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Senate Finance Committee Passes Drug Pricing Bill

July 30, 2019 | Blog | By **Theresa Carnegie**, Ellyn Sternfield, Michelle Caton, Matt Mora

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- Federal Government Relations
- Health Care

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- Federal Government Relations
- Health Care

Senators Chuck Grassley (R-IA) and Ron Wyden (D-OR), Chairman and Ranking Member (respectively) of the Senate Finance Committee, have fired the latest shot in Congress's ongoing battle against high drug prices. Last week, the Senators introduced their much-anticipated proposal to lower drug prices: a chairman's mark called the **Prescription Drug Pricing Reduction Act (PDPRA) of 2019**.

On July 25th, the Senate Finance Committee held a markup to consider the PDPRA. While contentious at times, the proposed legislation ultimately was voted out of committee favorably by a vote of 19-9. Despite the wide margin, buoyed by 13 Democrats and 6 Republicans on the Committee, the prospects for passage are not entirely clear given some of the divisions over key policies contained in the PDPRA. It is clear, however, that proponents of the proposed legislation will have to strike a delicate balance in order to advance it.

Throughout the hearing, key Republicans expressed opposition to different aspects of the PDPRA. Senator Pat Toomey (R-PA) led an effort to eliminate Section 128, which would levy an inflation penalty if manufacturers increase their list prices for certain Part D drugs above inflation, as further discussed below. That amendment was ultimately rejected 14-14. A number of senators suggested this section could be improved, and amendments are likely forthcoming when the debate continues before the full Senate.

Another source of division during the markup centered around one of the Trump Administration's signature drug pricing initiatives, the International Pricing Index (IPI) Demonstration. Senator Toomey offered an amendment to prevent the U.S. Department of Health and Human Services (HHS) from implementing the demonstration. The amendment was rejected by a vote of 14-14, with two Republicans joining all but one of the Democrats in rejecting the amendment.

As we **reported** earlier this month, the White House withdrew the proposed regulatory rebate rule that would have amended the discount safe harbor under the Anti-Kickback Statute to eliminate protections for certain drug rebates paid by pharmaceutical manufacturers. The rebate rule appears to have been revived, as Senator Grassley has announced his intentions to include such measure in the PDPRA.

The PDPRA takes a multi-pronged approach to lowering drug costs, including measures designed to improve transparency within the drug supply chain, retool the Medicare Part D program, and alter Medicare Part B drug payment methodologies. The CBO estimates that the reforms outlined in the PDPRA would save taxpayers $85 billion in Medicare spending between 2019 and 2029, along with $15 billion in Medicaid spending. It estimates that $27 billion would be saved in beneficiary cost-sharing during that same period, with an additional $5 billion in beneficiary savings on premiums.

Here are our key takeaways from the proposal:

Changes to Manufacturer Rebate and Refund Obligations

In an effort to lower drug costs and decrease federal and beneficiary spending, the PDPRA takes steps to widen manufacturer rebate and refund obligations. The proposed bill does not create a general drug rebate requirement in either Medicare Part B or Part D. However, the PDPRA does create an inflation penalty if price increases exceed the inflation rate as measured by the Consumer Price Index.

- The Part B rebate requirement is triggered when the prices for drugs and biologics exceed inflation. The rebate requirement is not applicable to biosimilars or vaccines.
- The Part D rebate requirement is triggered if the list price for brand drugs or biologics increases faster than the inflation rate over a six-month period. This rebate requirement is not applicable to biosimilars.

The PDPRA also creates a refund requirement to address "wasting" caused by overfilled vials in Part B.

- The provision applies to all drugs, biologics, and biosimilars packaged as single use. The refund requirement is triggered if Medicare payments attributed to the wasted amount of vials exceed 10% of the amount Medicare Part B paid for the total units of the product over a federal quarter.

The PDPRA also attempts to increase manufacturers' rebate obligations under the Medicaid Drug Rebate Program (MDRP).

- Under the MDRP, manufacturers are required to pay an inflation rebate if the price of a drug increases faster than the drug's inflation adjusted average manufacturer price (AMP). However, once inflation rebates equal 100% of a drug's AMP, additional price increases will not result in larger rebates. The proposed bill would increase the Medicaid inflation rebate cap from 100% of a covered outpatient drug's AMP to 125%.
- Rebates that are paid pursuant to the MDRP are based in part on the AMP of a brand name drug. In order to increase the rebates that manufacturers owe under the Medicaid program, the proposed bill excludes authorized generic drugs from the calculation of AMP under the MDRP. Moreover, the definition of wholesaler would be revised to exclude covered outpatient drug manufacturers.

Changes to Reimbursement Under Medicare Part B and Medicaid

The PDPRA aims to reduce federal spending and beneficiary cost-sharing by significantly changing how stakeholders are reimbursed under both Medicare Part B and the Medicaid program.

- In an effort to align the law with current Medicare payment rules, the proposed bill would statutorily cap WAC add-on payments at 3% when average sales price (ASP) is unavailable for new drugs, biologicals, and biosimilars.
- The proposed bill would also implement an overall maximum limit of $1,000 for all add-on amounts that a provider can be paid for a drug, biological, or biosimilar. A provider billing for a drug would be paid an add-on amount that is the lesser of: (i) 6% of the ASP for a drug or biological or 6% of the ASP for the reference product for a biosimilar; (ii) 3% of WAC for a new drug in the initial period; or (iii) $1,000.
- The PDPRA would also change the way that drug, biological, and biosimilar manufacturers calculate ASP. Moving forward, the PDPRA would require manufacturers to exclude the value of coupons provided to privately insured individuals from each drug's ASP.
- The definition of "bona fide service fees" would be narrowed. This change would effectively expand the fees that manufacturers pay to wholesalers and group purchasing organizations that must be treated as price concessions and included in the reported ASP.
- The PDPRA eliminates the exception for "grandfathered" hospital outpatient departments (HOPDs) under the Bipartisan Budget Act of 2015 and the 21st Century Cures Act of 2005. As a result, beginning January 1, 2021, the professional services provided in connection to the administration of Medicare Part B drugs would be paid at the physician fee schedule (PFS) rate rather than the higher outpatient prospective payment system (OPPS) rate at those HOPDs.

Increased Incentives for Biosimilars

Congress and federal agencies such as the FDA have advocated for greater adoption and use of lower cost biosimilars as one avenue to address rising drug prices. The PDPRA seeks to codify the payment rate for biosimilars during the initial two quarter product introduction period when ASP information may be unavailable at the lesser of: (i) the biosimilar's WAC plus 3%, or (ii) ASP plus 6% of the reference biological product. The PDPRA also proposes to increase the add-on payment for biosimilars from 6% to 8% of the reference product's ASP for five years.

Redesign of Medicare Part D

The PDPRA would revise the way in which outpatient prescription drug coverage is provided to Medicare beneficiaries under Part D. Under the current system, private insurers that provide Part D coverage must offer "standard coverage," which consists of four phases: (i) a deductible; (ii) initial coverage; (iii) the coverage gap (doughnut hole); and (iv) catastrophic coverage.

- The PDPRA would remove the coverage gap phase and eliminate an enrollee's cost-sharing obligations during catastrophic coverage.
- In addition, an enrollee's out-of-pocket costs that trigger catastrophic coverage would be reduced to $3,100. The proposed bill would also reduce federal payment obligations so that Medicare is responsible for 20% and insurers for 60% of drug spending during catastrophic coverage. The remaining amount would be paid by manufacturers participating in Part D, who would provide 20% discounts off negotiated prices of drugs covered during catastrophic coverage.

Changes to Increase Oversight and Transparency

The PDPRA proposes a variety of reporting obligations intended to increase transparency for the government and consumers with respect to the relative cost of services and the value exchanged between entities in the pharmaceutical supply chain, including manufacturers, PBMs, and pharmacies. The most significant of the reporting requirements relates to public disclosure of aggregate price concessions and differentials between insurer, PBM, and pharmacy reimbursement, DIR reporting discrepancies, and manufacturer justification of price increases above specified thresholds. While these reporting obligations may serve the laudable goal of increasing the information available to government agencies and beneficiaries, it is unclear whether such reporting will ultimately result in lower drug prices and reduced costs for consumers or whether they will only create administrative burdens for plans, PBMs, and manufacturers without achieving real change.

- In order to ensure accurate payment rates under Medicare Part B, the PDPRA proposes to expand ASP reporting requirements to require manufacturers that do not have a Medicaid drug rebate agreement to report ASP information on a quarterly basis to HHS.
- The 21st Century Cures Act requires HHS to make public the estimated Medicare payment rates to HOPDs and ambulatory surgery centers and corresponding patient cost-sharing obligations. The PDPRA expands these HHS disclosure obligations to require comparable information for services that can be furnished in physician offices.

- The PDPRA proposes to allow HHS to share Medicare Part D and Medicaid drug price and rebate data with MedPAC and MACPAC for purposes of monitoring, program recommendations, and analysis. MedPAC and MACPAC would be barred from disclosing specific information or amounts to third parties.
- The PDPRA would require HHS to make public, via a website, data that PBMs report to HHS, including information on aggregate price concessions and differentials between insurer, PBM, and pharmacy reimbursement. The proposed bill also requires Part D plans to conduct financial audits of data related to the PBM contracts. Part D plans would also be required to: (i) report to pharmacies at least annually any post point-of-sale adjustments for price concessions or incentive payments, and (ii) actual and projected DIR amounts in their bids, including those relating to pharmacies.
- The proposed bill would also require HHS to publicly report discrepancies related to DIR information reported by Part D plans, as well as the results of third-party financial audits of plans that include DIR information.
- The PDPRA would require Part D plans to provide a real-time benefit tool that enables electronic transmission of formulary and benefit information to each enrollee's prescribing clinician using technology that integrates e-prescribing and electronic health record systems.
- The proposed bill would create an exception to Part D plans' use of fee-for-service claims data for Part D coverage determinations for approved purposes, such as to improve therapeutic outcomes.
- The PDPRA proposes to amend the Social Security Act (SSA) to require manufacturers to report to HHS information and supporting documentation needed to justify drug price increases where the price increases exceed specified thresholds. HHS would publicly post the price justifications.
- Under the proposed bill, HHS would be required to publish a report on Medicaid provider prescribing patterns for outpatient drugs for each state.
- The PDPRA would authorize CMS to audit the pricing information manufacturers must submit quarterly (WAC, AMP, ASP and Best Price), as well as to verify prices submitted through surveys. CMS would be further authorized to assess civil penalties on any wholesaler, manufacturer, or direct seller who fails to respond to, or provides untruthful information in response to, a pricing survey. The PDPRA would also enhance the amount of penalties CMS can assess against manufacturers for failure to timely or accurately report pricing information.
- The PDPRA would expand HHS-OIG permissive exclusion authority to include owners, officers, and managing employees of an entity who were in those positions at the time of the alleged misconduct at issue in a sanction. The expanded authority stems from a concern that presently culpable individuals evade the exclusion process by resigning their positions or divesting their ownership before the exclusion process concludes.
- The PDPRA seeks to mandate increased oversight and transparency in states' use of pharmacy & therapeutics (P&T) committees and drug use review (DUR) boards to manage drug utilization and formularies in Medicaid and Medicaid managed care programs. State P&T committees and DUR boards would be required to meet certain minimum standards governing staffing and to implement conflict of interest policies addressing relationships/associations that "might affect their independent judgment." There are also requirements for publicly disclosing information on how the committees/boards address any disclosed conflicts.
- The PDPRA would further require the Government Accountability Office to investigate state DUR boards and P&T committees and report to Congress on how these entities operate and how they protect independence of members with respect to drug manufacturers, managed care organizations, and other entities or individuals with ties to the pharmaceutical industry.

Increased Coverage

The PDPRA also aims to increase and expand coverage of the Medicare Part D and Medicaid programs. To effectuate those goals, the PDPRA proposes to extend transitional Part D coverage for certain beneficiaries and to redefine which outpatient drugs are subject to Medicaid rebates or best pricing requirements.

- The proposed bill would permanently authorize HHS' current pilot program that provides temporary Medicare Part D coverage to eligible low-income beneficiaries and new dual-eligible beneficiaries who are transitioning into a Part D plan (the LI NET program).
- It would amend Section 1927(k)(3) of the SSA to permit states to define a "covered outpatient drug" as including any drug, biological product, or insulin as part of a bundled payment, if the drug is provided on an outpatient basis as part of, or incident to and in the same setting as, physicians' services or outpatient hospital services. By redefining covered outpatient drugs in this way, the current SSA requirements for participating pharmaceutical manufacturers to give the Medicaid program rebates or best pricing on such drugs would extend to drugs provided as part of a physician's or a hospital outpatient department's services.

Closing Thoughts

The PDPRA is an ambitious package of reforms that continues the ongoing congressional dialogue about drug pricing. Perhaps just as notable as the proposed reforms included in the PDPRA are the proposals that could have been, but were not, included. While the bill introduces some minor changes to the Medicaid drug rebate calculations, it does not provide for general Medicare Part B or Part D rebate provisions, instead offering limited rebate requirements relating to price increases that outpace inflation. The proposed bill does not include CMS negotiation rights (a frequent topic in the drug pricing debate) for Medicare Part C and D covered drugs. Similarly, the PDPRA entirely avoids 340B drug pricing program reform. As the PDPRA moves forward, we will continue to monitor and provide updates on this issue.

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