The Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Section by Section

Scheduled for Markup
By the Senate Committee on Finance
On July 25, 2019

TITLE I—MEDICARE

Subtitle A—Part B

Sec.101. Improving manufacturers' reporting of average sales prices to set accurate payment rates.

In the **first calendar quarter after the date of enactment**, all manufacturers of drugs covered under Part B would report average sales price (ASP) information to the Secretary of Health and Human Services (the Secretary). Specifically, it would add a new requirement under Medicare Part B for manufacturers that do not have a rebate agreement through the Medicaid Drug Rebate Program to report ASP information.

Sec.102. Inclusion of value of coupons in determination of average sales price for drugs and biologicals under Medicare Part B.

Under this section, manufacturers would exclude the value of coupons provided to individuals with private insurance from each drug's ASP, beginning in **July 2021**. Coupons are defined as any item of value that a drug manufacturer provides to an individual, either directly or indirectly, that reduces or eliminates the out-of-pocket costs associated with the drug.

Sec. 103. Reduced wholesale acquisition cost (WAC)-based payments for new drugs, biologicals, and biosimilars.

This section would establish a WAC add-on of no greater than plus 3% when ASP is unavailable for new drugs, biologicals, and biosimilars furnished on or after January 1, 2019. This provision would comport with current Medicare payment rules that pay WAC plus 3%, an amount that CMS established using administrative authority.

Sec.104. Payment for biosimilar biological products during first 6 months.

This section would change Part B payments for new biosimilars beginning in **July 2020**. The payment rate would be based on either the biosimilar's wholesale acquisition cost (WAC) amount, or the current ASP of reference product. This payment would be in place for the first calendar quarter of sales. Once the biosimilar has its own ASP data, the biosimilar would be paid based on its own ASP.

Section 105. Temporary increase in Medicare Part B payment for biosimilar biological products

This provision would increase the add-on payment for biosimilars from 6% of the reference product's ASP to 8% of the reference product's ASP for a period of five years beginning January 1, 2020.

Sec. 106. Improve site of service transparency tool.

This section would expand HHS's online price transparency comparison website. The additions would include information on payments and cost-sharing for services provided in hospital outpatient departments (HOPDs) and ambulatory surgery centers (ASCs) under the Physician Fee Schedule (PFS).

Sec.107. Medicare Part B rebate by manufacturers for drugs or biologicals with prices increasing faster than inflation.

This section would require drug manufacturers to pay a rebate for drugs and biologicals with ASPs that increase faster than inflation (the Consumer Price Index for all Urban Consumers (CPI-U)), beginning in **January 2021**. Manufacturers would provide mandatory rebates to CMS for each quarter that the ASP of a drug increased faster than CPI-U. The rebate amount would be equal to the difference between the inflation-adjusted ASP and the actual ASP during the quarter. Increases in price and inflation would be referenced to benchmarks to determine inflation-adjusted values. The benchmark inflation would be the CPI-U for **July 2019**. The payment amount benchmark would be the quarter beginning **July 1, 2019**. For new drugs, the first full quarter that the drug was marketed would be used as the payment amount benchmark and the first month of that quarter would be used as the inflation benchmark. The Secretary would be prohibited from making payments for a drug if the manufacturer fails to comply with the rebate requirements for that drug.

Sec.108. Requiring manufacturers of certain single-dose vial drugs payable under Part B of the Medicare program to provide refunds with respect to discarded amounts of such drugs.

This section would require drug manufacturers to refund the amount of payment made to providers for unused or discarded amounts of certain single-use vial drugs, beginning or after **July 2021**. Specifically, it would require the Secretary to establish a mechanism to capture a refund for discarded amounts using Part B claims. The refund owed would be the number of discarded units multiplied by the payment amount for the product. Refunds would not apply to drugs that are packaged as part of payment for another item or service. An allowance for a practical amount of product waste and product filtration per the drug label would be applied, with additional allowance for drugs with unique characteristics.

Sec.109. Lower ASP payment amounts by requiring manufacturers to report additional service fees.

This section would clarify that in calculating the ASP under Part B, manufacturers should include certain fees beginning **six months after enactment** that do not qualify as "bona fide", such as those based on a percentage of sales. Bona fide fees that are fair market value and are in exchange for services performed for the manufacturer would remain in the calculation of ASP.

Sec.110. Reform ASP add-on payment by establishing a cap on the add-on payment amount.

This section would limit the 6% add-on payment amount used by Medicare in setting provider

reimbursement for most Part B drugs and biologicals to a maximum of $1,000 per drug per day, beginning in **January 2021**.

Sec.111. Pay same rate for administering a drug whether service provided in HOPD or physician office.

This section would make payments for all Part B drug administration services at the Physician Fee Schedule (PFS) rate beginning in **2021**.

Subtitle B—Part D

Sec.121. Medicare Part D benefit redesign.

This section would change the structure of the Part D benefit in order to simplify the design and realign financial incentives to better manage spending for high cost drugs. Starting in **plan year 2022**, it would:

- Streamline the benefit between the deductible and catastrophic out-of-pocket threshold and eliminate the coverage gap ("doughnut hole"); and
- cap enrollee cost sharing above the catastrophic out-of-pocket threshold at $3,100 in **2022** and indexed to per capita Part D spending thereafter.

In addition, the provision would modify Part D financing mechanisms to:

- shift federal reinsurance to Part D plan sponsors in the catastrophic coverage period, resulting in 20% reinsurance and 60% plan responsibility in **2024**;
- sunset the existing manufacturer discount program in the coverage gap;
- and institute a new manufacturer discount program in the catastrophic portion of the benefit, which would require 20% discounts on brand-name spending.

Sec.122. Providing the Medicare Payment Advisory Commission and Medicaid and CHIP Payment and Access Commission with access to certain drug payment information, including certain rebate information.

This section would allow the Secretary to share Medicare Part D and Medicaid drug price and rebate data with the executive directors of the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC) for purposes of monitoring, making program recommendations, and analysis of the Medicare Part D and Medicaid programs and the State Children's Health Insurance Program.

Sec.123. Public disclosure of drug discounts and other PBM provisions.

This section would require the Secretary to make the information on aggregate price concessions currently reported by plans or pharmacy benefit managers (PBMs) under Part D publicly available on the HHS website no later than **July 1, 2022**.

Part D and MA plans would also conduct audits of PBM contract terms and direct and indirect remuneration data to account for the true net cost of covered Part D drugs beginning in **January 1, 2022**. Part D and MA plan sponsors would be required to report to pharmacies, at least

annually beginning in **plan year 2022**, any post-point-of-sale price concessions and payment incentives for covered part D drugs and provide the Secretary with statements of conflicts of interest from the members of any pharmacy and therapeutics committee used by the plan sponsor on and after **January 1, 2022**. Additionally, actual and projected direct and indirect remuneration amounts would be included in Part D bids by specific categories of receipt, beginning in plan year 2023.

Sec.124. Public disclosure of direct and indirect remuneration review and audit results.

This section would require the Secretary to publicly report on discrepancies with plan-reported DIR information, or the price concessions not passed on at the point of sale, demonstrating the accuracy with which plans report DIR. The Secretary would also be required to publicly report the results of the financial audits, which include DIR information, conducted under current law, beginning in 2020.

Sec.125. Increasing use of real-time benefit tools to lower beneficiary costs.

This section would require Part D plan sponsors to implement real-time benefit tools (RTBT) as part of their e-prescribing and electronic health record (EHR) systems that provide real-time, individual- and drug-specific information for a drug being prescribed, including alternatives and the negotiate price, out-of-pocket cost, and pharmacy options associated with the drugs. This section would also make RTBT functionality a requirement for determination by ONC as a qualified EHR and provide an optional physician incentive to use RTBTs through the Merit-based Incentive Payment System (MIPS) clinical practice improvement activities. Standards for RTBTs would be developed by the Secretary in consultation with the National Coordinator for Health Information Technology (ONC), the National Council for Prescription Drug Programs (NCPDP), and other stakeholders. Nothing in this section would prohibit the implementation of the RTBT requirements set out in the May 2019 Medicare Advantage and Part D Drug Pricing Final Rule.

Sec.126. Improvements to provision of parts A and B claims data to prescription drug plans.

This section would specify an exception to the limitation on Part D plan sponsors using Parts A and B data for Part D coverage determinations. The provision would allow plan sponsors to use the data for Part D coverage determinations specifically related to the approved purposes for providing the data (e.g., to improve therapeutic outcomes). It would also specify that the data are provided in a timely and efficient manner.

Sec.127. Permanently authorize a successful pilot on retroactive Medicare Part D coverage for low-income beneficiaries.

This section would permanently authorize the Limited Income Newly Eligible Transition (LI NET) demonstration to provide immediate temporary Part D coverage for certain individuals with low-income subsidies (LIS) while their eligibility is processed. It would include the existing coverage and eligibility provisions and begin no later than **2022**.

Sec.128. Medicare Part D rebate by manufacturers for certain drugs with prices increasing faster than inflation.

This section would establish price inflation rebates from manufacturers that choose to sell their products under Medicare Part D, beginning in **plan year 2022**. Manufacturers would provide mandatory rebates to CMS for each six-month period that the list price, or wholesale acquisition cost (WAC), for a rebatable drug increased faster than inflation (CPI-U). Increases in price and inflation for existing drugs would be referenced to **July 2019**. For drugs approved after July 2019, inflation would be referenced to **the first month** of the rebate period in which the drug is first marketed, and the price would be referenced to the WAC on **the first day** on which the drug was marketed. Rebate payments would be required for periods beginning **January 2022**.

Subtitle C—Miscellaneous

Sec.141.Drug manufacturer price transparency.

This section would require drug manufacturers to report information and supporting documentation, as determined by the Secretary, needed to justify launch prices and price increases for applicable prescription drugs and biological products, as measured by the WAC. The Secretary must post the justification publicly on the CMS website within 30 days of receiving it from the manufacturer. Qualifying drugs would include cases in which 1) The drug is at least $10 per dose and had a price increase of at least 300% over 5 years or 100% over 1 year; and 2) The drug is in the top 50th percentile of net drug spending in the Medicare or Medicaid programs and had a price increase of at least 50% over 5 years or 15% over 1 year; and 3) The drug is a new drug with an initial launch price that is high enough that the cost of a year supply or full course of treatment would exceed total gross drug spending at the Medicare Part D annual out-of-pocket threshold. These reporting thresholds would be phased in between 2020 and 2024 so that price increases occurring prior to enactment of this section would not be captured; however, any price increase or launch price occurring after enactment would be captured if it met criteria.

Sec.142. Allow revocation and denial of provider enrollment based on affiliation with a sanctioned entity.

This section expands the current authority to revoke or deny an individual's and entity's Medicare enrollment if they were affiliated with a sanctioned entity. This change would allow the Secretary to take administrative actions against entities that have owners, managing employees, officers, and/or directors that were previously affiliated with sanctioned Medicare entities.

Title II – Medicaid

Sec. 201. Developing standards across pharmacy and therapeutic committees in State Medicaid programs.

This provision would require states to establish and implement conflict of interest policies for pharmacy and therapeutics (P&T) committees including annual disclosures as well as processes for addresses conflicts and failure of members to report conflicts. This provision would also clarify membership requirements for P&T committees, apply the improvements to managed care, and encourage the Secretary to issue guidance to states as appropriate regarding conflicts of interest policies. This provision would be effective **one year after the date of enactment**.

Sec. 202. Improving reporting requirements and developing standards for the use of drug use review (DUR) boards in State Medicaid programs.

This provision would make a number of improvements to state Drug Use Review (DUR) board conflict of interest policies and membership requirements including requiring states to establish and implement conflict of interest policies for state DUR boards including annual disclosures and processes for addressing conflicts and failure of members to report conflicts. This provision would also clarify membership requirements for DUR boards, ensure that managed care descriptions of drug utilization review programs include prospective drug review activities and makes the DUR data available to the State and Secretary. This provision would also encourage the Secretary to create national standards for Medicaid drug use review programs and require the Secretary to issue guidance to help ensure compliance. This provision would be effective **one year after the date of enactment.**

Sec. 203. Government Accountability Office (GAO) report on conflicts of interest in state Medicaid program DUR boards and P&T committees.

This provision would direct GAO to conduct, **within 24 months** of the date of enactment, an investigation of conflicts of interest among members of state Medicaid program DUR boards and P&T committees. Among other information, the report would include a description of state DUR board and P&T committee operations, including details regarding how states operate separate committees for fee-for-service and managed care, the tools used to determine coverage and utilization management, and how participation and independence requirements are established. Finally, the report would provide recommendations for tools that states may use to prevent conflicts of interest, comply with requirements, and ensure appropriate access to drug treatments for Medicaid beneficiaries.

Sec. 204. Ensuring the accuracy of manufacturer price information under the Medicaid Drug Rebate Program.

This provision would require the Secretary to conduct ongoing audits of drug price and product information reported by manufacturers under the Medicaid Drug Rebate Program. It would also provide the Secretary with authority to survey wholesalers and manufacturers to verify

manufacturer price information and require the Secretary to submit annual reports to Congress with the results of such audits and surveys. The Secretary would also be able to impose a penalty of up to $185,000 on wholesalers or manufacturers that refuse requests or provide false information associated with an audit or survey. It would also increase the penalties for noncompliance with existing reporting requirements under the Medicaid Drug Rebate Program. The Secretary would also be directed to issue a report to Congress within 18 months after enactment regarding any additional regulatory or statutory changes necessary in order to ensure that manufacturer price and drug product information is reported accurately and in a timely manner. This provision would be effective on the **first quarter that begins after the date of enactment.**

Sec. 205. Excluding authorized generics from the calculation of average manufacturer price for the purpose of the Medicaid Drug Rebate Program.

This provision would modify the definition of average manufacturer price to exclude authorized generic drugs from the calculation of average manufactured price for brand-name drugs. This provision would also clarify the definition of a wholesaler to exclude manufacturers. The provision would be effective on the **first day of the first fiscal quarter that begins after the enactment date.**

Sec. 206. Preventing spread pricing and clarifying payment for drugs in State Medicaid programs.

The provision would ban spread pricing in Medicaid managed care contracts. Among other provisions, effective**18 months after enactment**, it would align reimbursement methodologies across Medicaid to ensure payment is based on ingredient costs and professional dispensing fees and that such pharmacy reimbursement payments are passed through in their entirety by PBMs to the managed care organizations and state. PBMs may be reimbursed for their administrative services but such payment must be separate and limited to the reasonable cost of providing the administrative functions. The provision would also make a number of improvements to the national drug acquisition cost survey including mandatory reporting and other improvements to help ensure survey information is reflective of the actual average acquisition cost. It would also instruct the Secretary to submit a report and recommendations to Congress on specialty drug coverage and reimbursement under Medicaid. This provision would also require public reporting of wholesale acquisition cost for covered outpatient drugs under the Medicaid Drug Rebate Program.

Sec. 207. T-MSIS drug data analytics reports.

This provision would require, beginning in **2021**, the Secretary to publish a public report analyzing state trends across pharmacy benefits employing data from the Transformed Medicaid Statistical Information System (T-MSIS). The report would include an analysis of prescribing patterns and prescription utilization management tools. The Secretary would also be able to include analyses of national, state, and local patterns of prescribing behaviors and recommendations for ways to improve the effectiveness of and reduce costs for prescription drugs.

Sec. 208. Allow states to pay for a subset of drugs over a period of time as long as certain conditions are met.

This provision would create a state option that would allow states to pay for covered outpatient drugs through risk-sharing value-based agreements beginning in **2022**. State requests would be subject to approval by the Secretary which would include certification by the Chief Actuary of the Centers for Medicare & Medicaid Services that net projected payments for each drug would not be greater than under the traditional rebate agreement. The manufacturer would be also be required to submit justifications for its launch and list price. Payments made by a state to a manufacturer under a risk-sharing value-based contract would be treated the same as prices paid under supplemental agreements as it relates to calculation of average manufacturer price and best price. The Secretary would be required to conduct an evaluation of approved agreements, including an assessment by the Chief Actuary of CMS, to determine whether program spending aligned with projections made in the Actuary's determination upon agreement review. If such evaluation finds that federal spending was higher under the agreement than it would have been otherwise, the manufacturer would be required to repay the government. The Secretary would be required to issue a report to Congress no later than five years after the first agreement is approved on the impact on access to covered outpatient drugs and related treatments, the overall state and federal spending, and launch price and price increases of drugs covered under these agreements.

Sec. 209. Modification of the maximum rebate amount under the Medicaid Drug Rebate Program.

Starting **fiscal year 2023**, this provision would increase the current 100% average manufacturer price (AMP) cap on Medicaid rebates to 125%. In addition, starting **fiscal year 2022**, if a manufacturer increases their AMP for a covered outpatient drug beyond their base year AMP trended forward by CPI-U, they would be subject to all rebate obligations that would otherwise be due if there was no cap on rebate obligations. Once the current quarter AMP is in alignment with the base year AMP trended forward by CPI-U for the covered outpatient drug, the manufacturer may continue to increase the AMP of the drug by no more than CPI-U with no additional rebate liability above the 125% AMP rebate cap.

Sec. 210. Applying Medicaid Drug Rebate requirements to drugs provided as part of outpatient hospital services.

Effective **one year after date of enactment**, this provision would provide states with the option to apply the Medicaid Drug Rebate Program requirements, including the requirement that manufacturers provide rebates, to bundled drugs provided in an outpatient basis including for outpatient hospital and physician services. The provision would also instruct the Secretary to issue relevant guidance and informational materials to States, manufacturers, and other stakeholders.