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Summary of Certain Provisions of the Prescription Drug Pricing Reduction Act (PDPRA) of 2019
Chairman's Mark
Scheduled for Markup
By the Senate Committee on Finance
On July 25, 2019

On July 23, Senate Finance Committee Chairman Chuck Grassley (R-Iowa) and Ranking Member Ron Wyden (D-OR) released the Chairman's Mark of the Prescription Drug Pricing Reduction Act (PDPRA) of 2019, bipartisan legislation to reduce health care costs. There are two titles in the bill - one addressing the Medicare program and the other the Medicaid program. Below is a brief description of provisions most relevant to AMCP and its members. AMCP will continue to engage with staff on the Finance committee on these provisions as we have with Members and staff on the Senate Health, Education, Labor, and Pensions (HELP) Committee.

Title I: Medicare

Subtitle A – Part B:

Section 101. Improving Manufacturers' Reporting of Average Sales Prices to Set Accurate Payment Rates

Under current law, manufacturers that participate in the Medicaid drug rebate program are required under Medicaid statute to report to the Secretary of Health and Human Services (HHS Secretary), through the Centers for Medicare and Medicaid Services (CMS), drug pricing information on a quarterly basis such as the average sales price (ASP).

This provision would require manufacturers that do not have a Medicaid drug rebate agreement to report ASP information to the HHS Secretary that would be used to help establish Medicare payment rates.

Section 102. Inclusion of Value of Coupons in Determination of Average Sales Price for Drugs, biologicals, and biosimilars under Medicare Part B

Manufacturers often provide coupons to help privately insured patients reduce their cost-sharing obligations. These coupons are not excluded when calculating ASP under current law. As such, for certain drugs with a large volume of coupons, ASP may overstate the revenue drug manufacturers receive, effectively resulting in higher Medicare Part B payments.

This provision would require that manufacturers exclude the value of these coupons, direct or indirect, from the calculation of ASP beginning on July 1, 2021, as reported to the HHS Secretary.

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

Currently, Medicare pays providers for most Medicare Part B drugs ASP plus a 6% add-on payment. In certain cases, ASP may not be available (such as is the case in the first two quarters a drug is available). In those situations, Medicare uses Wholesale Acquisition Cost (WAC) as the basis for payment. WAC is not adjusted for discounts; as a result, WAC is usually a higher price than ASP. Historically, Medicare has reimbursed at WAC+6% when basing payments on WAC, but CMS reduced this to WAC+3% in 2019. This provision would codify the current WAC+3% in statute.

Section 104. Payment for Biosimilar Biological Products During Initial Period

Beginning on July 1, 2020, the initial payment for a biosimilar for the two-quarter initial period of introduction would be the lesser of WAC+3% of the biosimilar, or ASP+6% of the reference biological.

Section 105. Temporary Increase in Medicare Part B Payment for Biosimilar Biological Products

To encourage development of biosimilars, Medicare pays for biosimilars at a rate of ASP+6% of the reference product. This section would, beginning in 2020, increase the add-on payment for a biosimilar biological product to 8% of the reference product ASP for a period of five years.

Section 107. Medicare Part B Rebate by Manufacturers for Drugs or Biologicals with Prices Increasing Faster than Inflation

This provision would require manufacturers to pay a rebate to Medicare for the amount that their Medicare Part B drugs or biologicals increased above inflation, as measured by the Consumer Price Index for All Urban Consumers (CPI-U). Within 6 months of the end of a quarter, starting in 2021, CMS would report the number of units, the excess amount paid, if any, and the total rebate amount requested.

Drugs paid under the End Stage Renal Dialysis (ESRD) payment system, drugs purchased under the 340B drug discount program, biosimilars, and vaccines are excluded from this provision. CMS could also reduce or waive the rebate requirements for drugs on the FDA's drug shortage list. Failure to pay the rebate would result in a Civil Monetary Penalty (CMP) on a manufacturer.

Section 108. Requiring Manufacturers of Certain Single-dose Vial Drugs Payable under Medicare Part B to Provide Refunds with Respect to Discarded Amounts of Such Drugs

Many Medicare Part B drugs are packaged in single-dose vials. In general, Medicare pays providers for the total amount of product indicated on the single-dose vial package including any product unused. In 2017 Medicare began capturing in claims data the units in a single-dose vial not administered to a patient. This provision would require that manufacturers refund the amount of payment made to providers for unused units in excess of 10% of the total units. It provides an incentive for manufacturers to produce efficient vial sizes while recognizing that the amount of a drug will vary based on beneficiary characteristics and needs. Radiopharmaceuticals and imaging agents are excluded from this rebate provision. CMS can increase the 10% threshold as necessary and manufacturers that fail to pay this refund will be subject to CMPs.

The HHS Secretary would impose a Civil Monetary Penalty (CMP) on a manufacturer that fails to pay a required refund that is equal to 125% of the required refund amount. In addition, non-compliant manufacturers could be subject to other penalties and assessments applicable under Title XI of the Social Security Act.

Section 110. Establishment of Maximum Add-on Payment for Drugs, biologicals, and biosimilars

This provision would establish $1,000 as the maximum add-on amount that a provider can be paid for a drug, biological, or biosimilar that is administered on a calendar date beginning on January 1, 2021. Specifically, the providers would be paid the lesser of the 6% of the ASP for a drug or biological, 6% of the ASP for the reference product for a biosimilar, 3% of WAC for a new drug in the initial period—and $1,000 through December 31, 2028. Beginning in 2029, the maximum ad-on would be updated by CPI-U.

<u>Subtitle B—Part D</u>

Section 121. Medicare Part D Benefit Redesign

One of the more significant sections of the bill deals with an overhaul of the Medicare Part D program. Starting January 1, 2022, it would:

1. Change enrollee cost sharing in the initial coverage limit and the coverage gap
2. Cap enrollee cost sharing above the catastrophic out-of-pocket threshold
3. Change the amount of annual out-of-pocket spending needed to trigger catastrophic coverage.

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

1. Lower federal reinsurance during the catastrophic coverage period
2. Sunset the existing manufacturer discount program in the coverage gap
3. Institute a new manufacturer discount program in the catastrophic coverage phase of the benefit

Medicare pays insurers for each Medicare beneficiary who enrolls in Part D and provides additional subsidies for low-income individuals. The low-income subsidy (LIS) takes two general forms:

1. The direct subsidy under which Medicare pays a monthly payment calculated as 74.5 percent of the national average of plan sponsors' bids, and
2. The reinsurance subsidy under which Medicare pays for 80 percent of drug spending when an enrollee's total drug cost exceeds a catastrophic threshold

Premiums for enrollees are based on 25.5 percent of the national average of plan bids and vary by the plan selected. Medicare also pays insurers low-income subsidies (LIS) to cover all or a portion of the cost sharing and premiums of their low-income enrollees.

Under current law, insurers must offer "standard coverage" Part D coverage, which consists of four phases:

1. A deductible ($415 in 2019),
2. Initial coverage in which the enrollee is responsible for 25 percent of the cost of drugs (with the plan covering the remaining 75 percent),
3. The coverage gap ("donut hole") in which the enrollee is responsible for coinsurance of 25 percent of the cost of brand-name drugs and 37 percent of the cost of generic drugs, with plans covering the remaining 63 percent of generic drug costs and 5 percent of brand-name drug costs and manufacturers providing discounts for the remaining 70 percent of brand-name drugs, and
4. Catastrophic coverage (reinsurance) in which the enrollee is responsible for 5 percent of drug costs, plans are responsible for 15 percent of costs, and Medicare subsidizes 80 percent of costs (the reinsurance subsidy).

Cost sharing for Part D benefits is not capped, as is customary with private insurance. Cost sharing is based on insurers' negotiated prices for drugs, which are the amounts an insurer (or intermediary) and the pharmacy have negotiated as payment for a drug. Reinsurance payments to insurers' for catastrophic coverage are the largest and fastest-growing component of Part D spending—increasing from 25 percent of Medicare payments in 2007 to 54 percent in 2017. Specialty drugs are deemed as high-priced and a major driver of spending growth in Part D. Enrollees who take expensive drugs may face high out-of-pocket costs due to the lack of an annual cap on enrollee out-of-pocket spending in the program.

Section 121 would eliminate the donut hole and establish 25 percent cost-sharing between the annual deductible and the catastrophic threshold. It would also completely eliminate cost-sharing during catastrophic coverage. The catastrophic out-of-pocket threshold would be set at $3,100 in 2022 - indexed to growth in Part D spending. Medicare's portion of reinsurance would be reduced from 80% under current law to 20% for brand drugs and 40% for generic drugs by 2024. Part D plans – currently responsible for 15% of reinsurance - would be responsible for 60% of the liability by 2024. Brand manufacturers would be responsible for reinsurance for the first time since enactment of Medicare Part D.

Current Law and Proposed Reinsurance Liability

	Current Law		2022		2023		2024 and subsequent years	
	Brand	Generic	Brand	Generic	Brand	Generic	Brand	Generic
Federal reinsurance	80%	80%	60%	80%	40%	60%	20%	40%
Plan	15%	15%	20%	20%	40%	40%	60%	60%
Manufacturer	--	--	20%	--	20%	--	20%	--
Beneficiary	5%	5%	--	--	--	--	--	--

The current coverage gap discount program in which manufacturers pay 70 percent of drug costs would be eliminated and replaced with a new discount program in which manufacturers provide a 20% discount during catastrophic coverage. The discounted prices would be provided at the point of sale at a pharmacy or through a mail-order service

Section 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 provision would allow the HHS Secretary to share Medicare Part D and Medicaid drug price and rebate data with the executive directors of MedPAC and the Medicaid and CHIP Payment and Access Commission (MACPAC) for purposes of monitoring, program recommendations, and analysis of the Medicare Part D and Medicaid programs and the State Children's Health Insurance Program. MedPAC and MACPAC would be subject to numerous disclosure and confidentiality measures. This provision would be effective immediately.

Section 123. Public Disclosure of Drug Discounts and Other PBM Provisions

Health insurers typically contract with or own pharmacy benefit managers (PBMs) that perform a range of services on behalf of a plan. PBMs generally negotiate prices for drugs provided in retail pharmacies, but in some cases PBMs dispense drugs from their own mail-order or specialty pharmacies. The terms of these contracts are confidential in order to preserve competition. PBMs and insurers are required to report some data about prescription drug sales and prices under Medicare Part D.

Prescription drug price concessions that are not passed on to enrollees at the point of sale are reported to CMS as direct and indirect remuneration (DIR). Plans must submit detailed DIR reports to CMS within six months after the close of a plan year.

This provision would require HHS to make public aggregate price concessions (including rebates and discounts) as well as the aggregate amount of the difference between what an insurer pays a PBM, and what a PBM pays retail pharmacies and mail order pharmacies, and the number of prescriptions dispensed. No data on individual drugs or contract terms may be disclosed. Part D insurers also would be required to report to pharmacies any sale-adjustment for price concessions after the point-of-sale.

Finally, this provision would require Part D insurers to report actual and projected DIR amounts in their bids for Part D coverage, including those related to pharmacies. The purpose is to ensure that projected remuneration related to pharmacies and manufacturers is based on actual remuneration in a prior year.

Section 124. Public Disclosure of Direct and Indirect Remuneration Review and Audit Results

Most insurers use rebates and discounts they receive to lower their premiums for Part D coverage. As mentioned above, concessions that are not passed on to enrollees at the point of sale are reported to CMS as DIR and may include discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by an intermediary organization with which the Part D insurer has contracted, such as a PBM. Plans must submit detailed DIR reports to CMS within six months after the close of a plan year.

This provision would require the Secretary to publicly report on discrepancies related to direct and indirect remuneration information submitted by plans, demonstrating the accuracy with which insurers report direct and indirect remuneration. The Secretary would also be required to publicly report the results of the independent third-party financial audits of plans, that includes DIR information, conducted under current law, beginning in 2020.

Section 125. Increasing Use of Real-Time Benefit Tools to Lower Beneficiary Costs

This provision would require Part D insurers to provide for a "real-time benefit tool (RTBT)," as adopted by CMS, that enables electronic transmission of formulary and benefit information to each enrollee's prescribing clinician, using technology that integrates with clinicians' electronic prescribing and EHR systems.

In addition, this provision would enable physicians to get credit for using a RTBT in the Medicare physician fee schedule Merit-based Incentive Payment System (MIPS) by adding it to a menu of practice improvement activity options.

Section 126. Improvements to Provision of Parts A and B Claims Data to Drug Plans

This provision would create an exception to the limitation on Part D insurers' use of fee-for-service claims data for Part D coverage determinations. The provision would allow insurers to use the data for Part D coverage determinations related to approved purposes, such as to improve therapeutic outcomes. This provision would go into effect January 1, 2021.

Section 128. Medicare Part D Rebate by Manufacturers for Certain Drugs with Prices Increasing Faster than Inflation

This provision would establish a mandatory rebate if a pharmaceutical manufacturer increases their list price for a Part D brand (not generic) or biologic (not biosimilar) drugs above inflation. These manufacturers would provide rebates to Medicare for each six-month period in which the list price exceeded the change in CPI-U. The rebate amount would be product of the quantity of each covered drug during the rebate period and the amount by which the drug's actual average daily list price exceeded the inflation-adjusted list price.

Subtitle C – Miscellaneous

Section 141. Drug Manufacturer Price Transparency

The provision would add a new SSA Section 1128L, effective July 1, 2022, requiring drug manufacturers to report to the HHS Secretary information and supporting documentation needed to justify price increases for prescription drugs and biological products, as measured by the WAC or changes in the WAC in cases where the Secretary determines the manufacturer's price increase met or exceeded certain thresholds. The Secretary would be required to publicly post the price justifications, as specified in the provision.

The reporting requirements for applicable drugs would apply to three categories, defined as:

1. Prescription drugs or biologics with list price of at least $10 per dose and price increase:
   a) In 2020 of at least 100% since enactment of the legislation;
   b) During 2021 of at least 100% in the preceding 12 months or at least 150% in the preceding 2 years;
   c) During 2022 of at least 100% in the preceding 12 months or at least 200% in the preceding 3 years;
   d) During 2023 of at least 100% in the preceding 12 months or at least 250% in the preceding 4 years; or,
   e) On or after January 1, 2024, of at least 100% in the preceding 12 months or at least 300% in the preceding 5 years;
2. Prescription drugs and biologics in the top 50% of net spending (per dose) in Medicare or Medicaid in at least one of the preceding 5 years and a list price increase:
   a) In 2020 of at least 15% since enactment of the legislation;
   b) During 2021 of at least 15% in the preceding 12 months or at least 20% in the preceding 2 years;
   c) During 2022 of at least 15% in the preceding 12 months or at least 30% in the preceding 3 years;
   d) During 2023 of at least 15% in the preceding 12 months or at least 40% in the preceding 4 years; or,
   e) On or after January 1, 2024, of at least 15% in the preceding 12 months or at least 50% in the preceding 5 years.

3. New drugs with a list price established for the first time, if the list price for a year supply or course of treatment exceeds the gross spending for covered Part D drugs necessary to meet the annual out-of-pocket threshold (about $10,000 in 2022).

The Secretary would notify a manufacturer within 60 days of identifying a drug as an applicable drug. After being notified, the manufacturer would have 180 days to provide a price justification to the Secretary, which would be posted on the CMS website no later than 30 days after receipt, along with a summary written in a way that would be easily understandable to Medicare and Medicaid beneficiaries. A price justification would not be required if a manufacturer, after it received notification, reduced the list price for an applicable drug so that, for at least 6 months, it no longer met the qualifying criteria. Drugs that qualify based on new launch price would remain applicable drugs until the Secretary determines there is a therapeutic equivalent.

TITLE II—MEDICAID

Section 201. Medicaid Pharmacy and Therapeutics (P&T) Committee Improvements

This section would amend the Social Security Act (SSA) Section 1927(d)(4) to enhance state Medicaid program requirements applicable to P&T committees.

If a state establishes a drug formulary as under current law, this provision would require state Medicaid programs to establish P&T committees to develop and review the Medicaid covered outpatient drug formularies. P&T committees would be required to include physicians, pharmacists, and other appropriate individuals appointed by a governor. The state would be required to establish and implement a P&T committee conflict of interest policy that would:

1. be publicly accessible;
2. require all P&T committee members at least annually to disclose any relationships, associations, and financial dealings that might affect their independent judgement on committee matters; and
3. identify committee processes, such as recusal from voting or discussion, for those members who report a conflict of interest, as well as processes if a member fails to report a conflict of interest.

States would be required to include at least one practicing physician and one practicing pharmacist who were independent and free of manufacturer, Medicaid plan, and PBM conflicts of interest. The required P&T physician and pharmacist committee members would also be required to have expertise in the care of at least one Medicaid-specific beneficiary population, such as elderly or disabled, children with complex needs, or low-income chronic, care individuals.

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

This provision would amend SSA Section 1927(k)(1) to exclude authorized generic drugs from the calculation of AMP under the Medicaid drug rebate program and for other purposes.

Section 206. Improving Transparency and Preventing the Use of Abusive Spread Pricing and Related Practices in Medicaid

This provision would amend the Social Security Act (SSA) Section 1927(e) to require pass-through pricing for outpatient drugs in Medicaid including under managed care. It would require payment for pharmacy management services to be limited to ingredient cost and a professional dispensing fee that is not less than the professional dispensing fee that the State plan or waiver would pay, passed through in their entirety to the pharmacy that dispenses the drug. It would require payment to the PBM for administrative services to be limited to a reasonable administrative fee It would make any form of spread pricing unallowable for purposes of claiming Federal matching payments under Medicaid.

The HHS Secretary would also be instructed to issue a report to Congress examining specialty drug coverage and reimbursement under Medicaid.

Section 208. Risk-Sharing Value-based Agreements for Covered Outpatient Drugs under Medicaid

Prescription drugs are an optional Medicaid benefit, but all states provide an outpatient drug benefit. Drug manufacturers that voluntarily participate in the Medicaid Drug Rebate Program (MDRP) are required to offer their products to all state Medicaid programs at their lowest "best" price or to pay a rebate, whichever results in a lower price to the Medicaid program.

The current pipeline for new drugs includes an increasing number of gene therapies, which may be administered once and lead to remission of symptoms or potential genetic cures. While the FDA has designated a number of these as rare diseases or conditions, the high cost of these drugs can have a significant impact on state Medicaid spending even with Medicaid receiving the best price.

The provision would add an option for states to pay for certain covered outpatient drugs through risk-sharing value-based agreements. States would be able to use the risk-sharing value-based agreements with drug manufacturers for covered outpatient drugs that are potentially curative treatments intended for one-time use.

The payments for the agreement would be structured as installment-based payments with the state paying equal installments of the total installment year amount at regular intervals.

The HHS Secretary would be required to submit a report to Congress with specified information no later than five years after the first risk-sharing value-based agreement is approved including an assessment of the impact of such agreements on access to medically necessary covered

outpatient drugs and related treatments for Medicaid enrollees, analysis of the impact of such agreements on overall State and Federal spending, an impact of such agreements on drug prices, and recommendations to Congress as appropriate.

Section 209. Modification of Maximum Rebate Amount under Medicaid Drug Rebate Program

There are two statutory Medicaid rebates, a basic rebate and an additional rebate. The additional rebate, also referred to as the inflation rebate, is added to the amount of basic rebate to equal the total statutory rebate. The inflation rebate is applied when drug manufacturers increase product prices faster than the drug's inflation adjusted average manufacturer price (AMP).

Drug manufacturers' Medicaid rebate obligations attributable to the inflation rebate do not continue to increase once a drug's AMP reaches the maximum rebate cap of 100% of the product's rebate period AMP. Once a drug reaches the maximum rebate of 100% of the product's AMP, additional price increases will not result in larger rebates.

This provision would revise SSA Section 1927(c)(2) by increasing the maximum allowable Medicaid rebate permissible in a rebate period from 100% of a covered outpatient drug's average manufacturer price (AMP) to 125% effective for rebate periods beginning October 1, 2022.For rebate periods between December 31, 2009 and October 1, 2022, the maximum allowable Medicaid rebate would remain at 100% of the product's rebate period AMP.

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.