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More Federal Action in the Pharmaceutical Sector as PBM Bill Advances in the Senate

Article By:

Constance A. Wilkinson

Alan J. Arville

Alexis Boaz

On May 11, the U.S. Senate Committee on Health, Education, Labor, and Pensions (the "HELP Committee" or the "Committee") passed a bipartisan bill to expand federal regulation of pharmacy benefit managers ("PBMs") for group health plans.[1] As a compromise by Health Sub-Committee Chair Bernie Sanders (I-VT) and ranking Republican Bill Cassidy (LA), the Pharmacy Benefit Manager Act (S. 1339) reflects the overarching legislative push by members from both sides of the aisle and chambers of Congress to address drug pricing issues through federal fixes to the PBM framework. Further, Congress's efforts build on the momentum from the enactment of the high-profile Medicare prescription drug pricing provisions of the Inflation Reduction Act (the "IRA") in 2022. [2]

While it is still relatively early in the legislative process, enactment of provisions in the current iteration of S. 1339 would pose significant impacts to entities across the prescription drug distribution chain, particularly given the ongoing implementation of the IRA, the recent uptick in state-level legislative activity on regulating the relationship between PBMs and pharmacies due to the 2020 *Rutledge v. PCMA* court decision,[3] and other moving policy levers at both the state and Federal level in the pharmaceutical sphere.

An Overview of the Proposed Legislation

On May 2, 2023, the HELP Committee marked up S. 1339, adding several new amendments to create the version of S. 1339 the Committee passed last week. Unlike the IRA, which targeted the Medicare program, the provisions of S. 1339 would apply to the commercial sector, including to both state-regulated group health plans and group health plans regulated under the Employee Retirement Income Security Act ("ERISA"). Summarized at a high-level below,[4] S. 1339's next stop will be the Senate floor.

Notably, many of the policies proposed in S. 1339 may appear familiar as they consist of previously-proposed policy concepts on the federal level, next steps or analogs to relatively recent federal legislation, and/or previous, recent, or ongoing policy initiatives on the state level. Earlier iterations of

the IRA legislation[13] included provisions that would have expanded regulation of the PBM sector in both the commercial market and Medicare but were removed before the legislation's passage.[14] Additionally, many provisions of S. 1339 build off of—or appear parallel or analogous to—changes imposed by the Consolidated Appropriations Act of 2021, including the new reporting requirements, disclosures about direct and indirect compensation, the provisions regarding plan data access for patients and providers, and the prohibition on blocking consumer decision-support tools.

Other provisions in the legislation are similar to policy proposals to regulate PBM activity in other payor markets, such as Medicaid. For example, Representative Buddy Carter (R-GA) recently introduced legislation, Drug Price Transparency in Medicaid Act (H.R. 1613), to impose a federal ban on spread pricing in Medicaid managed care and require pharmacies to be reimbursed a minimum of a drug's national average drug acquisition cost ("NADAC").[15] CMS establishes NADAC—a federal pricing benchmark utilized by CMS for Medicaid reimbursement based on pharmacy reports of acquisition cost to CMS—using the average cost. While NADAC reporting for pharmacies is currently voluntary, Representative Carter's bill would require all pharmacies to report their NADAC to the survey to increase the accuracy of the benchmark.[16] States have also increasingly focused on addressing "spread pricing" in the context of their Medicaid-managed care programs.[17] Indeed, 9 states have currently banned the usage of spread pricing in their respective state programs.

Impact to the PBM Market

Enactment of the current version of S. 1339 would alter the dynamics of how PBMs bid, market to, and contract with health plans. Particularly, S. 1339 restricts PBMs' ability to offer plans multiple options based on spread pricing and rebates. As a result, some mid-size and new PBMs that currently distinguish themselves based on transparency, non-spread pricing, and 100% rebate pass-through may find it more difficult under the S. 1339 framework to differentiate their services. Further, enactment of S. 1339 would likely force entities to reconsider both how to define and negotiate "rebates" in PBM contracts. In its current form, S. 1339 describes "rebates" broadly in a manner that could potentially capture fees paid by manufacturers to PBMs, not currently identified by PBMs as "rebates" under PBM contracts, to the extent such amounts are based on the level of drug utilization.

Significantly, although S. 1339 would increase transparency and pass rebates along to plans, the policies contained in the proposed legislation would not change the ability of PBMs to negotiate rebates for plans, and thus, does not directly address the position generally espoused by manufacturers that the concentrated negotiating power of PBMs to increase rebates leads to higher list prices.[18] Additionally, while the HELP Committee ultimately advanced S. 1339 with a provision to study the impacts of designating PBMs as fiduciaries and without incorporating an amendment to actually designate PBMs as fiduciaries, the proposed policy could still reemerge as the bill advances through the legislative process.[19] Such provisions could hold PBMs to the same standards as other plan fiduciaries, including imposing the requirement to "discharge duties with respect to a plan solely in the interest of the participants and beneficiaries and for the exclusive purpose of providing benefits to participants and their beneficiaries; and defraying reasonable expenses of administering the plan."[20]

Other PBM Activity on Capitol Hill

Passage of S. 1339 by the HELP Committee represents a larger bipartisan movement across both chambers of Capitol Hill to address PBMs. A few days before the markup of S. 1339, discussion during the HELP Committee's hearing meant to address "The Need to Make Insulin Affordable for

All Americans," shifted in part to focus on policies proposed in S. 1339, as—in addition to drug manufacturer executives—the hearing's panelists included top executives from major PBM companies.[21] Interest in PBMs extends to other committees of healthcare jurisdiction. Earlier this spring, Senate Finance Committee Chair Ron Wyden (D-OR) and Ranking Member Mike Crapo (R-ID)—leadership of the Senate Committee on Finance—issued a bipartisan "legislative framework" to address PBMs and the prescription drug supply chain following a hearing by the Senate Committee on Finance.[22] With jurisdiction over programs such as Medicare and Medicaid, the framework lists the following as potential policy solutions for PBMs:

- "Delinking PBM compensation from drug prices to align incentives for lower costs;
- Enhancing PBM accountability to health plan clients to drive cost-cutting competition and produce better choices for beneficiaries;
- Ensuring discounts negotiated by PBMs produce meaningful savings for seniors;
- Addressing and mitigating practices that unfairly inflate the prices patients and government programs pay for prescription drugs;
- Modernizing Medicare's 'Any Willing Pharmacy' requirements to improve options and access for seniors; and
- Increasing transparency to foster a better understanding of how financial flows across the prescription drug supply chain impact government health care programs."[23]

As a similarly high priority on the House side of the Hill, Representatives Annie Kuster (D-NH), Carter (R-GA), Anna Eshoo (D-CA), and Brett Guthrie (R-KY) introduced a bipartisan bill, the Pharmacy Benefits Manager Accountability Act (H.R. 2679), which includes several provisions similar to S. 1339. H.R. 2679 has been referred to the Committee on Energy and Commerce for consideration.[24]

Looking Forward

The flurry of state and federal-based efforts to address and regulate PBMs within the context of Medicare, Medicaid, and commercial insurance signals that enactment of PBM legislative reform may not be a question of *if*, but—rather—*when*. With 33 Senate seats and all 435 House seats up for re-election in 2024, that *when* may be soon.

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[1] HELP Committee Markup, S. 1339 (as of May 12, 2023) (hereinafter, "S. 1339").

[2] Pub. Law No. 117-169 (signed into law Aug. 16, 2022).

[3] *Rutledge v. Pharmaceutical Care Management Association, 141 S. Ct. 474 , 479 , 208 L. Ed. 2d 327 (2020).*

[4] This summary does not include the amendment addressing exceptions to certain step therapy requirements.

[5] S. 1339.

[6] Herein, “group plans” refer to group health plans issued by health insurance issuers and group health plans as defined under ERISA. Please note that the high-level summary does not capture more specific nuances with respect to differences S. 1339 may apply to the different plan types.

[7] Amendment from Sen. Tammy Baldwin (D-WI).

[8] Amendment from Sen. Markwayne Mullin (R-OK).

[9] Sen. Roger Marshall (R-KS).

[10] Sen. Ed Markey (D-MA).

[11] Sen. Ed Markey (D-MA).

[12] Sen. Mike Braun (R-IN).

[13] Cong. Research Servs., Build Back Better Act (BBBA) Health Coverage Provisions: House-Passed and Senate-Released Language (Mar. 30, 2022).

[14] Cong. Research Servs., Build Back Better Act (BBBA) Health Coverage Provisions: House-Passed and Senate-Released Language (Mar. 30, 2022).

[15] Drug Price Transparency in Medicaid Act. The Health Subcommittee of the House Energy and Commerce Committee has already held a markup on the bill. See Subcommittee Markup Announcement (May 15, 2023).

[16] *Id.*

[17] *Id.*

[18] Outside of the legislative process, the Federal Trade Commission (FTC) is conducting an inquiry into PBMs and their impact on the accessibility and affordability for prescription drugs. On May 17, 2023, the FTC expanded its inquiry of PBMs to two Group Purchasing Organizations (GPOs) that negotiate drug rebates on behalf of other PBMs. *See* FTC Deepens Inquiry into Prescription Drug Middlemen (May 17, 2023).

[19] Gabrielle Wanneh, Employers Look to Senate Floor to Move PBM Fiduciary Policy; Senator Scraps Amendments to RARE Act; Generic Access Bill Moves Despite Lawyer Warnings, Inside Health Policy (May 15, 2023).

[20] 29 U.S.C. § 1104.

[21] U.S. Senate Committee on Health, Education, Labor & Pensions, Full Committee Hearing “The Need To Make Insulin Affordable for All Americans" (May 10, 2023).

[22] *Id.*

[23] U.S. Senate Committee on Finance, Crapo, Wyden Release Legislative Framework to Address PBMs, Prescription Drug Supply Chain (Apr. 20, 2023).

[24] Pharmacy Benefits Manager Accountability Act, H.R. 2679.

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