

Description of the Chairman's Mark
The Prescription Drug Pricing Reduction Act (PDPRA) of
2019

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Table of Contents

TITLE I—MEDICARE	4
Subtitle A – Part B	4
Section 101. Improving Manufacturers’ Reporting of Average Sales Prices to Set Accurate Payment Rates.....	4
Section 102. Inclusion of Value of Coupons in Determination of Average Sales Price for Drugs, biologicals, and biosimilars under Medicare Part B	4
Section 103. Reduced wholesale acquisition cost (WAC)-based payments for new drugs, biologicals, and biosimilars	5
Section 104. Payment for Biosimilar Biological Products During Initial Period	6
Section 105. Temporary Increase in Medicare Part B Payment for Biosimilar Biological Products ...	6
Section 106. Improvements to Medicare Site-of-Service Transparency.....	7
Section 107. Medicare Part B Rebate by Manufacturers for Drugs or Biologicals with Prices Increasing Faster than Inflation.....	7
Section 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	9
Section	10
109. Clarification of Medicare Average Sales Price Payment Methodology	10
Section 110. Establishment of Maximum Add-on Payment for Drugs, biologicals, and biosimilars.	11
Section 111. Treatment of Drug Administration Services Furnished by an Off-Campus Outpatient Department of a Provider	11
Subtitle B—Part D	12
Section 121. Medicare Part D Benefit Redesign.....	12
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.....	16
Section 123. Public Disclosure of Drug Discounts and Other PBM Provisions	17
Section 124. Public Disclosure of Direct and Indirect Remuneration Review and Audit Results.....	19
Section 125. Increasing Use of Real-Time Benefit Tools to Lower Beneficiary Costs.....	20
Section 126. Improvements to Provision of Parts A and B Claims Data to Drug Plans	21
Section 127. Permanently Authorize a Successful Pilot on Retroactive Part D Coverage for Low-Income Beneficiaries.....	22
Section 128. Medicare Part D Rebate by Manufacturers for Certain Drugs with Prices Increasing Faster than Inflation	23
Subtitle C – Miscellaneous	26
Section 141. Drug Manufacturer Price Transparency	26

Section 142. Permissive Exclusion from Federal Health Care Programs Expanded to Individuals and Entities Affiliated with Sanctioned Entities	28
TITLE II—MEDICAID	28
Section 201. Medicaid Pharmacy and Therapeutics Committee Improvements.....	28
Section 202. Medicaid Drug Use Review Conflict of Interest and Reporting Requirements	30
Section 203. GAO Report on Conflicts of Interest in State Medicaid Program Drug Use Review Boards and Pharmacy and Therapeutics (P&T) Committees.....	31
Section 204. Ensuring the Accuracy of Manufacturer Price and Drug Product Information under the Medicaid Drug Rebate Program	32
Section 205. Excluding authorized generics from the calculation of average manufacturer price for purposes of the Medicaid Drug Rebate Program	33
Section 206. Improving Transparency and Preventing the Use of Abusive Spread Pricing and Related Practices in Medicaid	33
Section 207. T-MSIS Drug Data Analytics Reports	35
Section 208. Risk-Sharing Value-based Agreements for Covered Outpatient Drugs under Medicaid	36
Section 209. Modification of Maximum Rebate Amount under Medicaid Drug Rebate Program.....	39
Section 210. Applying Medicaid Drug Rebate Requirement to Drugs Provided as Part of Outpatient Hospital Services	40

TITLE I—MEDICARE

Subtitle A – Part B

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

Current Law

Prescription drug, biological, and biosimilar 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), certain calendar quarter drug pricing information such as the average sales price (ASP), the number of units sold, and for some drugs, the wholesale acquisition cost (WAC) or list price. ASP is defined as a manufacturer’s quarterly sales of a drug to all U.S. purchasers; divided by the drug’s total units sold for the same quarter.

Medicare pays providers for most Part B drugs, biologicals, and biosimilars based on the ASP. In general, in setting Medicare Part B drug payment rates, CMS aggregates drug manufacturer ASP data by Medicare billing codes, so that ASP is the weighted average of the manufacturer ASPs for each product classified under a Medicare billing code. Generally, there is one billing code for brand name products, but there can be many generic drugs that are equivalent products grouped under a single billing code.

Provision

This provision would require prescription drug, biological, and biosimilar 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. These manufacturers would be required to report quarterly ASP information beginning with the first calendar quarter after the date of enactment.

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

Current Law

Prescription drug, biological, and biosimilar manufacturers often provide drug coupons for specific drugs to help privately insured patients reduce their cost-sharing obligations, including deductibles, copayments, and coinsurance. Manufacturers provide drug coupons for brand name products as well as generic and biosimilar drugs. Manufacturers use coupons to help patients access needed medications but also to encourage patients to continue to use to their products, which can help generate more sales. Under Medicare statute, manufacturers are directed to calculate ASP for individual prescription drugs, biologicals, and biosimilars based on the price they sell to purchasers net of most price concessions, including volume, prompt-pay, and cash discounts and rebates, except Medicaid rebates. In calculating ASP, manufacturers are not required to include sales net of price concessions provided directly to patients, such as through drug coupons. When the value of patient coupons is high, ASP tends to overstate the amount

drug manufacturers are receiving for their product, effectively resulting in higher Medicare Part B payments.

Provision

This provision would require prescription drug, biological, and biosimilar manufacturers to exclude the value of coupons provided to privately insured individuals from each drug's ASP, as reported to the HHS Secretary. This provision would apply to manufacturers' product sales for calendar quarters beginning on July 1, 2021. This provision would define coupons to mean financial support provided by a manufacturer to a patient, either directly or indirectly, specific to the manufacturer's drug through a physician, prescriber, pharmacy, or other provider that is used to reduce or eliminate cost sharing or other out-of-pocket costs, including costs related to a deductible, coinsurance, or copayment. Manufacturers would not have to exclude contributions to patient assistance programs or foundations, which are generally provided to patients based on need and not specific to the contributing manufacturer's drug.

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

Current Law

Medicare pays providers for most Medicare Part B drugs, biologicals, and biosimilars at 100% of each product's ASP plus a 6% add-on payment. In certain situations, however, Medicare may use different benchmark prices to pay providers for drugs, biologicals, and biosimilars, such as a drug's WAC, and also may use a different add-on payment. Medicare statute directs manufacturers to calculate ASP for individual prescription drugs, biologicals, and biosimilars net of most price concessions, including volume, prompt-pay, and cash discounts and rebates, except Medicaid rebates. WAC is a published price that is not adjusted for discounts; as a result, WAC is usually a higher price than ASP.

Medicare uses WAC to set the Part B drug benchmark price in several situations. WAC is used to set the payment when the ASP is unavailable during a product's first two quarters on the market as manufacturers have not yet recorded sales that can be used to determine the average price. In these situations, by statute, the HHS Secretary may use either a WAC-based payment methodology or a payment methodology in effect on November 1, 2003 when the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173) was enacted. Even though the statute does not specify the add-on payment amount when using the WAC methodology (or a payment methodology in effect on November 1, 2003), Medicare has used a 6% add-on when basing payments on WAC, but CMS reduced the WAC-based add-on to 3% starting on January 1, 2019 through rulemaking.

When ASP becomes available, the statute requires the HHS Secretary to pay Medicare Part B drugs and biologicals at ASP plus a 6% add-on payment.

Provision

This provision would establish a WAC add-on payment 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 pays WAC plus 3%, an amount that CMS established using administrative authority.

Section 104. Payment for Biosimilar Biological Products During Initial Period

Current Law

Biological products are drugs derived from living organisms or contain components of living organisms, whereas conventional drugs are manufactured from chemicals. In contrast to generic drugs, which are exact copies of brand-name chemical drugs, biosimilar biologic products are similar, but not identical to brand-name biologicals (reference products).

Medicare pays providers for most Part B drugs, biologicals, and biosimilars at the rate of the product's ASP plus a 6% add-on payment. To encourage development of lower priced biosimilars, under Medicare statute the payment rate for biosimilars is the ASP of the biosimilar plus an add-on payment equal to 6% of the reference biological product's ASP.

Medicare statute does not specifically address the payment rate for biosimilars during the initial product introduction period when ASP information may be unavailable, but current Medicare payment rules establish that biosimilars are paid at their WAC plus 3% during the roughly two-quarter initial period.

Provision

This provision would establish a payment rate for biosimilars furnished on or after July 1, 2020 for the roughly two-quarter initial period that would be the lesser of: (1) the biosimilar's WAC plus a 3%; or (2) ASP plus 6% of the reference biological product.

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

Current Law

In contrast to generic drugs, which are exact copies of brand-name chemical drugs, biosimilar biologic products are similar, but not identical to brand-name biologicals (reference products). Medicare pays providers for most Part B drugs, biologicals, and biosimilars at the rate of the product's ASP plus a 6% add-on payment. To encourage development of lower priced biosimilar biological products, under Medicare statute the payment rate for biosimilar biologics is the ASP of the biosimilar product plus an add-on payment equal to 6% of the reference biological product's ASP.

Provision

This provision would increase the add-on payment for a biosimilar biological product from 6% of the reference product's ASP to 8% of the reference product ASP for a period of five years. The temporary add-on payment increase would apply to a biosimilar: (1) paid by Medicare as of December 31, 2019, for a five-year period beginning January 1, 2020; and (2) paid on or after

January 1, 2020, for a five-year period that would begin on the first day of the first calendar quarter in which the product was paid under Medicare Part B.

Section 106. Improvements to Medicare Site-of-Service Transparency

Current Law

Medicare payments are generally determined by the type of service and the site where it is delivered. Differences across Medicare's payment systems have created instances where Medicare payment rates for similar or identical services differ depending on the site. This includes Medicare payments across hospital outpatient departments (HOPDs), ambulatory surgical centers (ASCs), and physician offices. Generally, beneficiaries are responsible for a 20% coinsurance payment for Part B services. Therefore, different Medicare payment rates across sites of service result in different cost-sharing amounts for similar or identical services depending on the site.

To facilitate price transparency, the 21st Century Cures Act of 2015 (Public Law 114-255) required, beginning in 2018 and for each year thereafter, the HHS Secretary to make available on a public website the Medicare estimated payment to HOPDs under the outpatient prospective payment system (OPPS) and ASCs under the ASC payment system as well as the estimated beneficiary cost-sharing liability in each setting.

Provision

This provision would modify the transparency tool provision in the 21st Century Cures Act of 2015 to require comparable information for services that can also be furnished in a physician office. Specifically, the HHS Secretary would be required to add the estimated payment to a physician under the Medicare physician fee schedule (PFS) and the associated estimated beneficiary cost-sharing liability, beginning in 2021, to allow beneficiaries to compare across the three settings.

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

Current Law

No provision in current law.

Provision

This provision would require prescription drug and biological manufacturers to pay a rebate to Medicare for the amount that their Medicare Part B drugs or biologicals increased above the inflation rate, as measured by the Consumer Price Index for All Urban Consumers (CPI-U).

This provision would define a "rebateable" drug as a brand prescription drug or biological that is separately payable when furnished in a physician office, HOPD, and ASC setting. This definition of rebateable drug would not include biosimilars or vaccines paid under Part B.

Beginning on or after January 1, 2021, the HHS Secretary would be required within six months of the end of each calendar quarter to provide prescription drug and biological manufacturers with: the total number of billing units for each rebatable drug for the quarter; the amount, if any, of the excess ASP increase for the quarter; and the rebate amount for the rebatable drug.

Manufacturers would be required to pay the HHS Secretary the quarterly rebate within 30-days of receiving information from the invoice.

The HHS Secretary would be required to establish procedures for a manufacturer to request reconsideration of the calendar quarter rebate amount.

The total number of billing units would exclude: (1) units paid under the End Stage Renal Dialysis (ESRD) payment system; and (2) units for which a manufacturer provides a discount under Section 340B of the Public Health Service Act or a rebate under the Medicaid Drug Rebate Program.

The HHS Secretary would use the ASP payment amount for a rebatable drug in effect for the calendar quarter beginning July 1, 2019 (the ASP “payment amount benchmark”) and apply the CPI-U percentage change in each subsequent quarter to adjust the benchmark payment amount (the ASP “inflation-adjusted payment amount”). A manufacturer would owe a rebate in each quarter that the ASP payment amount exceeded the inflation-adjusted ASP payment amount.

For new drugs, the Secretary would establish the “payment amount benchmark” as the date that the drug is first marketed by the manufacturer, with that payment amount benchmark being adjusted by the CPI-U percentage change in each subsequent quarter to arrive at the inflation-adjusted payment amount. The initial WAC-based payment amount benchmark would be compared to an inflation-adjusted WAC amount until an ASP-based payment amount is established. That ASP payment amount benchmark would then be compared to an inflation-adjusted ASP in each subsequent calendar quarter.

The HHS Secretary would be authorized to reduce or waive the rebate requirements for rebatable drugs if those products are on the FDA drug shortage list.

Manufacturer rebates would be deposited in the Medicare Supplementary Medical Insurance Trust Fund.

The HHS Secretary would impose a Civil Monetary Penalty (CMP) on a manufacturer that fails to pay a required rebate that is equal to 125% of the required rebate amount. The HHS Secretary would ensure that no payment under Medicare Part B is available for a drug for which the manufacturer failed to pay a CMP imposed by the Secretary for non-payment of the rebate. In addition, non-compliant manufacturers could be subject to other penalties and assessments applicable under Title XI of the Social Security Act.

This provision would amend the definition of Medicare ASP to exclude Medicare Part B rebatable drug rebates from the calculation of ASP.

Section 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

Current Law

Medicare pays for most prescription drugs, biologicals, and biosimilars covered under Medicare Part B based on a product's ASP plus a 6% add-on payment. Many Medicare Part B drugs, biologicals, and biosimilars are packaged in single-dose vials as identified from information included in the FDA approval, such as the label or package insert. Generally, Medicare pays providers for the total amount of product indicated on the single-dose vial package including the number of units of any unused product as well as the number of units administered to the patient.

To help identify and track the amount of unused Medicare Part B prescription drugs, biologicals, and biosimilars beginning January 1, 2017, Medicare started to require providers to enter on Part B claims the number of units of a prescription drug or biological packaged in a single-dose vial that were not administered to the patient. CMS's guidance accompanying the reporting requirement, directed providers to include a modifier, identified as the "JW" modifier, on the billing claim form to indicate the unused portion. Providers were also required to record the amount administered in the patient medical record. Prior to January 1, 2017, Medicare contractors had discretion as to whether to require providers to identify the unused portion of single-dose vials on the claims form.

Provision

This provision would require the manufacturer of prescription drug, biological, and biosimilar beginning on July 1, 2021 to refund the amount of payment made to providers for unused amounts of certain single-use vials that exceed a minimum threshold.

This provision would define "refundable" drugs as all drugs, biologicals, and biosimilars packaged as single-dose vials covered under Medicare Part B except radiopharmaceuticals and imaging agents.

For each calendar quarter beginning on or after July 1, 2021, the HHS Secretary would be required to report to the manufacturer the number of units of a refundable drug that were discarded, as identified by the JW modifier that the billing provider included on the claim form. The HHS Secretary would be required to exclude units that are "packaged" and not paid separately under Part B.

The amount that a manufacturer would owe for a refundable drug during a quarter is: the amount by which the Medicare payment attributed to the unused units exceeds 10% of the amount Medicare paid for the total units.

This formula would ensure that a manufacturer of a refundable drug only pay a refund if the unused units are 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.

The HHS Secretary may increase the 10% allowance threshold before which a manufacturer would have to pay a refund through notice and comment rulemaking. The HHS Secretary may exercise this authority for refundable drugs: (1) for which preparation instructions approved by the Food and Drug Administration (FDA) include filtration during the preparation process; and (2) that have unique circumstances that involve similar product loss.

Manufacturer refunds would be deposited in the Medicare Supplementary Medical Insurance Trust Fund.

This provision would require the HHS Secretary to conduct periodic audits on payment claims submitted by providers for refundable single dose vial drugs.

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 This provision 109. Clarification of Medicare Average Sales Price Payment Methodology

Current Law

Medicare pays providers for most Part B drugs, biologicals, and biosimilars at the ASP plus a 6% add-on fee. Manufacturers calculate ASP for each drug, biological, and biosimilar and are required to report to the HHS Secretary ASP and the number of Medicare Part B units sold during a calendar quarter.

In calculating ASP, Medicare statute directs manufacturers to calculate their Part B drug sales net of price concessions such as volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on purchase requirements, chargebacks, and rebates, other than Medicaid rebates. For sales after 2004, the HHS Secretary may include other price concessions, as recommended by the HHS OIG, that result in a reduction in cost to the purchaser, such as physicians, hospitals, or wholesalers. Drug transactions often include service and other fees that are added to Part B drug purchasers' cost. Service and other fees not deducted from ASP generally increases ASP and thereby the cost of Part B drugs to Medicare as well as Medicare Part B beneficiary cost-sharing for Part B drugs.

Provision

This provision 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. Specifically, this provision would narrow the existing definition of bona fide service fees that the HHS Secretary established using administrative authority. The more narrow definition of bona fide service fees exempt from ASP reporting that would be established by this provision would explicitly prohibits: 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. This provision would result expand the fees

that manufacturers pay to wholesalers and group purchasing organizations that must be treated as a price concession and included in the reported ASP.

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

Current Law

Medicare pays providers for most Part B drugs, biologicals, and biosimilars at the rate of the product's ASP plus a 6% add-on payment. The Medicare payment rate for biosimilars is the ASP of the biosimilar plus an add-on payment equal to 6% of the reference biological product's ASP. Medicare payment rate for a new drug during the first two quarters it is on the market is typically WAC plus a 3% add-on.

Provision

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 provider billing for the drug would be paid the lesser of the add-on amount that would otherwise be paid—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. For 2029 and each subsequent year, the \$1,000 maximum add-on amount would be updated by CPI-U. The provision would apply to drugs that are separately payable when furnished in a physician office, HOPD, and ASC setting.

Section 111. Treatment of Drug Administration Services Furnished by an Off-Campus Outpatient Department of a Provider

Current Law

Medicare Part B generally covers outpatient drugs that are administered by health professionals in a physician offices and an HOPD. Health professionals receive a payment intended to cover the cost of purchasing the drug and another payment for the professional service of administering the drug to the beneficiary. Payments are determined under the PFS or OPSS depending on the site of service. Beneficiaries generally face cost sharing equal to 20% of the Medicare payment rate for the drug and administration of the drug.

In addition to covered drugs, some Medicare-covered services can also be provided in a physician office, HOPD, or ASC. The payment amount for these services is determined under the payment system for each different site. The payment amount typically differs for the same or similar service under Medicare PFS, the OPSS, and ASC payment system.

The Bipartisan Budget Act of 2015 (Public Law 114-74) and the 21st Century Cures Act of 2005 (Public Law 114-255) specified that most HOPDs off the campus of the main hospital that had not billed Medicare under the OPSS prior to the date of enactment (or were in the process of being built) would be paid the lower rates under the PFS or ASC payment system, instead of the generally higher OPSS rates. Off-campus HOPDs paid under OPSS at the time of enactment of these laws are excepted from the policy and continue to be paid under the OPSS.

Provision

This provision would remove the exception for “grandfathered” off-campus HOPDs that were established by the Bipartisan Budget Act of 2015 and the 21st Century Cures Act of 2015. Thus, the payment for the professional service of administering a Medicare Part B drug be made at the PFS rate rather than the OPPS rate beginning January 1, 2021. The HHS Secretary would be instructed not to apply this provision in a budget neutral manner, meaning that the reduced payments would lower federal spending and beneficiary cost-sharing.

Subtitle B—Part D

Section 121. Medicare Part D Benefit Redesign

Current Law

Medicare Part D provides outpatient prescription drug coverage for Medicare beneficiaries and is the primary source of drug coverage for low-income individuals enrolled in both Medicare and the state-federal Medicaid program. Part D coverage is voluntary and administered through private health insurers, often referred to as plan sponsors. Congress designed Part D as a market-oriented program in which insurers compete for enrollees based on plan premiums and scope of benefits, including cost-sharing amounts for enrolled beneficiaries.

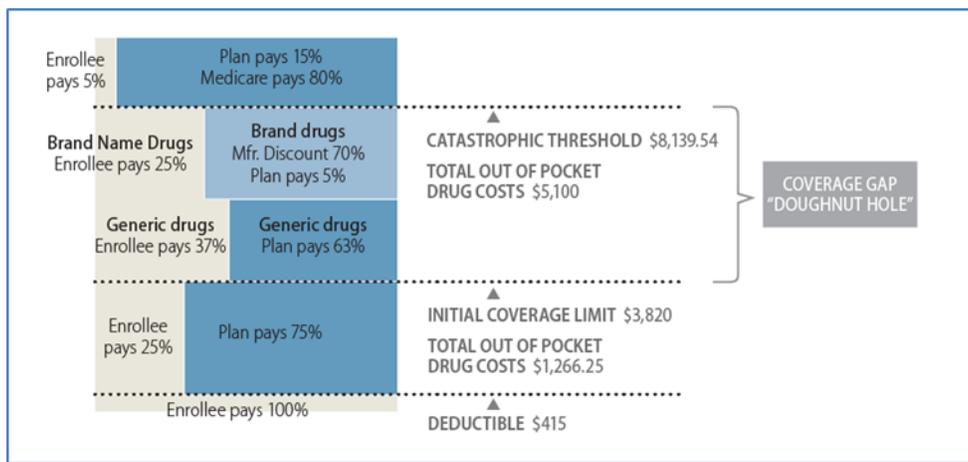
Medicare pays insurers for each Medicare beneficiary who enrolls in Part D and provides additional subsidies for low-income individuals. The Part D payments to insurers takes two general forms: the direct subsidy under which Medicare pays a monthly payment calculated as 74.5 percent of the national average of plan sponsors’ bids, and 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.

Insurers must offer “standard coverage” Part D coverage which consists of four phases (See Figure 1.):

- a *deductible* (\$415 in 2019);
- *initial coverage* in which the enrollee is responsible for 25 percent of the cost of drugs (with the plan covering the remaining 75 percent);
- the *coverage gap* (“doughnut 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
- *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. Insurers may pass on to enrollees the full value of any rebates and discounts negotiated with manufacturers and pharmacies in the price paid at the pharmacy counter, but the majority do not, according to data from the Centers for Medicare and Medicaid Services (CMS). Most insurers use the majority of rebates and discounts to lower their premiums for Part D coverage. As a result, although list price may not reflect the final amount a manufacturer receives for a drug, it is often used as the basis for consumer drug spending at the pharmacy counter.

Figure 1. Medicare Part D Standard Coverage Benefit for 2019



Source: CRS graphic based on Centers for Medicare & Medicaid Services data.

Note: Above the catastrophic threshold, enrollee cost-sharing is the greater of a nominal set co-payment for drugs or 5 percent coinsurance. In addition to prescription cost sharing in the standard benefit figure, enrollees pay monthly premiums.

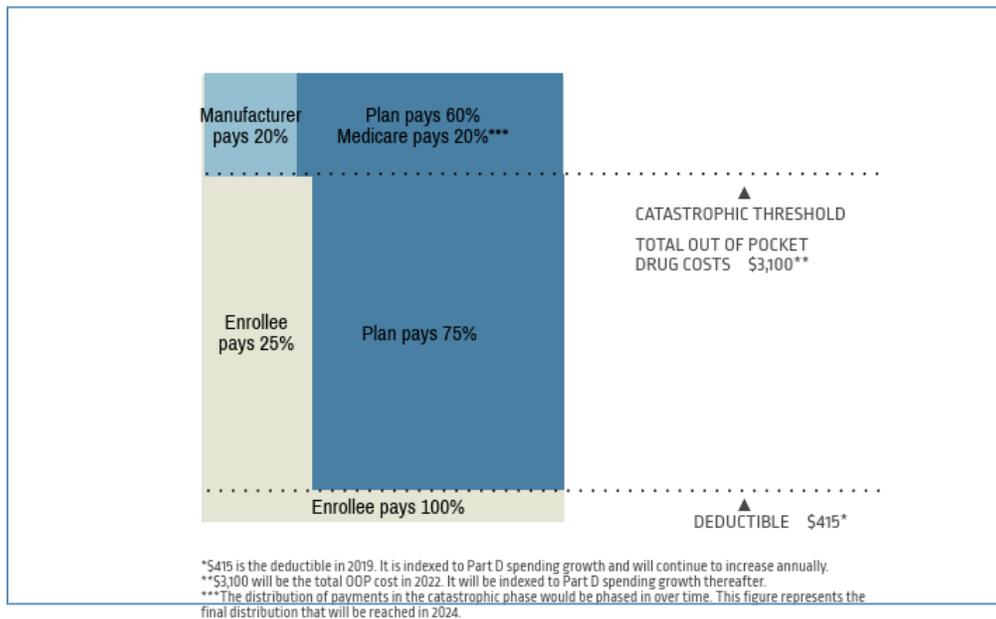
The Medicare Payment Advisory Commission (MedPAC) has noted that Medicare's reinsurance payments to insurers' for catastrophic coverage are the largest and fastest-growing component of Part D spending—increasing from 25 percent of Medicare payments in 2007 to 54 percent in 2017. Specialty drugs are deemed 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.

Additionally, MedPAC analysis suggests that insurers' limited liability for drug spending during the coverage gap and catastrophic coverage phases of the benefit reduces their financial incentive to steer utilization toward the lowest cost drugs, including generic and biosimilar versions of brand-name drugs.

Provision

This provision would make substantial changes to the structure of the Part D benefit in order to simplify the benefit design and realign incentives to encourage more efficient management of drug spending. 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; and (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; and (3) institute a new manufacturer discount program in the catastrophic coverage phase of the benefit. See Figure 2.

Figure 2. Medicare Part D Standard Coverage Benefit Redesign



To simplify and reduce cost sharing for Part D enrollees, this provision would eliminate the coverage gap 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 and indexed to growth in Part D spending. This amount reflects the true out-of-pocket spending enrollees face before reaching catastrophic coverage under Part D today. Additionally, the provision would reduce federal reinsurance payments so that Medicare is responsible for 20 percent and insurers for 60 percent, respectively, of total drug spending during catastrophic coverage. See Table 1.

Finally, this provision would sunset the current coverage gap discount program in which manufacturers pay 70 percent of drug costs. Instead, the provision would establish a new

manufacturer discount program in which manufacturers provide discounts for drugs and biologics utilized during catastrophic coverage. Under the provision, manufacturers that choose to have their drugs covered under Part D would enter into agreements with the Secretary of Health and Human Services (HHS) to provide 20 percent discounts off negotiated prices during catastrophic coverage, including for LIS beneficiaries. Insurers would subtract the anticipated manufacturer discounts from the actuarial value of the Part D benefit when submitting annual bids to CMS.

Table 1: 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%	--	--	--	--	--	--

Manufacturers would provide catastrophic coverage discounts to applicable beneficiaries, defined as individuals who are: 1) enrolled in a Part D plan; 2) are not enrolled in a qualified retiree prescription drug plan; and 3) have incurred costs for covered part D drugs in a year that are equal to or exceed the annual out-of-pocket threshold. The discounts would be provided for applicable drugs, which are defined as brand-name drugs and biologics and biosimilars on the formulary of a Part D plan or otherwise covered by a Part D plan, including through an enrollee exception or appeal. The discounted prices would be provided at the point of sale at a pharmacy or through a mail-order service. Manufacturers would provide appropriate data to demonstrate they comply with the program.

The catastrophic coverage discount would be administered in the same way as the coverage gap discount program is today. CMS would contract with one or more third parties to administer the discounts. If a third party administrator determined a manufacturer was not in compliance, the third party would be required to notify the Secretary. The Secretary could collect appropriate data from insurers in a timeframe that allowed for discounted prices to be provided for applicable drugs. Manufacturers would be subject to periodic CMS audits. HHS could impose civil monetary penalties on manufacturers that failed to provide required catastrophic coverage discounts. The penalty would be commensurate with the sum of: (1) the amount the manufacturer would have paid with respect to such discounts under the agreement; and (2) 25 percent of such amount. The Secretary could terminate a manufacturer agreement for a “knowing

and willful violation” of program requirements. A manufacturer could request a hearing, which would be allowed with sufficient time for the effective date to be repealed if determined appropriate. A manufacturer would be allowed to terminate an agreement to provide discounts for any reason.

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

Current Law

Private insurers and pharmaceutical manufacturers that participate in Medicare Part D or the state-federal Medicaid program must provide drug price information to HHS for use in program payment and administration. For market competition reasons, federal law protects the confidentiality of the data.

Under current law, Part D insurers must provide information as the HHS Secretary determines is necessary to calculate and administer payments (such as direct subsidies and reinsurance payments). During each plan year, CMS makes monthly prospective payments to insurers, based on cost and revenue estimates in their annual bids to provide benefits. Six months after the end of each year, CMS reconciles the projected payments with actual plan costs, based on updated data including actual enrollment, LIS eligibility, enrollee health risk scores, and prescription drug price data. Information disclosed or obtained pursuant to the drug data reporting requirements may be used by HHS to administer the program and conduct oversight, evaluation, and enforcement. The data may also be provided to the Department of Justice and the U.S. Government Accountability Office (GAO) for oversight.

Under current law, manufacturers must provide price data necessary to allow HHS to implement the Medicaid prescription drug rebate program. Under the program, manufacturers that want to sell covered outpatient drugs, including biologics and insulin, to state Medicaid agencies must enter into rebate agreements with the Secretary. The agreements require manufacturers to provide state Medicaid programs with rebates on drugs purchased for Medicaid beneficiaries and to ensure that Medicaid receives the lowest or best price for which the manufacturer sold the drug during the previous quarter. The price information is confidential and may not be disclosed by the Secretary in a form that reveals the identity of a specific manufacturer or wholesaler, or prices charged for drugs by such manufacturer or wholesaler, except: as the Secretary determines to be necessary to administer the program; to the GAO and Congressional Budget Office (CBO) for review; to states to administer Medicaid; and for display on the HHS website in the form of a weighted average of the most recently reported monthly average price and retail survey price data.

Provision

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 barred from disclosing information about the specific amounts or identity of the source of rebates, price concessions, and other forms of direct or indirect remuneration negotiated by insurers or price information submitted as part of an insurer's annual bid to offer program benefits. MedPAC and MACPAC could not publicly disclose Medicaid data in a form that identified a specific manufacturer or wholesaler or prices charged for drugs by such manufacturer or wholesaler. This provision would be effective immediately.

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

Current Law

Health insurers typically contract with, or own, pharmacy benefit managers (PBMs) that perform a range of services including design of health plan formularies (or lists of covered drugs); set up of contracted networks of retail pharmacies that dispense drugs to enrollees; and drug price negotiation with pharmaceutical manufacturers, including up-front discounts or rebates after the point of sale. 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.

PBM contract terms with insurers, and information about net drug prices negotiated by PBMs, generally are confidential in order to preserve competition for drug price concessions. For this reason, it is difficult to monitor and assess the impact of the role of PBMs in managing Part D drug spending. PBMs and insurers are required to report some data about prescription drug sales and prices under Medicare Part D and Qualified Health Plans (QHPs) sold on the health insurance exchanges. (QHPs are individual health insurance plans that undergo an additional certification process by HHS, compared to other health insurance products sold to individuals.) PBMs that manage prescription drug coverage under Part D or for a QHP report the following data to the HHS Secretary each year:

- The percentage of prescriptions provided through retail pharmacies compared to mail order pharmacies;
- The percentage of prescriptions for which a generic drug was available and dispensed by a pharmacy;
- The aggregate amount of rebates, discounts, or price concessions (excluding certain bona fide service fees), negotiated by a PBM on behalf of insurers; the aggregate amount of rebates, discounts, or price concessions negotiated by PBMs and passed on to insurers; and the total number of prescriptions dispensed; and,
- The aggregate amount of the difference between what insurers pay a PBM, and what a PBM pays retail pharmacies and mail order pharmacies, and the number of prescriptions dispensed.

The reported data are confidential, and may not be disclosed by the Secretary or an insurer, with limited exceptions. Only the Secretary may disclose information—if in a form that does not disclose the identity of a PBM or insurer, or prices charged for individual drugs—in order to

administer specific provisions of law, or for review by congressional agencies, such as the GAO and CBO. PBMs and insurers that do not comply with the provisions or that provide false information are subject to penalties.

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). DIR includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by an intermediary contracting organization with which the Part D plan sponsor has contracted. Plans must submit detailed DIR reports to CMS within six months after the close of a plan year.

Provision

This provision would require HHS to make public on its website, beginning on July 1, 2022, data that has been reported under this section, which includes information on 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. The Secretary would ensure information displayed in a manner that prevented the disclosure of price concessions with respect to an individual drug or an individual plan in order to preserve competition for lower drug prices.

Additionally, this provision would require Part D insurers to conduct, beginning January 1, 2022, financial audits of data related to their PBM contracts. The purpose is to ensure Part D insurers – large and small – monitor PBM compliance with contract terms, including with respect to accounting for the net price of Part D covered drugs. The audits would be conducted at least every two years by an independent third party. Insurers would require PBMs to make their rebate contracts with drug manufacturers available for review during the audits and data available within 45 days of the audit request. PBMs that do not comply with insurers’ audit requests would be reported to the Secretary and upon confirmation subject to civil monetary penalties of \$10,000 per day. Audits would be subject to confidentiality agreements to prevent disclosure of confidential information. Audit reports would be submitted to the Secretary within 30 days and reviewed to determine the extent to which net price transparency between Part D insurers and PBMs occurs.

Under this provision, Part D insurers also would be required to report to pharmacies, beginning plan year 2022, at least annually, any post-point-of-sale adjustments for price concessions or incentive payments for covered Part D drugs, including those made by a PBM. These payment adjustments would be reported at the claim level, or approximated, if applied at another level. This provision also would require Part D insurers to report annually to the Secretary any statements of conflicts of interest from the members of pharmacy and therapeutics committee used by the insurer, effective immediately.

Finally, this provision would require Part D insurers to report, beginning in plan year 2022, actual and projected direct and indirect remuneration 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

Current Law

Under Medicare Part D, enrollee cost-sharing for drugs dispensed by network pharmacies is based on insurers' negotiated prices for covered drugs. The negotiated price, as defined by CMS, is the payment network pharmacies have negotiated to receive from Part D insurers for dispensing a covered drug, inclusive of all pharmacy price concessions except those that cannot reasonably be determined at the point of sale. Negotiated prices generally include pharmacy dispensing fees. Negotiated prices may not be rebated back to the insurer in full or in part. Insurers may pass on to enrollees the full value of any rebates and discounts negotiated with manufacturers and pharmacies in the price paid at the pharmacy counter, but the majority do not, according to data from the Centers for Medicare and Medicaid Services (CMS). Most insurers use the majority of rebates and discounts to lower their premiums for Part D coverage.

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). DIR includes 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.

Medicare provides subsidies for each enrollee in a Part D plan that equal 74.5 percent of average, standard coverage. Six months after the end of each year, CMS reconciles the projected payments with actual plan costs based on updated data including enrollment, low-income subsidy eligibility, health risk, and drug cost data from PDE and DIR reports. The final reconciled payments are also subject to Medicare risk corridors that limit a plan's overall losses or profits.

Federal regulations give HHS and GAO, or their designees, the right to audit, evaluate and inspect any books, contracts, records, computers, or other electronic systems, including medical records and documentation involving transactions related to CMS contracts with Part D sponsors. These rights continue for 10 years from the final date of the contract period or the date of audit completion, whichever is later.

Provision

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. This would include the number of potential errors CMS identified for plan review, the extent to which plans resubmitted reports making changes to past contract years, and the extent to which errors in DIR reports resulted in an increase or decrease in DIR for a past year. The Secretary shall exclude PACE organization and Retiree Drug Subsidy information in calculating publicly available information.

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. The report shall include information including the number of audits that: were closed without further action; prompted a corrective action plan; and resulted in an adverse opinion. It shall also include the number of plans for which a previously closed reconciliation was reopened and extent to which the reopening of a reconciliation resulted in recoupment of an overpayment or issuance of an underpayment.

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

Current Law

Under Medicare Part D, insurers and other plan sponsors enter into annual contracts with CMS to provide a defined package of outpatient drug benefits. There is no federally required formulary in Part D, except insurers must cover at least two drugs in each class and category and substantially all drugs in six protected classes. There is wide variation among Part D insurers with respect to their benefits offered, include drugs covered on formularies, prescription cost-sharing amounts, and utilization management requirements (e.g., prior authorization or quantity limits). While variation in benefit design provides plan choice for beneficiaries, it can be difficult for clinicians to sort through the information with their patients at the point of prescribing.

Part D insurers are now required to support an electronic prescription (e-prescribing) program, which enables transmission of prescription information between a clinician, pharmacy, PBM, and/or health plan, either directly or through an intermediary, such as an e-prescribing network. Technical transmission requirements for e-prescribing networks are based on standards set by the National Council for Prescription Drug Programs (NCPDP SCRIPT) and other outside organizations. While e-prescribing is optional for physicians and pharmacies, if they choose to transmit e-prescriptions and related communications then Part D insurers must comply with CMS standards. CMS also requires Part D insurers and prescribers to convey electronic formulary and benefits information amongst themselves using NCPDP Formulary and Benefits Standard Implementation Guides, referred to as F&B.

Part D e-prescribing standards are updated periodically to take into account new technology or to respond to statutory requirements. In May 2019, CMS issued final regulations requiring Part D insurers, no later than January 1, 2021, to implement one or more electronic real-time benefit tools (RTBT). According to CMS, the existing NCPDP SCRIPT standard allows prescribers to conduct electronic prescribing, while the F&B standard allows prescribers to see what drugs are on a plan's formulary. However, neither of these standards provides patient-specific, real-time cost or coverage information, such as formulary requirements or utilization management data, at the point of prescribing.

The Office of the National Coordinator for Health Information Technology (ONC) has the authority to establish a voluntary certification program for health information technology (HIT) developers to certify their HIT products are in compliance with specified certification criteria. Use of certified EHR technology is a requirement under the CMS Medicare Promoting Interoperability Program (formerly the EHR Incentive Program). The ONC established this

voluntary certification program in 2011 (the “ONC Health IT Certification Program”). The Secretary has the authority, through rulemaking, to require specified conditions of certification and maintenance of certification requirements for the Program, including that an HIT developer does not take any action that constitutes information blocking, among others.

Provision

This provision would require Part D insurers to provide for a “real-time benefit tool (RTBT)” 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. Information transmitted would include a list of any clinically-appropriate alternatives to a drug included on the formulary of such plan; pharmacy options (including the individual’s preferred pharmacy and other retail pharmacies and a mail-order pharmacy, as applicable); the formulary status and any applicable prior authorization or other utilization management policies applied by insurers. Plans would be required to implement these requirements no earlier than standards are adopted by the Secretary.

To be considered a RTBT, the electronic transmissions would have to comply with technical standards adopted by the HHS Secretary in consultation with the ONC; standard-setting organizations including NCPDP and others determined appropriate by the Secretary; and stakeholders including Part D insurers, health care professionals, and HIT software vendors. RTBT data would be used in conjunction with existing systems to provide a more complete view of a Medicare beneficiary's Part D drug benefit.

This provision would also add a requirement for tools used by clinicians. That is, qualified EHRs under the ONC Health IT Certification Program also must include a real-time benefit tool that conveys patient-specific cost and coverage information as well as the Part D information specified in this provision. The Secretary would implement the EHR requirements through notice and comment rulemaking, but not before standards for RTBTs for Part D plans have been adopted. Nothing in this section would prohibit implementation of RTBT requirements for Part D plans that have been set out through regulation.

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

Current Law

Private insurers offering Medicare Part D benefits through stand-alone plans that cover only prescription drugs generally do not have access to medical claims data collected under Medicare. Such data could provide more comprehensive information about an enrollee’s medical condition and current treatments and enable Part D insurers to design formularies that reflect total costs of care. Under the BBA 2018, Congress required HHS to establish a process, by 2020, under which a Part D insurer could request Medicare Parts A and B medical claims data for enrollees in their drug plan. The data, which are to be as current as possible, may be used by Part D insurers for specified purposes including to improve therapeutic outcomes by improving

medication use, improving care coordination to prevent adverse outcomes such as emergency room visits, and for other purposes approved by the Secretary.

Congress specified limitations on the use of the Parts A and B claims data, including prohibiting use of the data to inform Part D coverage determinations. A coverage determination is any decision (whether an approval or denial) by an insurer with regard to covered benefits. Examples of coverage determinations include whether to provide or pay for a Part D drug that an enrollee believes to be covered; a decision concerning a request to cover a drug that is not included on an insurer's formulary; or a decision regarding whether an enrollee has satisfied a prior authorization or other utilization management policy.

Provision

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. The provision would also require claims data to be as current as practicable, specifying options that the HHS Secretary may use to deliver the data in the most timely and efficient manner. This provision would go into effect January 1, 2021.

Section 127. Permanently Authorize a Successful Pilot on Retroactive Part D Coverage for Low-Income Beneficiaries

Current Law

There is no means test for eligibility for Medicare Part D coverage, but individuals who meet specified income and assets thresholds are eligible for low-income subsidies (LIS), which cover a greater share of out-of-pocket spending, including premiums and cost sharing for covered drugs. The actual amount of LIS varies based on an enrollee's assets and income and whether a beneficiary is institutionalized, or is receiving community-based care. Full-subsidy LIS enrollees—including dual-eligible enrollees who qualify for Medicare and full Medicaid benefits, enrollees who qualify for Supplemental Security Income (SSI), as well as other specified individuals—have no deductible, minimal cost sharing for prescription drugs and a cap on annual out-of-pocket spending. Partial-subsidy LIS enrollees—including individuals with assets below set thresholds and income up to 150 percent of the federal poverty level (FPL)—may also qualify for this extra benefit, but they have somewhat higher prescription cost sharing compared to full-subsidy LIS enrollees.

A beneficiary must first meet the income and asset thresholds to be eligible for LIS benefits. Next, the beneficiary must be enrolled in a Part D plan. Since inception of Part D, there has been concern about gaps in coverage for beneficiaries who qualify for the LIS but are not yet covered by a Part D plan. To address this, in 2010, HHS authorized a pilot program, the Limited Income Newly Eligible Transition (LI NET), to provide immediate temporary Part D coverage for certain LIS individuals. LI NET provides drug coverage for up to two months until an LIS-eligible individual is covered in a Part D plan, as well as up to 36 months retroactive coverage for full-subsidy LIS dual-eligibles and SSI beneficiaries, in cases where their dual or SSI eligibility is

retroactive. LI NET coverage, currently administered through health insurer Humana, reimburses pharmacies for all Part D-covered drugs.

Provision

This provision would permanently authorize the LI NET program, beginning no later than 2022. Individuals would qualify for LI NET if they were either full or partial LIS-eligible and a) had not yet enrolled in a Part D plan or b) had enrolled, but coverage under the plan had not yet taken effect. The LI NET benefit would provide transitional coverage including immediate access to covered Part D drugs at the point of sale starting on the first day of the month such individual was determined to be LIS-eligible, and ending on the day Part D coverage took effect. For LI NET-eligible individuals who are full-benefit duals or receive SSI benefits, retroactive coverage of covered drugs would begin on the later of a) the date the individual was first eligible for the LIS or 2) 36 months prior to the date such individual enrolled in a Part D plan. Retroactive coverage would end on the day Part D coverage took effect. To the extent feasible, HHS would operate the program through a single administrator.

HHS would ensure that LI NET coverage 1) provides access to all covered Part D drugs under an open formulary, 2) permits all pharmacies determined to be in good standing to process claims, 3) operates consistent with requirements the Secretary considers necessary to improve patient safety and ensure appropriate dispensing, and 4) meet other requirements established by the Secretary. The provision would waive Part D marketing, formulary, and medication therapy management requirements for the LI NET program and would allow the Secretary to waive certain other requirements as may be necessary.

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

Current Law

As noted, under Medicare Part D, insurers submit annual bids to CMS to offer outpatient prescription drug benefits, and compete against each other for enrollees. Part D insurers, and the PBMs they own or contract with, seek to control costs, in part, by negotiating lower drug prices from manufacturers. Lower prices primarily take the form of manufacturer rebates or discounts off list prices for brand-name drugs and biologics. Insurers and PBMs are able to secure rebates from a manufacturer in return for including a brand-name drug on a plan formulary or by setting favorable cost-sharing that leads to higher market share for the manufacturer. The final value of a manufacturer rebate may be tied to sales volume, bundled with other drug products, and paid to insurers in quarterly installments.

While there is no federally required Part D formulary, plan sponsors must cover at least two drugs in each class or category and substantially all available drugs in the following six categories: immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic. Part D sponsors and PBMs have the most leverage to negotiate price concessions when there are competing drugs on the market for treating a condition. They have less ability to negotiate price concessions for sole-source drugs (as manufacturers hold monopoly pricing power in those circumstances) and for drugs in the six protected classes (as insurers must cover

all drugs). Manufacturers' rebates have risen from 11.1% of Part D prescription drug costs in 2008 to an estimated 25.3% in 2018.

Pharmaceutical manufacturers are not required to participate in Part D and are not required to provide price concessions from their list prices. Since 2011, manufacturers that choose to participate in Part D have been required to provide a discount on brand-name drugs (and starting in 2019, on biosimilars) purchased by enrollees in the doughnut hole (or coverage gap).

By comparison, the state-federal Medicaid program administers a system of statutory rebates for covered outpatient drugs, including biologics and insulin, to ensure that Medicaid receives the lowest or *best price* for such drugs from the manufacturers. Medicaid drug rebates vary depending on the specific product, including whether the product is a brand-name drug or generic. In addition to a flat rebate, manufacturers who choose to have their products sold through Medicaid must also provide a supplemental rebate if they increase the average price of a prescription drug faster than the rate of retail inflation, as measured by the Consumer Price Index for all urban consumers (CPI-U). Several studies by the CBO and the HHS Office of Inspector General (OIG), based on confidential HHS drug rebate data, have found that Part D plans pay higher average net prices for brand-name prescription drugs than Medicaid and that the Medicaid supplemental inflation rebate is a major factor in the price difference.

Manufacturers set their own list prices for drugs and biologicals sold in the U.S. List prices are generally reflected in the "wholesale acquisition cost (WAC)" defined under SSA Section 1847A(c)(6)(B). The WAC does not include rebates, prompt pay or other discounts, or reductions in price and is reported in wholesale price guides or other publications of drug or biological pricing data.

Provision

This provision would establish a mandatory rebate if a pharmaceutical manufacturer increases their list price for certain covered Part D drugs above inflation. Beginning on January 1, 2022, manufacturers that choose to sell their products under Part D would provide rebates to Medicare for each six-month period in which the list price for a rebatable drug, as specified in the provision, increased faster than the change in CPI-U for the same period. A manufacturer's list price under this provision would be based on a drug's WAC.

Rebatable drugs would be defined as Part D-covered products that are brand drugs (and not a generic drug) or that are licensed as a biologic (and not a biosimilar).

To determine whether the price of a rebatable drug increased faster than inflation, and to calculate the amount of any required rebate, HHS would determine the inflation-adjusted average list price for each drug. The inflation-adjusted average list price would be the price for each unique 11-digit National Drug Code, as of July 1, 2019 (or as of the day the drug was first marketed for newly approved drugs), increased by the percentage change in the 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.

HHS would provide participating manufacturers with information on rebatable covered Part D drugs, no later than six months after the end of each rebate period. Such information would include the number of dispensed drugs, the excess list price increase, if any; and the amount of any required rebate. The HHS Secretary would be allowed to reduce or waive a required rebate in the case of a drug shortage.

A manufacturer would have 30 days from receipt of the HHS notice to pay the required amount or request a reconsideration of the rebate amount. Manufacturers would be subject to civil monetary penalties if they did not comply with rebate requirements. The penalty for failing to provide a required rebate would be the amount of the original rebate plus 25 percent. There would be no judicial review of the rebate amount.

Manufacturers would enter into rebate agreements with the Secretary for their drugs to be covered under Part D, and would be required to provide specific information to HHS to implement the rebate. Manufacturers would be subject to HHS audits to ensure reporting compliance and civil monetary penalties for noncompliance.

Information disclosed by manufacturers or wholesalers would be confidential and could not be disclosed by the Secretary in a form which reveals the identity of a specific manufacturer or wholesaler, or prices charged for drugs by such manufacturer or wholesaler, except as the Secretary determined would be necessary to carry out this provision.

The inflation-based rebates would have no impact on formulary design or manufacturer discounts negotiated by Part D insurers. Rebates paid to Medicare would be deposited into the Medicare Supplementary Medical Insurance Trust Fund.

Subtitle C – Miscellaneous

Section 141. Drug Manufacturer Price Transparency

Current Law

Pharmaceutical manufacturers set initial, or list prices, for the prescription drugs and biological products they sell. There are different, published drug list prices, but one commonly used commercial list price is the wholesale acquisition cost, or WAC, defined at SSA Section 1847A(c)(6)(B). Pharmaceutical list prices can differ substantially from final, net prices that manufacturers may receive after negotiations with wholesalers, pharmacies, and other entities along the distribution chain as well as separate negotiations with PBMs that work for or are owned by health plans.

Although a list price may not reflect the final amount a *manufacturer* receives for a drug, it is often used as the basis for *consumer* drug spending. Insurers may require enrollees to pay coinsurance for prescriptions (a percentage of the drug price) based on a list price rather than the health plan's lower net price. Consumers may also be charged a drug's list price if they are uninsured or have not met a health plan deductible, which is a period during the benefit when they are responsible for 100% of costs, when the deductible covers spending on drugs as well as medical services.

Contract terms and statutory or regulatory provisions in government health care programs generally prohibit government agencies from publicly releasing specific information in a form that discloses the identity of a specific manufacturer or wholesaler, or prices charged for specific drugs by such manufacturer or wholesaler.

Provision

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:
 - In 2020 of at least 100% since enactment of the legislation;
 - During 2021 of at least 100% in the preceding 12 months or at least 150% in the preceding 2 years;
 - During 2022 of at least 100% in the preceding 12 months or at least 200% in the preceding 3 years;
 - During 2023 of at least 100% in the preceding 12 months or at least 250% in the preceding 4 years; or,
 - 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:
 - In 2020 of at least 15% since enactment of the legislation;
 - During 2021 of at least 15% in the preceding 12 months or at least 20% in the preceding 2 years;
 - During 2022 of at least 15% in the preceding 12 months or at least 30% in the preceding 3 years;
 - During 2023 of at least 15% in the preceding 12 months or at least 40% in the preceding 4 years; or,
 - 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.

The required information for the price justifications may include: individual factors contributing to the price increase; the role of each factor in the price increase; and manufacturer spending for materials and manufacturing, patents and licenses, or purchasing or acquiring the drug from another company, if applicable. Manufacturers may also describe the percentage of total research and development spending for the drug that came from federal funds; total manufacturer research and development spending on the drug; total revenue and net profit from the drug each year since approval; total costs for marketing and advertising the drug; and additional information about the manufacturer such as total revenue and net profit for the period of the price increase, metrics for setting executive compensation, and other information such as total spending on drug research and development or clinical trials on drugs that failed to receive FDA approval.

HHS would establish a process for allowing a manufacturer to request that certain proprietary information in the justification be excluded from public posting. Data would be excluded if the Secretary (in consultation with the HHS OIG) determined that public disclosure would directly lead to increased prescription drug prices. If proprietary information were excluded, the information posted on the website is to include a summary of the proprietary information, to the extent possible.

Drug manufacturers would be subject to current Medicare civil monetary penalties of \$10,000 per day for failing to submit a timely price justification and up to \$100,000 per false information item for knowingly submitting false information.

Section 142. Permissive Exclusion from Federal Health Care Programs Expanded to Individuals and Entities Affiliated with Sanctioned Entities

Current Law

Under current law, the HHS Office of Inspector General (OIG) has authority to exclude health care providers (individuals and entities, but not beneficiaries) from federal health care program participation. OIG exclusion authority is mandatory in some circumstances and optional in others. Sanctioned entities include entities convicted of federal health care program related crimes, patient abuse, fraud, or excluded from federal health care program participation.

Provision

This section would permit the HHS Secretary to exclude individuals or entities affiliated with sanctioned entities from federal health care program participation. This provision would limit the ability of officers, managing employees, or owners of sanctioned entities to evade exclusion from federal health programs by resigning their positions or divesting their ownership interests. Individuals with an ownership or control interest in a sanctioned entity or an affiliated entity (or who had such an interest at the time of misconduct) would be subject to HHS Secretary's enhanced permissive exclusion authority.

TITLE II—MEDICAID

Section 201. Medicaid Pharmacy and Therapeutics Committee Improvements

Current Law

Prescription drugs are an optional Medicaid benefit, but all states cover outpatient drugs. Since 1990, pharmaceutical manufacturers who voluntarily agree to participate in Medicaid are required to rebate a portion of the cost of covered outpatient drugs back to states. When a manufacturer participates in Medicaid, states must make the manufacturer's drugs, with a few limited exceptions, available to Medicaid beneficiaries. States share the manufacturer rebates with the federal government. Beginning in 2010, drug manufacturers also were required to pay rebates on drugs provided to Medicaid beneficiaries enrolled in managed care.

Even though states are required to cover most drugs offered by drug manufacturers, states are authorized to use certain drug utilization and other tools to manage drug expenditures, such as certain types of formularies. Under Medicaid statute, states may establish formularies as long as they meet certain requirements, including that the formulary was developed by a committee—formulary committees often are referred to as pharmacy and therapeutics committees (P&T committees)—composed of physicians, pharmacists, and other appropriate individuals appointed by the state governor. States must also ensure access to medically necessary covered outpatient drugs. States may elect for a drug use review (DUR) board to serve as a P&T committee. Under current law, state Medicaid programs are not required to identify, monitor, or report P&T committee member conflicts of interest.

Under the Medicaid outpatient drug benefit statute, states are required to have a DUR program and board. The DUR program is required to ensure that covered outpatient drug (COD) prescriptions are appropriate, medically necessary, and are unlikely to result in adverse reactions.

Medicaid DUR programs must include prospective and retrospective DUR activities. Prospective DUR requires review of Medicaid prescriptions prior to dispensing to prevent over- or under-utilization, harmful drug interactions, and clinical abuse or misuse. Retrospective DUR involves review of state prescribing to identify patterns such as gross misuse, fraud, or inappropriate or medically unnecessary care.

Statutorily required DUR boards can be established directly or under contract, but must include health care professionals with recognized knowledge and expertise in appropriate COD prescribing, appropriate monitoring of COD prescribing, drug use review, evaluation, and intervention, and medical quality assurance. The DUR board also must be composed of at least one-third but no more than 51% licensed practicing physicians and at least one-third licensed practicing pharmacists.

State DUR boards are required to submit annual reports to the state Medicaid program and state Medicaid programs are required to submit an annual report to the HHS Secretary on the DUR program that identifies state Medicaid prescribing patterns, DUR cost savings, and adoption of innovative practices. State Medicaid programs may contract with companies, such as pharmacy benefit managers (PBMs), and other organizations and academic institutions to conduct DUR activities and prepare a report, but must have a DUR board that manages or oversees the DUR contract.

Beginning October 1, 2019, Medicaid managed care organizations with contracts to provide services to state Medicaid programs were required to be in compliance with statutory DUR requirements.

Provision

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 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: be publicly accessible; 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 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.

Under this provision, states would have the option for the state DUR board to serve as the P&T committee as long as the DUR board met the enhanced P&T committee requirements.

The HHS Secretary would be authorized to issue state Medicaid program guidance on P&T committee conflict of interest policies if GAO found or recommended, based on an investigation required under Section 203 of the Prescription Drug Pricing Act of 2019 that guidance was necessary related to appropriate standards and requirements for identifying, addressing, and reporting conflict of interest.

The provision would amend SSA Section 1903(m)(2)(A) to require states to apply the state Medicaid program P&T committee requirements under this provision to formularies used by managed care organization or other entities that dispensed CODs to Medicaid beneficiaries. This provision would be effective one year after the enactment date of this law.

Section 202. Medicaid Drug Use Review Conflict of Interest and Reporting Requirements

Current Law

Medicaid statute requires state Medicaid programs to establish state Medicaid DUR boards. DUR boards can be established directly or under contract, but must include health care professionals with recognized knowledge and expertise in appropriate COD prescribing, appropriate monitoring of COD prescribing, DUR, evaluation, and intervention, and medical quality assurance. The DUR board also must be composed of at least one-third but no more than 51% licensed practicing physicians and at least one-third licensed practicing pharmacists.

State DUR boards are required to submit annual reports to the state Medicaid program and state Medicaid programs are required to submit an annual report to the HHS Secretary on the DUR program that identifies state Medicaid prescribing patterns, DUR cost savings, and adoption of innovative practices. Under current law, state Medicaid programs are not required to identify, monitor, or report DUR board member conflicts of interest.

Provision

This provision would amend SSA Section 1927(b)(3) to require states to establish and implement conflict of interest policy for individuals who are members of state Medicaid DUR boards that would be: be publicly accessible; require all DUR board members at least annually to disclose any relationships, associations, and financial dealings that might affect their independent judgement on board matters; and include clear 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. DUR boards would be required to submit to the state Medicaid program an annual report that identified DUR board members as well as any member conflicts of interest. This provision also would amend SSA Section 1932(i) to require that managed care plans under contract to state Medicaid programs comply with the conflict of interest reporting requirements for DUR boards.

The HHS Secretary would be authorized to promulgate regulations or guidance to establish national standards for Medicaid FFS and managed care DUR programs in order to align prospective and retrospective DUR reporting criteria across all state Medicaid programs and help ensure alignment of standards across state Medicaid fee-for-service and managed care DUR programs.

Within 18 months of the enactment date, the HHS Secretary would be required to issue guidance to state Medicaid programs outlining the steps necessary for states to comply with the DUR requirements.

The amendments made under this provision would be effective one year after the enactment date of this law.

Section 203. GAO Report on Conflicts of Interest in State Medicaid Program Drug Use Review Boards and Pharmacy and Therapeutics (P&T) Committees

Current Law

Medicaid statute does not have a current requirement for a GAO report on state DUR Board and P&T committee conflicts of interest.

Provision

This provision would require GAO to investigate potential and existing state Medicaid program DUR board and P&T committee conflicts of interest. GAO would be required to submit a report to Congress within 24 months of the enactment date that addressed the following:

- (1) A description of state DUR board and P&T Committee operations, including details on:
 - The DUR board and P&T committee structure and operation;
 - states that operate separate FFS and Medicaid managed care organization (MCO) P&T; and
 - states that allow Medicaid MCOs to operate separate P&T committees and the extent to which PBMs administer or participate in these separate P&T committees.
- (2) A description of differences between state Medicaid DUR boards and P&T committees.
- (3) A description outlining the tools P&T committees may use to determine Medicaid drug coverage and utilization management policies.
- (4) An analysis of whether and how states or P&T committees establish participation and independence requirements for DUR boards and P&T committees, including with respect to entities with connections with drug manufacturers, state Medicaid programs, managed care organizations, and other entities or individuals in the pharmaceutical industry.
- (5) A description outlining how states, DUR boards, or P&T committees define conflicts of interest.
- (6) A description of how DUR boards and P&T committees address conflicts of interest, including who is responsible for implementing such policies.
- (7) A description of tools states use to ensure that there are no DUR Board and P&T committee member conflicts of interest.

(8) An analysis of state effectiveness in ensuring there are no DUR board and P&T committee member conflicts of interest and, applicable recommendations to improve state conflict of interest tools.

(9) A review of state strategies to guard against DUR board and P&T committee conflicts of interest to ensure compliance with Medicaid and HHS requirements and access to effective, clinically appropriate, and medically necessary Medicaid beneficiary drug treatments, including GAO legislative and administrative action recommendations.

Section 204. Ensuring the Accuracy of Manufacturer Price and Drug Product Information under the Medicaid Drug Rebate Program

Current Law

COD manufacturers that participate in the Medicaid drug rebate program are required under Medicaid statute to report to the HHS Secretary certain calendar quarter drug pricing information such as the average manufacturer price (AMP), average sales price (ASP), the number of units sold, and when applicable, best price and the wholesale acquisition cost (WAC) or list price. ASP is defined as a manufacturer's quarterly sales of a drug to all U.S. purchasers; divided by the drug's total units sold for the same quarter. AMP is defined in Medicaid statute and generally is the price manufacturers sold their products to retail community pharmacies, excluding most price concessions and sales at nominal price.

Provision

This provision would amend SSA Section 1927(b)(3) to improve oversight of the information COD manufacturers agree to submit when they participate in the Medicaid drug rebate program.

This provision would require the HHS Secretary to audit the price and drug product information reported by COD manufacturers to ensure its accuracy and timeliness. The HHS Secretary would be authorized to use evaluation surveys, statistical sampling, predictive analytics, and other tools and methods.

The HHS Secretary also would be authorized to survey wholesalers and manufacturers, including direct seller manufacturers, when necessary, to verify manufacturer prices, including WAC and AMP. A direct sale occurs when a drug manufacturer sells directly to a provider, such as a hospital or nursing home.

In addition to other penalties as may be prescribed by law, the HHS Secretary would be authorized to impose civil monetary penalties (CMPs) up to \$185,000 on wholesalers, manufacturers, or direct sellers of CODs if those entities refused to provide information about audit or surveyed charges or prices or knowingly provides false information. Certain additional civil money penalties applicable under SSA Section 1128A (other than SSA Section 1128A(a) and (b)) would also apply to entities that failed to comply with information requests or knowingly provided false information.

Within 18 months of the enactment date, the HHS Secretary would be required to submit a report to the congressional committees of jurisdiction on the need for additional regulatory or statutory changes that might be required to ensure accurate and timely reporting and oversight of drug price and product information.

On at least an annual basis, the HHS Secretary would be required to submit a report to the congressional committees of jurisdiction summarizing the results of the drug price and product audits and surveys. This provision identifies requirements for the HHS Secretary's annual report to Congress on the drug price and product audit and surveys.

In preparing annual reports to Congress, to prevent disclosure and safeguard the information, the HHS Secretary would be required to redact any manufacturer proprietary information.

Out of any Treasury funds not otherwise appropriated, this provision would appropriate \$2 million for fiscal year 2020 and each fiscal year thereafter to be used implement this provision.

This provision would also amend SSA Section 1927(b)(3)(C) to increase the CMP penalties for noncompliance with COD manufacturer reporting requirements from \$10,000 per day for required information to \$50,000 for the first day information is not reported for each drug and \$19,000 for each subsequent day per drug. Civil money penalties for knowingly reporting false information also would be increased from up to \$100,000 to up to \$500,000.

This provision would be effective on the first day of the first fiscal quarter that begins after the date of enactment of this law.

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

Current Law

According to the HHS Office of Inspector General (OIG), an authorized generic drug is a brand name drug that a brand manufacturer either sells or permits another manufacturer (referred to as the secondary manufacturer) to sell as a generic drug. Two statutory requirements related to calculating a brand name drug AMP have the effect of lowering the product's AMP, thereby decreasing manufacturers' Medicaid rebate obligations for those products. These include: (1) the requirement that authorized generics be included with brand product sales and (2) the requirement that secondary manufacturers be included as wholesalers.

Provision

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. In addition, this provision would amend the statutory definition of wholesaler to exclude COD manufacturers. The provision would be effective on the first day of the first fiscal quarter that begins after the enactment date.

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

Current Law

State Medicaid programs reimburse statutorily defined retail community pharmacies (RCPs) for covered outpatient drugs dispensed to Medicaid beneficiaries. Even though state Medicaid programs make only one payment to RCPs for covered outpatient drug payments, the payment has two components: an amount to cover the cost of acquiring the drug (ingredient cost) and an amount for the pharmacist's professional services in filling a prescription (dispensing fee).

States, subject to CMS approval, determine the reimbursement amount for ingredient costs and dispensing fees. Dispensing fees usually are a fixed amount, but can vary depending on the drug or pharmacy. The ingredient cost is an approximation of a drug's market price, the drug's cost to the pharmacy. Medicaid statute requires CMS to limit the maximum federal payment for certain generic drug ingredients to no less than 175% of the most recently reported national weighted average of average manufacturer price (AMP). However, when the amount paid to RCPs is less than the average acquisition cost for these drugs, states may base their RCP reimbursement for these drugs on the average acquisition cost from the current national RCP survey. The HHS Secretary is authorized to conduct the national drug acquisition cost (NADAC) survey in order to provide states a resource to determine drug costs to comply with federal maximum payment requirements.

The ACA required drug manufacturers that participate in the Medicaid drug rebate program to provide rebates on covered outpatient drugs that are dispensed to beneficiaries whose care is covered under an MCO that contracts with the state Medicaid program. Many MCOs and other entities that provide Medicaid prescription drug benefits contract with PBMs to manage and administer the drug benefits. Generally, MCOs pay PBMs for generic drugs supplied to Medicaid beneficiaries based on a published price, such as the average wholesale price (AWP) for all generic claims. Even though the difference (spread) between AWP-based MCO payments to PBMs and PBM payments to pharmacies may be small for individual drugs, it can be substantial when aggregated for all generic drugs, since generic drugs account for as much as 90% of prescription volume.

Provision

This provision would amend the Social Security Act (SSA) Section 1927(e) to require pass-through pricing for CODs 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, and made in a manner that is consistent with Section 1902(a)(30)(A) and sections 447.512, 447.514, and 447.518 of title 42, Code of Federal Regulations. It would require payment to the pharmacy benefit manager (PBM) for administrative services to be limited to a reasonable administrative fee and require that the entity or PBM make available to the State, and the HHS Secretary upon request, all costs and payments related to CODs and accompanying administrative services. It would make any form of spread pricing unallowable for purposes of claiming Federal matching payments under Medicaid. Such changes would be apply to contracts that are entered into or renewed on or after 18 months after the date of enactment of this law.

The provision would also amend Section 1927(f) to require the HHS Secretary to conduct a survey of retail community drug prices to include the national average drug acquisition cost. The HHS Secretary would be able to employ a vendor to contract for services with respect to the survey. Retail community pharmacies that receive payment related to the dispensing of CODs to individuals receiving benefits under Medicaid would be required to respond to the survey. Information on retail community prices obtained through the survey would be made publicly available and include at least the following: the monthly response rate and the list of pharmacies out of compliance with reporting requirements; the sampling frame and number of pharmacies sampled monthly; characteristics of reporting pharmacies; reporting of a separate national

average drug acquisition cost for each drug for independent retail pharmacies and chain operated pharmacies; information on price concessions including on and off invoice discounts, rebates, and other price concessions; and information on average professional dispensing fees. A pharmacy that fails to respond to the survey or knowingly provides false information in response to the survey could be subject to penalties in addition to other penalties that may be imposed under law.

The HHS Secretary would also be instructed to issue a report to Congress examining specialty drug coverage and reimbursement under Medicaid including a description of how State Medicaid programs define specialty drugs, how much State Medicaid programs pay for specialty drugs, how States and managed care plans determine payment for specialty drugs, the settings in which specialty drugs are dispensed, whether acquisition costs for specialty drugs are captured in the national average drug acquisition cost survey, and recommendations as to whether specialty pharmacies should be included in the survey of retail prices. The provision would appropriate \$5 million for fiscal year 2020 and thereafter to carry out the survey and related activities. These changes would take effect 18 months after the date of enactment of this law.

The provision would also require manufacturers to report wholesale acquisition cost for covered outpatient drugs and for the Secretary to make such information available on a public website.

Section 207. T-MSIS Drug Data Analytics Reports

Current Law

States are required as a condition of receiving federal financial participation (FFP), to provide for the electronic transmission of claims data in a format specified by the HHS Secretary and consistent with the Transformed, Medicaid Statistical Information System (T-MSIS). These systems are capable of providing provider, physician, and patient profiles sufficient to provide specific information as to the use of types of services and supplies, including covered outpatient drugs. Enhanced federal funding is available to the states for the planning and operation of these systems.

State Medicaid programs are required to submit an annual report to the HHS Secretary on covered outpatient drug payment rates, dispensing fees, and utilization rates for generic drugs. State Medicaid programs also are required to operate a DUR program to assure that covered outpatient drug prescriptions are appropriate, medically necessary, and unlikely to result in adverse medical results. The DUR program is required to compare drug use to certain industry standards. States are required to submit an annual report to the HHS Secretary on specified DUR activities. These reports are not submitted via T-MSIS.

The HHS Secretary is required to encourage state Medicaid programs to implement point-of-sale claims processing information systems to perform on-line, real time eligibility verification, claims data capture, adjudication, and pharmacy assistance in covered outpatient drug claim payment. All states implemented these systems.

Provision

The HHS Secretary would be required to publish a report on Medicaid provider prescribing patterns for covered outpatient drugs for each state, and to the extent possible, for the five U.S.

territories. The report would be required to be prepared by the CMS Administrator, and published on the CMS website each year beginning calendar year 2021.

The report would be required to include a comparison of drug prescribing patterns for Medicaid covered outpatient prescription drugs across the following dimensions: (1) all forms or models of reimbursement used under the plan or waiver; (2) within specialties and subspecialties, as defined by the HHS Secretary; (3) by episodes of care for (a) the 10 highest cost chronic disease categories, as defined by the HHS Secretary, (b) procedural groupings, and (c) rare disease diagnosis codes; (4) by patient demographic characteristics (e.g., race (as determined by the HHS Secretary), gender, and age); (5) by high-utilizer or high-risk patient status; and (6) by high and low resource settings by facility and place of service categories, as determined by the HHS Secretary. The report would be required to include an analysis of the differences in Medicaid prescribing patterns for covered outpatient drugs prescribed under managed care as compared to the FFS delivery system.

In addition, the report would be permitted to include a State-specific comparison of prescription utilization management tools used: (1) for populations covered under a Medicaid Section 1115 demonstration waiver as compared to models applicable to non-waiver populations; (2) by Medicaid managed care organizations, pharmacy benefit managers, and related entities within the state; (3) for each Medicaid enrollment category; and (4) for high-utilizer or high-risk status patients. In addition, the report may include information about Medicaid prescription utilization management tools under programs to provide Medicaid long-term services and supports.

If practical, the HHS Secretary would be required to include: (1) analyses of national, state, and local patterns of Medicaid population-based prescribing behaviors; and (2) recommendations for administrative or legislative action to improve the effectiveness of, and reduce costs for, Medicaid prescription drugs while ensuring timely beneficiary access to medically necessary covered outpatient drugs. The reports would be required to be prepared using data and definitions from the T-MSIS data set that is not more than 24 months old on the date the report is published; and as appropriate, include a description of the quality and completeness of the data for each state (or territory), as well as any necessary limitations associated with the state-reported data.

The provision would appropriate \$2 million to the HHS Secretary to carry out this section for each fiscal year beginning FY 2020.

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

Current Law

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. Under the statutory terms of the MDRP, the best price is the lowest price drug manufacturers offer their product for sale in the United States to retail community pharmacies during a rebate period. If a drug manufacturer sells their drug at a low price to any buyer, it is obligated to match that price for all state Medicaid programs. In addition, drug manufacturers are statutorily required to pay additional inflation rebates to the Medicaid program when they increase the price of their drug

products faster than the inflation rate. States may also negotiate other, supplemental rebates, from drug manufacturers in exchange for a commitment to purchase a certain drug volume or to direct all providers to prescribe only the manufacturer's product. Under these supplemental rebate agreements, states must make a process available for providers to prescribe other similar medically necessary products.

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. At present, many of these gene therapies are designated by the Food and Drug Administration (FDA) for rare diseases or conditions, which is one that affects less than 200,000 individuals. The high cost of newer drugs can have a significant impact on state Medicaid spending even with Medicaid receiving the best price.

Under current law, states may submit state plan amendments outlining supplemental rebate agreements, including for new drugs. Once supplemental rebate templates are approved, additional details are typically arranged between the state and manufacturer. Payments under approved supplemental rebates agreements do not trigger Medicaid's best price provision with savings shared between the state and federal government.

Provision

The provision would add an option for states under SSA Section 1927 to pay for certain covered outpatient drugs through risk-sharing value-based agreements beginning January 1, 2022. Under the option, 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. Specifically, the covered outpatient drugs would be a form of gene therapy for a rare disease that, if administered based on the drug's label to a patient for the treatment of a serious or life-threatening disease or condition, is expected to cure or reduce the symptoms of the disease after not more than three administrations.

In order for the HHS Secretary to be able to approve the risk-sharing value-based agreement submitted by the state, the drug manufacturer would need to have a rebate agreement that is in effect and be in compliance with all the Medicaid requirements. Also, the Chief Actuary of CMS would need to certify that the agreement would not result in increased federal Medicaid payments.

In consideration of an agreement, the HHS Secretary would be required to treat the state's request in the same manner as a Medicaid state plan amendment, including the timing requirements. The HHS Secretary would be required to consult with the FDA Commissioner, as needed, to determine whether the relevant clinical parameters specified in the agreement are appropriate.

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 over the period of time. The first installment payment would be made no later than 30 days after the end of such year. The total installment year amount would be the amount equal to the product of the unit price of the drug charged under the agreement and the number of units dispensed under the agreement. The period of time the state would be able to make the installment payments would be no longer than five years. States would have the ability to not provide an installment payment

or pay a reduced amount of the installment payment if the covered outpatient drug fails to meet the relevant clinical parameters of the agreement.

The manufacturer of a covered outpatient drug approved under Section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under Section 351 of the Public Health Service Act would be required to notify the HHS Secretary that the manufacturer is interested in entering into an agreement not more than 90 days after meeting with the FDA following the phase II clinical trials for such drug. The HHS Secretary, in coordination with the CMS Administrator and the FDA Commissioner, would be able to provide parallel approval to a state's request for an agreement that otherwise meets the requirements of this state option.

For Medicaid enrollees who are administered a unit of a covered outpatient drug purchased under a risk-sharing value-based agreement in an installment year (i.e., a 12-month period during which a covered outpatient drug is dispensed), the state would remain liable to the drug manufacturer for payment for each installment year without regard to whether the enrollee remains enrolled in Medicaid, unless the Medicaid enrollee dies. The HHS Secretary would be required to provide guidance to states no later than January 1, 2022 about how to establish a process to notify the HHS Secretary when a Medicaid enrollee ceases to be enrolled in Medicaid before the end of the installment period. Subject to the approval of the Secretary, the terms of a proposed risk-sharing value-based payment agreement may provide that such requirements do not apply. The state would not be liable for remaining payment under the agreement if the HHS Secretary withdraws approval of the drug.

For the purposes of determining the average manufacturer price and best price for the covered outpatient drug and the rebate period, the HHS Secretary would treat any payment made to the drug manufacturer under the agreement during such period in the same manner as the prices paid under a state supplemental rebate agreement. Payments under the agreement would be in lieu of rebates that would otherwise be paid under the MDRP with the decision to enter into such an agreement remaining solely within the discretion of a state upon HHS Secretary and actuarial certification as required under the provision.

Not later than 180 days after each assessment period of an agreement, the HHS Secretary would be required to conduct an evaluation of the agreement, which would include an evaluation by the Chief Actuary of CMS to determine whether the actual program spending aligned with the projections. If the Chief Actuary of CMS finds the spending under the agreement is more than what expenditures would have been under a traditional rebate agreement including basic, additional, and any relevant supplemental rebates, then the HHS Secretary may terminate the agreement and would be required to conduct an evaluation of other ongoing risk-sharing value-based payment agreements to which the manufacturer is a party. The manufacturer would also be required to repay the difference to the state and federal government in a timely manner. Failure to comply with repayment obligations would result in various actions including termination of manufacturer risk-sharing value-based agreements and possible suspension or termination from the program.

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.

The HHS Secretary would be required to issue guidance no later than January 1, 2022 to states seeking to enter into a risk-sharing value-based agreement that includes a model template for such agreements. The HHS Secretary would be able to share approved agreements between a state and a manufacturer with states expressing interest in pursuing an agreement. The HHS Secretary would also be required to consult with the HHS OIG to determine whether there would be potential program integrity concerns with any such agreements. All other provisions of Section 1927 would continue to apply unless expressly provided under the new state option.

For FY2020 and each following fiscal year, there would be appropriated to the HHS Secretary \$5 million for the purpose of carrying out this state option.

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

Current Law

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. 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.

Provision

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. 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 in effect as of October 1, 2022.

Section 210. Applying Medicaid Drug Rebate Requirement to Drugs Provided as Part of Outpatient Hospital Services

Current Law

Medicaid covered outpatient drugs are generally FDA-approved drugs, biologicals, other than vaccines, and insulin available by prescription in the United States. Drugs provided as part of or incident to and in the same setting as other services, and where payment is made as part of the service, rather than separately for the drug, are not considered covered outpatient drugs such as drugs provided as part of the following: inpatient hospital services; hospice services; dental services, except if the state authorizes direct reimbursement to the dispensing dentist; physician services; outpatient hospital services; nursing facility services and services provided by an intermediate care facility for the mentally retarded; other laboratory and x-ray services; and renal dialysis.

Under current law, a number of drugs are considered covered outpatient drugs even though they are administered by physicians in offices or in outpatient hospital outpatient departments because the drugs are separately payable. Increasingly, newer covered outpatient drugs could be paid for as part of a service bundle or as part of value-based treatment where providers are paid a single rate for a treatment that includes the administration of drugs as well as other services necessary to diagnose, plan treatment, and provide post-treatment follow up. Medicaid statute requires participating drug manufacturers to provide the Medicaid program rebates or their best price on covered outpatient drugs.

Provision

This provision would amend the Social Security Act (SSA) Section 1927(k)(3) to provide, at the option of a state, that the term “covered outpatient drug” may include any drug, biological product, or insulin as part of a bundled payment if it is provided on an outpatient basis as part of, or as incident to and in the same setting as, physicians’ services or outpatient hospital services. The provision would take effect one year after date of enactment. The HHS Secretary would also be instructed to issue guidance and relevant informational bulletins for States, manufacturers and other relevant stakeholders, including health care providers, regarding implementation of the provision.