

The Prescription Drug Pricing Reduction Act (PDPRA) of 2019

Section by Section

TITLE I—MEDICARE

Subtitle A—Part B

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

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

This section would require manufacturers to include the value of coupons provided to individuals with private insurance in calculating the ASP for a drug, biological, or biosimilar, beginning in **July 1, 2021**. Coupons are defined as any financial support that a manufacturer provides to an individual, either directly or indirectly (e.g. through a physician office or pharmacy), that reduces or eliminates the out-of-pocket costs associated with the manufacturer’s product.

Sec. 103. Payment for biosimilar biological products during initial period.

This section would change Part B payments for new biosimilars beginning in **July 1, 2020**. The payment rate would be the lesser of the biosimilar’s wholesale acquisition cost (WAC) plus 3 percent and the current ASP plus 6 percent of the reference product. This payment would be in place for the initial period that typically spans up to two calendar quarters. Once the biosimilar has its own ASP data, the biosimilar would be paid based on its own ASP.

Sec. 104. Temporary increase in Medicare Part B payment for biosimilar biological products.

This section would increase the add-on payment for biosimilars from 6 percent of the reference product’s ASP to 8 percent of the reference product’s ASP for a period of five years **beginning January 1, 2020**. This payment would not exceed the total payment amount for the reference product.

Sec. 105. Improvements to Medicare site-of-service transparency

This section would expand the HHS online price transparency tool that allows beneficiaries to compare payment and cost-sharing information for services furnished in multiple settings. Beginning in **2021**, beneficiaries would be able to compare price information for services furnished in the physician office setting that are also available in hospital outpatient departments (HOPDs) and ambulatory surgery centers (ASCs).

Sec. 106. Medicare Part B rebate by manufacturers for drugs or biologicals with prices increasing faster than inflation.

This section would require manufacturers to pay a rebate for drugs and biologicals for which the ASP increases faster than inflation, as measured by the Consumer Price Index for all Urban Consumers (CPI-U), beginning in **January 1, 2021**. Manufacturers would provide mandatory rebates to the Secretary 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 1, 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. 107. Requiring manufacturers of certain single-dose container or single-use package drugs payable under Part B of the Medicare program to provide refunds with respect to discarded amounts of such drugs.

This section would require manufacturers to provide a refund to the Secretary for the discarded amounts of separately payable single-dose container or single-use package drugs, biologicals, and biosimilars beginning **July 1, 2021**. Specifically, the manufacturer would owe for a quarter an amount by which the Medicare payment attributed to the discarded units exceeds 10 percent of the amount Medicare paid for the total units. The 10 percent allowance would be increased by a practical amount for products that require filtration per the drug label, with the Secretary having the authority to increase the threshold for other products with unique characteristics.

Sec. 108. Clarification of Medicare average sales price payment methodology.

This section would establish a statutory definition of “bona fide service fees,” which manufacturers do not have to include as a concession when calculating and reporting the ASP for a drug, biological, or biosimilar, beginning on the **calendar quarter six months after enactment**. Specifically, it would narrow the existing definition of bona fide service fees that the Secretary established using administrative authority. The more narrow definition of bona fide service fees exempt from ASP reporting would explicitly prohibit: fees based on the percentage of sales; and fees determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties, expanding the types of fees that manufacturers must treat as a price concession that is included in their calculation of ASP.

Sec. 109. Establishment of maximum add-on payment for drugs, biologicals, and biosimilars.

This section would establish a maximum add-on amount that a provider can be paid for each Part B separately payable drug, biological, or biosimilar that is administered to a beneficiary on a calendar date beginning **January 1, 2021**. Specifically, the provider billing for the drug would be paid the lesser of the add-on amount that would otherwise be paid—6 percent of the ASP for a drug or biological, 6 percent of the ASP for the reference product for a biosimilar, 3 percent of WAC for a new drug in the initial period—and \$1,000 through December 31, 2028. For 2029 and each subsequent year, the \$1,000 maximum add-on amount would be updated by CPI-U.

Sec. 110. Treatment of drug administration services furnished by an off-campus outpatient department of a provider.

This section would make payment for the service of administering a Part B drug based on the Physician Fee Schedule (PFS) rate, beginning in **January 1, 2021**, for certain HOPDs located off-campus from a main hospital that were previously excepted from such payment reduction. Specifically, it would eliminate the exception for off-campus HOPDs that were already billing Medicare or were in the process of being built for the purposes of drug administration services. HOPDs part of Prospective Payment System-exempt cancer hospitals would continue to be excluded and receive the Hospital Outpatient Prospective Payment System (OPPS) amount for these services.

Sec. 111. Study and report of average sales price.

This section would require the Government Accountability Office (GAO) to assess how Medicare spending and beneficiary cost-sharing would change if the average sales price of Part B drugs was based solely on sales for products paid by private payers in the commercial market. GAO would be required to submit the report to Congress not later than **two years after enactment**.

Sec. 112. Authority to use alternative payment for drugs and biologicals to prevent drug shortages.

This section would provide the Secretary authority, beginning **January 1, 2021**, to use a WAC-based (or other reasonable drug price measure) payment methodology for Part B drugs, biologicals, and biosimilars in shortage. It would also require the Secretary to: establish a mechanism that hospitals use to track and report on the use of products in shortage; and issue a public report to Congress related to shortages in the Medicare program.

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 (“donut 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 section would modify Part D financing mechanisms to:

- Shift federal reinsurance to Part D plan sponsors in the catastrophic coverage period, resulting in 20 percent reinsurance and 60 percent 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 percent discounts on brand-name drugs.

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, analysis, and making program recommendations.

Sec. 123. Public disclosure of drug discounts and other pharmacy benefit manager 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 by **July 1, 2022**.

It would also require Part D and Medicare Advantage plans to conduct audits of PBM contract terms and direct and indirect remuneration (DIR) data to account for the true net cost of covered Part D drugs beginning **January 1, 2022**. Part D and MA plan sponsors would also be required to:

- Report to pharmacies, at least annually beginning in **2022**, any post-point-of-sale price concessions and payment incentives for covered part D drugs;
- Provide the Secretary with a completed conflict of interest statement from each pharmacy and therapeutics (P&T) committee member beginning **January 1, 2022**; and

- Include actual and projected DIR amounts in Part D bids, **beginning 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 Part D plan-reported DIR information, 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) integrated with provider e-prescribing and electronic health record (EHR) systems that provides:

- A list of any clinically-appropriate alternatives to a drug included on the formulary of such plan; information relating to cost sharing; pharmacy options (including the individual's preferred pharmacy); and
- Any applicable prior authorization or other utilization management policies.

The Secretary would develop standards for RTBTs in consultation with stakeholders. Existing efforts by the Secretary to promote RTBTs would be unaffected.

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

This section would provide an exception to a current limitation on how Part D plan sponsors can use Medicare Parts A and B data by allowing use of the data to inform Part D coverage determinations that are aimed at optimizing beneficiary outcomes. It also would direct the Secretary to provide Part A and B data to plans 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, with the permanent program beginning **no later than 2022**.

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

This section would require manufacturers to pay a rebate for Part D drugs for which the list price, based on the WAC, increases faster than inflation, as measured by CPI-U, **beginning in 2022**. Manufacturers would provide mandatory rebates to the Secretary for each six-month period that a drug's price, measured at the dosage form and strength level, increased faster than CPI-U. The rebate amount would be equal to the difference between the inflation-adjusted price

and the price during that period. Increases in price and inflation for existing drugs would be referenced to **July 1, 2019**. For drugs approved after July 2019, inflation would be referenced to **the first month** of the first full rebate period following the initial six months in which the drug is first marketed.

Sec. 129. Prohibit branding on Part D benefit cards.

This section would prohibit Part D plan sponsors from including any pharmacy branding information on the cards provided to beneficiaries for the purpose of accessing Part D benefits. This prohibition would apply to plan years beginning **January 1, 2022**.

Sec. 130. Preventing fraud in Medicare Part D.

This section would require Part D plan sponsors to report any substantiated or suspicious activities of waste, fraud, and abuse as well as report any actions taken to address these instances beginning **January 1, 2021**.

Sec. 131. To establish pharmacy quality metrics in Medicare Part D.

This section would require the Secretary to establish standardized pharmacy quality metrics that Part D plans must use in any pharmacy incentive payment program. It would require that the Secretary use a consensus and evidence-base entity in establishing such quality metrics, with such metric focused on patient outcomes that are reliable for measuring pharmacy performance. The Secretary would require plans to use these measures as soon as they are sufficient in number but no later than **January 1, 2023**.

Sec. 132. Star rating measures to encourage biosimilar uptake.

This section would require the Secretary to establish a set of quality measures for the Medicare Advantage star rating program that assesses plan benefit and formulary design on utilization and beneficiary access to biosimilars that are covered under Part D (and Part B) beginning in **2025**.

Sec. 133. Department of Health and Human Services study and report on the influence of pharmaceutical manufacturer distribution on provider prescribing behavior.

This section would require the Secretary to conduct a study on the influence of pharmaceutical manufacturer distribution models that provide third-party reimbursement hub services on health care providers who prescribe the manufacturer's drugs. The report, which the Secretary would submit to Congress by **January 1, 2021**, would assess the extent that these hub services influence provider prescribing and whether they violate any existing federal laws.

Subtitle C—Miscellaneous

Sec. 141. Drug manufacturer price transparency.

This section would require manufacturers to report information and supporting documentation, as determined by the Secretary, needed to justify launch prices and price increases for drugs, biologicals, and biosimilars, as measured by the WAC, that meet certain criteria. The qualifying criteria for reporting would be that the drug is:

- At least \$10 per dose and had a price increase of at least 300 percent over 5 years or 100 percent over 1 year;
- In the top 50th percentile of net drug spending in the Medicare or Medicaid programs and had a price increase of at least 50 percent over 5 years or 15 percent over 1 year; or
- 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. The Secretary would post the justifications publicly within 30 days of receipt from the manufacturer. The Secretary would be prohibited from making proprietary information, such as trade secrets, public.

Sec. 142. Strengthen and expand pharmacy benefit manager transparency requirements.

This section would require health plans or PBMs that manage prescription drug coverage to report aggregate information on prescriptions, price concessions, and PBM payments to pharmacies. It would expand the situations in which PBMs are required to report information to include a contract with a state Medicaid program. It would also remove the current exemption of reporting bona fide fees from the reporting of the aggregate amount of price concessions negotiated and reported by a PBM. In addition, it would permit the Secretary to share the information submitted by a PBM with:

- States in carrying out their administration and oversight of state Medicaid programs;
- The Federal Trade Commission; and
- The Department of Justice.

Sec. 143. Medicare and Medicaid prescription drug pricing dashboard.

This section would codify and expand the current HHS website-based dashboard that contains information on drug, biological, and biosimilar utilization and spending in Medicare Part B, Medicare Part D, and Medicaid.

Sec. 144. Improving coordination between the Food and Drug Administration and the Centers for Medicare & Medicaid Services.

This section would require the Secretary to convene a public meeting, **within 12** months of

enactment, to discuss the challenges associated with the next generation of treatments and therapies that will be available to beneficiaries. It would also require the Secretary to publish a report, **within 18 months of enactment**, on Medicare coding, coverage, and payment processes related to novel medical products.

Sec. 145. Patient perspectives in Medicare local coverage determinations and national coverage determinations.

This section would authorize the Secretary to include patient perspectives in Medicare local and national coverage determinations, as a means to improve these processes.

Sec. 146. Government Accountability Office study on increases to Medicare spending due to pharmaceutical manufacturer contributions to copayment and patient assistance organizations.

This section would require GAO to study the impact of copayment coupons and other patient assistance programs on prescription drug pricing and expenditures within the Medicare and Medicaid programs and provide a report **within 24 months of enactment**.

Sec. 147. To require the Medicare Payment Advisory Commission to submit to Congress a report on shifting coverage of certain Medicare Part B drugs to Medicare Part D.

This section would require MedPAC to issue a report describing the differences in reimbursement for drugs under Parts B and D and the feasibility of moving coverage of such drugs currently payable under Part B into Part D, with recommendations no later than **June 1, 2021**.

Sec. 148. Taking steps to fulfill treaty obligations to tribal communities.

This section would require GAO to conduct a study of access to and cost of prescription drugs among American Indians. The study would review what tribal communities pay for drugs relative to other consumers and include recommendations to align the value of discounts available to the Medicaid program and discounts available to tribal communities through the purchased and referred care program for physician administered drugs. The study will also include an examination of how tribal communities utilize the Medicare Part D program and recommendations to improve enrollment among these populations. GAO would provide a report **within 18 months of enactment**.

Title II – Medicaid

Sec. 201. Medicaid pharmacy and therapeutics committee improvements.

This section would require states to establish and implement conflict of interest policies for P&T committees including annual disclosures as well as processes for addressing conflicts and failure of members to report conflicts. This section 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 section would be effective **one year after the date of enactment**.

Sec. 202. Medicaid drug use review conflict of interest and reporting requirements.

This section 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 section would also clarify membership requirements for DUR boards, ensure that managed care descriptions of DUR programs include prospective drug review activities and make the DUR data available to the State and Secretary. This section would also encourage the Secretary to create national standards for Medicaid DUR programs and require the Secretary to issue guidance to help ensure compliance. This section 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 section 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 section would require the Secretary to conduct ongoing audits of drug price and product information reported by manufacturers under the MDRP. 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 MDRP. 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 section 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 section would modify the definition of average manufacturer price (AMP) to exclude authorized generic drugs from the calculation of average manufacturer price for brand-name drugs. This section would also clarify the definition of a wholesaler to exclude manufacturers. The section would be effective on the **first day of the first fiscal quarter that begins after the enactment date**.

Sec. 206. Improving transparency and preventing the use of abusive spread pricing and related practices in Medicaid.

The section would ban spread pricing in Medicaid managed care contracts. Among other sections, 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 section 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 section would also require public reporting of WAC cost for covered outpatient drugs under the MDRP.

Sec. 207. Transformed Medicaid Statistical Information System drug data analytics reports.

This section 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. Risk-sharing value-based agreements for covered outpatient drugs under Medicaid.

This section 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 CMS 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 AMP 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 section would increase the current 100 percent AMP cap on Medicaid rebates to 125 percent. 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 percent AMP rebate cap.

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

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