Pharmacy Benefit Manager Reform Remains Legislative Priority

Article By:

Sarah B. "Cissy" Jackson

The 2022 midterms have concluded, but the Republican underperformance is not expected to dampen Congressional enthusiasm for Pharmacy Benefit Manager (PBM) reform. The issue remains at the forefront of the healthcare pricing debate, and the perception that this is a Republican-driven effort has begun to fade in light of drug pricing reforms in the Inflation Reduction Act (IRA) and a shift in Democrats' attention from manufacturers to other players in the pharmaceutical supply chain. We expect these trends to continue into the 118th Congress.

Changes in Key Committee Leadership

With the Senate firmly in Democratic hands, the leadership of the primary committees with jurisdiction over health care issues on that side of the Hill is likely to remain the same, with a few exceptions noted below. On the House side, a Republican majority, though slight, will entail changes in leadership.

The House Energy and Commerce Committee (E&C) has broad jurisdiction over myriad health policy issues and conducts oversight over federal agencies including the National Institutes of Health (NIH), U.S. Food and Drug Administration (FDA), and other programs administered by the U.S. Department of Health and Human Services (HHS). E&C Ranking Member Rep. Cathy McMorris Rodgers (R-WA) ("CMR") has been very active on health policy issues and is poised to serve as Chair in a Republican majority, with Rep. Frank Pallone (D-NJ) assuming the Ranking Member role at the full committee, and Rep. Anna Eshoo (D-CA) shifting to the same position on the Health Subcommittee.

The other House committee with substantial health policy jurisdiction, including Medicare, is the Ways and Means Committee. Three Republicans are vying for their party's top slot (likely the chairmanship) with observers seeing a toss-up race at this point between Rep. Vern Buchanan (R-FL) and Rep. Jason Smith (R-MO). A flip in majority will likely mean that the current Chairman, Rep. Richard Neal (D-MA), will serve as Ranking Member for Democrats.

Due to the retirement of Sen. Richard Burr (R-NC), and Sen. Susan Collins' ascendance to the Ranking Member's spot on the Senate Appropriations Committee, Sen. Bill Cassidy (R-LA) will become the Ranking Member on the Health, Education, Labor, and Pensions (HELP) Committee in January.

Current HELP Chair Patty Murray (D-WA) will become Chair of the Senate Appropriations Committee, clearing the way for Sen. Bernie Sanders (I-VT) to take the gavel on the HELP Committee. Sen. Sanders is known to be an ardent supporter of his pet priorities and has been known to throw the occasional rhetorical elbow during legislative debates. There could be a real change in committee culture with Senator Sanders in a leadership position. If there is friction between Senators Cassidy and Sanders, it will be even more essential for stakeholders to develop and deepen relationships throughout the Committee as a means of getting traction on legislative initiatives.

We expect Sen. Mike Crapo (R-ID) to remain Ranking Member on the Senate Finance Committee, which has oversight over Medicare, Medicaid, and tax-related health care provisions. Sen. Crapo opposed the Inflation Reduction Act's efforts to lower drug prices and will likely lead Republican efforts to repeal the IRA's drug pricing provisions. Ron Wyden (D-OR), the current Chairman of the Senate Finance Committee, will continue to lead Democrats in that role during the next Congress.

With the Republican takeover of the House majority, Kay Granger (R-TX), the current Ranking Member of the House Appropriations Committee, will serve as Chair of the full Appropriations Committee. She has not fully committed to retaining earmarks if she serves in that role because House Republicans continue to have deep divisions about the need to fund Congressionally directed initiatives in spending bills. Based on a recent conversation with Rep. Tom Cole (R-OK), he expects to be able to serve as Chair of the Labor, Health and Human Services, Education, and Related Agencies Appropriations Subcommittee, where he has been an avid supporter of many bedrock HHS programs. The current Committee and LHHS Subcommittee Chair, Rep. Rosa DeLauro (D-CT) will serve as the Ranking Member in both roles, where she can be expected to fight hard for the Biden Administration's health care initiatives. Their Senate counterparts on the Labor, HHS, Education, and Related Agencies Appropriations Subcommittee will change because Sen. Roy Blunt (R-MO) is retiring. That could clear the way for a Senator like Lindsey Graham (R-SC) or Jerry Moran (R-KS) to take the Ranking Member's role alongside Sen. Murray, who would likely continue as Chair of that subcommittee.

Anticipated PBM Policy Agenda in Congress

Based on conversations with policymakers, we can estimate where PBM reform efforts will develop in both the lame duck session and in the next Congress, and our belief is that efforts will be most prominent in the House Oversight, House E & C, Senate Finance, and Senate Commerce and HELP committees. In 2023, reform-minded Members will find allies through the nascent "Anti-PBM" caucus, which Rep. Buddy Carter (R-GA) intends to formally launch at the commencement of the 118th Congress.

Specific drug pricing/PBM-related legislation we expect will either receive consideration in the lame duck or be reintroduced in the 118th Congress includes:

- the Lower Costs, More Cures Act of 2021 (H.R. 19) (S. 2164),
- the Pharmacy Benefit Manager Transparency Act of 2022 (S. 4293),
- the Shaheen-Collins INSULIN bill,[1] and
- Rep. Harshbarger's PBM Transparency, Accountability, and Reform Act.[2]

The House Committee on Oversight and Reform, which will likely be chaired by Rep. James Comer (R-KY), has clearly indicated that PBM reform will be a priority topic in the 118th Congress. "Pharmacy Benefit Managers must be held accountable for their role in rising prescription drug prices, and Congress must take on PBMs to implement transparency and restore competition. Republicans on the House Oversight and Reform Committee are shining a light on this issue in the healthcare system and will continue to examine solutions to make prescription drugs more affordable for all Americans," Comer said in connection with the release of the report from a forum he led in late 2021 which outlined how pharmacy benefit managers' (PBMs) practices increase prescription drug prices, impact patient health, hurt competition, and distort the marketplace. While the Oversight committee maintains a slightly dubious reputation as a venue for deploying partisan attacks – and will no doubt be utilized to that effect – Rep. Comer's staff has indicated that PBM reform will remain a hot button issue for them.

Both House E & C and the Senate Finance Committee will likely see a modified version of the Lower Costs, More Cures Act as one vehicle for drug pricing reform. We know that the staffs of the bill's bipartisan and bicameral sponsors -- CMR and Sen. Crapo -- are hard at work rewriting the legislation before the 118th and soliciting input, as many of the drug pricing provisions were rendered irrelevant by the IRA's passage. The current Chair of Senate Finance, Sen. Ron Wyden (D-OR), also has recognized the need for PBM reform, saying in reference to price concessions and DIR fees, "This unfair squeeze by PBMs on independent pharmacies in Oregon and throughout the country poses a direct threat to these community mainstays' ability to stay open for their patients who count on them for quality local service." His staff have signaled that he plans to push PBM reform in the next Congress, perhaps in part in response to the recent report from the Oregon State Pharmacy Association and 3Axis Advisors, which details a number of disturbing findings regarding PBM practices in Medicare, Medicaid, and commercial markets.[3]

And in October, E & C Health Subcommittee member Rep. Buddy Carter (R-GA) announced a new "Pulling Back the Curtains on PBMs" campaign that is meant to educate members of Congress and the public on the role of PBMs in driving up drug costs. "PBMs have been allowed to rob patients blind for decades," Carter said, "and Congress cannot afford to continue ignoring a system that is forcing our loved ones to stay sick, sacrifice their mental health, go into debt, and put their lives on hold just to convince a man behind a computer that they need the care their doctor says that they do."

PBM reform enjoys bipartisan support in the Senate Commerce Committee also, with the Pharmacy Benefit Manager Transparency Act of 2022 (S. 4293), having been cosponsored by Sens. Maria Cantwell (D-WA) and Sen. Chuck Grassley (R-IA). And Sens. Cantwell and Grassley led a letter to Federal Trade Commission Chair Lina Khan supporting the FTC's investigation into PBM practices, emphasizing, "There is widespread bipartisan support for examining PBMs and looking into whether they are causing Americans to pay higher prices for prescription drugs. This is why we support the FTC's decision to conduct a PBM study. We hear stories about rising drug costs all the time."

Not to be left out on this issue, the new leadership on both sides of the dais in the Senate HELP Committee, Sens. Cassidy and Sanders, have also expressed interest in drug pricing reform, among other priorities.

As noted above, Republicans have made clear that they will use their oversight authority to seek to undo the Biden Administration's policies and legislative successes, including the drug pricing provisions in the Inflation Reduction Act. As we move into the presidential election cycle, enacting

legislation with a Republican-led House and a Democrat-led Senate will become even more difficult over the next two years. For these reasons, we expect to see more policy-making via executive action, meaning that stakeholders will want to be sure to make their policy priorities known to the White House, as well as with Congress and the relevant agencies.

Agency Action

Federal Trade Commission (FTC)

On June 7, the FTC issued a Section 6(b) order conducting a study of PBMs' business practices, and as noted above, Sens. Cantwell and Grassley wrote FTC Chair Khan in October, urging the agency to publicly commit to complete the study no later than June 6, 2023, explaining that "consumers and taxpayers cannot afford any delay." We will be watching for the release of the study's findings, as that will present opportunities for stakeholders to engage with the agency on next steps.

Also, on November 10, the FTC announced its intention to expand its interpretation of Section 5 of the FTC Act, which bans "unfair methods of competition" and instructs the agency to enforce that prohibition. The policy shift will make it easier for the agency to challenge an array of what it sees as anticompetitive behavior in the market, because, according to the FTC's statement, it wouldn't need to show that conduct harmed other market participants or consumers, but simply that it "has a tendency to generate negative consequences." The implementation of this new policy will be on our radar, as this lower burden may prove helpful to FTC efforts to challenge future consolidations and mergers like those that have helped give the three largest PBMs almost monopolistic power.

Department of Justice Antitrust Division

Although it suffered several losses in court this year, including failing to halt the union of UnitedHealth Group and Change Healthcare, the Antitrust Division finally scored a win on October 31, preventing the merger of two publishing houses, and the Division has been on a recent hiring spree, possibly signaling major enforcement actions to come. This agency, too, offers an opportunity for stakeholders to voice their concerns about pending mergers in the pharmaceutical supply chain.

Centers for Medicare and Medicaid Services

In May of this year, CMS issued a final rule that put an end to PBM's retroactive application of direct and indirect remuneration (DIR) fees, requiring that they be reflected in the negotiated price the patient pays at the pharmacy counter. The rule will apply to all price concessions beginning on January 1, 2024. Although a good start, this rule by no means addresses all problematic PBM practices, and stakeholders should seek opportunities to engage with the agency on these issues in the new year.

Conclusion

While the aforementioned bills are broad in scope and imperfect in application, there are three bullish factors playing into PBM reformers' hands. They are 1) the need for reform has bipartisan, bicameral buy-in, though the specific strategies differ; 2) there has been a considerable uptick in interest about the issue; and 3) manufacturers are no longer the primary drug-pricing reform target, as a result of the IRA. We are confident that, despite the strong potential for political stagnation in a divided government, PBM reform will continue its positive trajectory over the next two years.

FOOTNOTES

^[1] Yet to be filed

^[2] Yet to be filed

^[3] <u>https://oregonpharmacy.org/2022/10/27/oregon-report/</u>

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