provide additional detail on each of the above-mentioned regulatory developments.

A. HHS and CMS

CMS has renewed its focus on PBM practices, including the use of copay accumulator programs and direct and indirect remuneration (DIR) fees. This is especially true following the partial repeal of the Trump Administration's "rebate rule," which would have affected the PBM supply chain.

Below we summarize key actions since 2020:

- **Copay Accumulator Programs** – Copay accumulator programs and copay maximizer programs allow insurance plans to exclude manufacturer assistance programs' coupon value from accruing towards a beneficiary's deductible or out-of-pocket maximum.[8] The following two final rules address PBMs' use of copay accumulators in the private and Medicaid markets:

    - **The 2020 and 2021 Notice of Benefit and Payment Parameters final rules**: CMS formally established that non-grandfathered individual and group plans, including Qualified Health Plans, can implement copayment adjustment programs for all drugs.

    - **The 2020 Medicaid Value-Based Purchasing final rule:** CMS finalized exclusion of PBM copayment accumulators for Medicaid's calculation of best price. Prior to the final rule,

[3] https://www.federalregister.gov/documents/2022/01/12/2022-00117/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and
[4] https://www.federalregister.gov/documents/2021/11/23/2021-25183/prescription-drug-and-health-care-spending
[5] https://www.ftc.gov/news-events/news/press-releases/2021/05/federal-trade-commission-sends-report-congress-rebate-walls
[6] https://www.ftc.gov/news-events/news/press-releases/2022/02/ftc-announces-tentative-agenda-february-17-open-commission-meeting
[7] https://www.ftc.gov/news-events/news/press-releases/2022/02/ftc-requests-public-comments-impact-pharmacy-benefit-managers-practices
[8] https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2021-AccumulatorsPolicyBrief.pdf

manufacturer coupons were excluded from the calculation of best price to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other entity does not receive any price concession. With the rise of copay accumulator programs, CMS asserted that health plans are benefiting from the coupon value instead of the patient.

Furthermore, CMS asserts that manufacturers are fully aware of such accumulator programs and have the ability to establish covered criteria around their manufacturer-sponsored assistance programs to ensure that the benefit goes exclusively to the patient. This proposal takes effect January 2023.

- **DIR Fees** – In the Contract Year (CY) 2023 Policy Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs proposed rule, CMS proposed to amend the definition of "negotiated price" to ensure that all price concessions, including DIR fees, are reflected at the point of sale. CMS asserts that the current definition results in the negotiated price not reflecting any performance-based pharmacy price concessions that lower the price that plan sponsors pay. CMS expects the new definition to reduce beneficiary cost sharing, as the out-of-pocket costs would be calculated using the price net of all concessions, including direct and indirect renumeration and rebate

  Part D sponsors and PBMs would be required to load revised drug pricing tables reflecting the lowest possible reimbursement into their claims processing systems that interface with contracted pharmacies. If finalized, the proposal would take effect January 1, 2023.

B. Tri-Agency & OPM

Pursuant to Section 204 of the Consolidated Appropriations Act of 2021, the Tri-Agencies and OPM issued an interim final rule with comment period (IFC) to implement the health insurance plan reporting requirements on prescription drug and health care spending. Under the IFC, group plans will be required to report aggregate data on the costliest prescription drugs, the most frequently prescription drugs, and the prescription drugs with the greatest increase in expenditures. Using this information, the Departments will biannually issue a Section 204 public report on prescription drug pricing trends, and the role of prescription drug costs in contributing to premium increases or decrease, to aid in future policymaking.

While this is not specific to PBM reporting, plans will be required to report any impact on premium by rebates, fees, and any other remuneration paid by drug manufacturers to the plan or its PBM, including:

- The amounts paid for each therapeutic class of drugs;
- The amounts paid for each of the 25 drugs that yielded the highest amount of rebates and other renumeration under the plan from drug manufacturers during the plan year; and
- Any reduction in premiums and out-of-pocket costs associated with rebates, fees, or other renumeration.

C. FTC

In May 2021, pursuant to request from Congress, the FTC released a report on the rebate walls. The report defines rebate walls as "a situation in which a dominant pharmaceutical manufacturer uses rebate strategies in its contracts with third party payors to maintain market power, by giving its products preferred status in drug formularies, and to prevent sales of competing products." The report asserts that rebate walls may give payers strong incentives to block patient access to lower-priced medicines, which can lead to an increase in overall drug spending. The FTC also examines the antitrust implications for rebate walls, including instances in which the practice may illegal.

At the conclusion of the report, the FTC notes that it is considering rulemaking, including competition guidance with respect to pharmaceutical industry practices. The FTC already has existing guidance on Antitrust Enforcement Policy in Health Care but may issue guidance specifically aimed the pharmaceutical supply chain.[9]

In February 2022, the FTC convened a meeting to vote on whether to investigate PBM pricing and contractual practices. Specifically, the FTC voted on whether to issue orders to large PBMs to study the competitive impact of contractual provisions, reimbursement adjustments, and other practices affecting drug prices, including those practices that may disadvantage independent or specialty pharmacies. The vote resulted in a 2-2 split, meaning that the study was not approved.

Later that month, the FTC issued a request for public comments on the ways that pharmacy benefit managers (PBMs) affect drug affordability and access. The agency details that the public input will help inform the FTC's policy and enforcement work and notes that agency is currently exploring a variety of PBM practices and seeks feedback on how these practices impact patients, physicians, employers, independent and chain pharmacies, and other businesses across the distribution system. Submissions are due April 25.

III. Recent Legislation

Legislation in the 117th Congress and at the state level looks to build upon recent regulatory efforts by imposing even greater transparency, requiring licensure, and prohibiting certain actions. Federally, Congress remains interested in establishing enhanced reporting requirements and public transparency of those reports. At the state level, many states have enacted legislation to increase oversight, including licensure requirements and prohibiting certain PBM actions.

A. Federal Legislation

While the CAA of 2021 enacted provisions to promote greater PBM transparency, major pieces of legislation in 2021 have looked to build upon this initial phase and impose greater transparency while limiting certain actions. Legislators had considered prohibiting PBM spread pricing in Medicaid in the Infrastructure Investment and Jobs Act, and the House-passed version of the Build Back Better Act included a section to expand PBM reporting requirements.

[9] https://www.ftc.gov/system/files/attachments/competition-policy-guidance/statements_of_antitrust_enforcement_policy_in_health_care_august_1996.pdf

Additional federal bills aimed at PBMs are included in the table below.

Proposed Federal Legislation Addressing PBMs

Bill	Summary
House-approved version of the Build Back Better Act	The bill would require health plans and PBMs to report every six months on a variety of information including amount of copay assistance applied, total gross spending on drugs by class, total amount received in manufacturer rebates; total net spending on drugs; and amounts paid directly or indirectly in rebates, fees, or other renumeration to brokers.
H.R. 5260, Reduced Costs and Continued Cures Act	The bill would strengthen PBM transparency requirements by publicly disclosing PBM rebate information. It also requires a report on the pharmaceutical supply chain, intermediaries, and merger activity, which includes an examination of specified PBM practices.
H.R. 19,the Lower Costs, More Cures Act, and H.R. 1829 / S. 298, the Pharmacy Benefit Manager Accountability Study Act of 2021	The bills require the Government Accountability Office (GAO) to study the role of PBMs in the pharmaceutical supply chain and provide recommendations with appropriate policy recommendations.
H.R. 6101, the Drug Price Transparency in Medicaid Act of 2021	The bill would prohibit PBMs from engaging in spread pricing in Medicaid. It would also prohibit PBMs from discriminating against 340B entities and contract pharmacies.

B. State Legislation

Over the past few years, state legislatures have explored a variety of bills aimed at PBMs, including licensure requirements, reporting and transparency requirements, and prohibiting certain actions. Currently, 44 states have PBM licensure requirements, 42 states have a regulatory agency for PBM enforcement, and 31 states have reporting and transparency requirements.[10]

Regarding prohibited actions, 10 states have laws that address PBMs and non-discrimination against 340B entities, 14 states ban spread pricing; and 22 states have laws that address utilization management practices, including prior authorization, step-therapy, and non-medical switching. The chart below provides illustrative examples of passed PBM legislation this year.

[10] https://www.ncsl.org/research/health/state-policy-options-and-pharmacy-benefit-managers.aspx#/

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Enacted State Legislation Addressing PBMs

Bill	Summary
MI HB 4348	The bill increases transparency and oversight of PBMs in the following ways: 1) PBMs to obtain a license to operate within the state; 2) PBMs must submit annual transparency reports detailing aggregate rebate information; and 3) PBMs may not discriminate against 340B entities regarding reimbursement nor participation in network.
NE LB 767	The bill prohibits the use of gag clauses by PBMs and requires PBMs to reimburse 340B entities at the same rate as non-340B entities, and prevents PBMs from interfering with a patient's choice to receive a prescription drug from their pharmacy of choice,
NY A 8838	This measure prohibits the use of gag clauses by PBMs in their contracts with pharmacies and PBMs must also make an annual report to the Superintendent of Financial Services detailing pricing discounts and rebates.

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