

# Health Care Provisions of the Budget Reconciliation Measure P.L. 117-169

January 24, 2023

Congressional Research Service

<https://crsreports.congress.gov>

R47396



# Health Care Provisions of the Budget Reconciliation Measure P.L. 117-169

On August 16, 2022, President Joe Biden signed into law a budget reconciliation measure often referred to as the Inflation Reduction Act of 2022 (P.L. 117-169).

Congress began the legislative process on this measure in August 2021, when the House and the Senate adopted S.Con.Res. 14, a budget resolution for FY2022 that included reconciliation directives to 25 House and Senate committees. On September 25, 2021, the House Budget Committee voted to report the resulting reconciliation bill, H.R. 5376. On November 19, 2021, the House passed H.R. 5376, as amended, by a vote of 220-213. For more than eight months, Congress took no further formal action on H.R. 5376. On August 7, 2022, the Senate passed H.R. 5376, as amended, by a vote of 51-50. On August 12, 2022, the House voted to agree to the bill as amended by the Senate by a vote of 219-208. On August 16, 2022, President Joe Biden signed the bill into law (P.L. 117-169).

The new law includes provisions addressing a number of issues, such as taxes, climate change, health, and agriculture. This report provides information about provisions in P.L. 117-169 related to Medicare, Medicaid, the State Children's Health Insurance Program (CHIP), and private health insurance.

P.L. 117-169 makes wide-ranging changes to Medicare prescription drug coverage and more targeted changes to Medicaid, CHIP, and private health insurance. The budget reconciliation measure requires the Secretary of Health and Human Services (Secretary) to negotiate prices for certain drugs covered under Medicare Part B (physician-administered drugs) and Part D (retail prescription drugs), starting with 10 high-spending, single-source drugs for 2026 and increasing to 20 drugs by 2029. Effective in 2023, manufacturers that sell drugs through Parts B and D have to pay rebates to Medicare if they increase prices of the Medicare-covered drugs above the rate of consumer inflation. Also in 2023, the law eliminates enrollee cost sharing for certain vaccines in Medicare Part D, Medicaid, and CHIP and sets a \$35 cap on enrollee cost sharing for insulin in Medicare Parts B and D.

Effective in 2025, P.L. 117-169 will reconfigure the Part D benefit to include an annual \$2,000 out-of-pocket spending cap, expanded subsidies for low-income enrollees, and limits on annual premium increases, among other changes. In addition, the law extends through 2025 more generous premium subsidies for commercial health plans sold on exchanges, which originally were approved in the American Rescue Plan Act (ARPA; P.L. 117-2).

**R47396**

January 24, 2023

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## Introduction

The budget reconciliation measure often referred to as the Inflation Reduction Act of 2022 (P.L. 117-169) was enacted on August 16, 2022.<sup>1</sup> The law includes provisions addressing a number of issues, such as taxes, climate change, health, and agriculture. This report provides information about the budget reconciliation law provisions related to Medicare, Medicaid, the State Children’s Health Insurance Program (CHIP), and private health insurance.

The report begins with a summary of the process for considering budget reconciliation measures. It next provides a table with abbreviated summaries of each health provision in P.L. 117-169. Following the table, the report provides a detailed summary of each provision. **Appendix A** contains commonly used prescription drug and health insurance terms referenced throughout the report. **Appendix B** includes a table with a list of the abbreviations used in this report.

## Budget Reconciliation Process

In August 2021, the House and the Senate adopted S.Con.Res. 14, a budget resolution for FY2022.<sup>2</sup> A budget resolution generally represents an agreement between the House and the Senate on a budgetary plan for the upcoming fiscal year and allows Congress to employ the budget reconciliation process.

S.Con.Res. 14 triggered the reconciliation process by including reconciliation directives to 13 House committees and 12 Senate committees, instructing each committee to develop and report legislation within its jurisdiction that would increase or decrease the deficit by a specified amount.<sup>3</sup> Under reconciliation procedures, once instructed, committees transmit such legislation to their respective Budget Committees; in this instance, committees were directed to transmit such legislation to their respective Budget Committees by September 15, 2021. The appropriate Budget Committee then packages the responses together into an omnibus budget reconciliation bill and reports the bill without “any substantive revision.”<sup>4</sup> The resulting reconciliation bill is eligible to be considered under special expedited procedures. These procedures are especially important in the Senate, as they exempt the reconciliation bill from the general requirement that legislation garner the support of at least three-fifths of Senators to bring debate to a close.<sup>5</sup>

In responding to reconciliation instructions, three House committees developed legislation affecting Medicare, Medicaid, CHIP, and private health insurance.<sup>6</sup>

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<sup>1</sup> The abbreviation IRA is sometimes used for this law in other sources.

<sup>2</sup> For more information on S.Con.Res. 14, see CRS Report R46893, *S.Con.Res. 14: The Budget Resolution for FY2022*.

<sup>3</sup> Compliance with reconciliation instructions is measured on a net basis. This means that a committee’s response might include both deficit increases and deficit decreases as long as, taken as a whole, the legislative text complies with the instruction.

<sup>4</sup> Pursuant to §310(b)(2) of the Congressional Budget Act of 1974, as amended (P.L. 93-344). In fulfilling this requirement, the Budget Committee typically will hold a business meeting before voting to report to the chamber. Although amendments are not in order during the markup, members of the Budget Committee may communicate support or concern related to the underlying legislation.

<sup>5</sup> For more information on the reconciliation process, see CRS Report R44058, *The Budget Reconciliation Process: Stages of Consideration*.

<sup>6</sup> For information about the legislation affecting Medicare, Medicaid, the State Children’s Health Insurance Program (CHIP), and private health insurance developed by House committees in response to reconciliation instructions, see CRS Report R47056, *Build Back Better Act (BBBA) Health Coverage Provisions: House-Passed and Senate-Released Language*.

- In response to a reconciliation instruction to increase the deficit by no more than \$779.5 billion over the period FY2022-FY2031, the House Committee on Education and Labor held a markup on September 9-10, 2021,<sup>7</sup> and voted to transmit the legislation to the House Budget Committee.<sup>8</sup>
- In response to a reconciliation instruction to increase the deficit by no more than \$486.5 billion over the period FY2022-FY2031, the House Committee on Energy and Commerce held a markup on September 13-15, 2021,<sup>9</sup> and voted to transmit the legislation to the House Budget Committee.<sup>10</sup>
- In response to a reconciliation instruction to reduce the deficit by at least \$1 billion over the period FY2022-FY2031, the House Committee on Ways and Means held a markup on September 9-10 and September 14-15, 2021,<sup>11</sup> and voted to transmit the legislation to the House Budget Committee.<sup>12</sup>

As required, the House Budget Committee packaged together the reconciliation responses transmitted by each of the 13 instructed House committees. On September 25, 2021, the House Budget Committee voted to report the resulting reconciliation bill, known as the Build Back Better Act (H.R. 5376).<sup>13</sup>

On November 6, 2021, the House adopted H.Res. 774, a special rule reported from the House Committee on Rules that brought H.R. 5376 to the House floor for consideration.<sup>14</sup> Upon adoption of H.Res. 774, the text of H.R. 5376 as reported from the House Budget Committee was automatically replaced with the text of Rules Committee Print 117-18, modified by Rules Committee Print 117-19.<sup>15</sup>

<sup>7</sup> U.S. Congress, House Committee on Education and Labor, *Committee Print to Comply with the Reconciliation Directive Included in Section 2002 of the Concurrent Resolution on the Budget for Fiscal Year 2022*, S.Con.Res. 14, 117<sup>th</sup> Cong., 2<sup>nd</sup> sess., September 9, 2021, at <https://edlabor.house.gov/hearings/committee-print-to-comply-with-the-reconciliation-directive-included-in-section-2002-of-the-concurrent-resolution-on-the-budget-for-fiscal-year-2022-s-con-res-14>.

<sup>8</sup> U.S. Congress, House Committee on the Budget, *Build Back Better Act*, report to accompany H.R. 5376, 117<sup>th</sup> Cong., 1<sup>st</sup> sess., H.Rept. 117-130, September 27, 2021, p. 54 (hereinafter, H.Rept. 117-130). The letter of transmission from the House Committee on Education and Labor to the Budget Committee is dated September 14, 2021.

<sup>9</sup> U.S. Congress, House Committee on Energy and Commerce, *Markup of the Build Back Better Act*, 117<sup>th</sup> Cong., 1<sup>st</sup> sess., at <https://energycommerce.house.gov/committee-activity/markups/markup-of-the-build-back-better-act-full-committee-september-13-2021>.

<sup>10</sup> H.Rept. 117-130, p. 151. The letter of transmission from the House Committee on Energy and Commerce to the Budget Committee is dated September 12, 2021.

<sup>11</sup> U.S. Congress, House Committee on Ways and Means, *Markup of the Build Back Better Act*, 117<sup>th</sup> Cong., 1<sup>st</sup> sess., at <https://waysandmeans.house.gov/legislation/markups/markup-build-back-better-act>.

<sup>12</sup> H.Rept. 117-130, p. 785. The letter of transmission from the House Committee on Ways and Means to the Budget Committee is dated September 17, 2021.

<sup>13</sup> *Ibid.*, p. 1493.

<sup>14</sup> H.Res. 744 was considered by the House on November 5, 2021, and was adopted in the early morning hours of November 6, 2021, by a vote of 221-213. During consideration of H.Res. 744, a point of order was raised against the resolution under §426(a) of the Congressional Budget Act of 1974, which prohibits the consideration of a special rule that waives the application of requirements included in the Unfunded Mandates Reform Act of 1995. Because such a point of order is required to be disposed of by the question of consideration, the House proceeded with 20 minutes of debate, after which the House voted to consider the resolution (in light of the point of order) by a vote of 215-212.

<sup>15</sup> Rules Committee Prints 117-18 and 117-19 are available at U.S. Congress, House Committee on Rules, “H.R. 5376—Build Back Better Act,” at <https://rules.house.gov/bill/117/hr-5376>.

On November 18, 2021, the House adopted H.Res. 803, a special rule reported from the House Committee on Rules that provided for further consideration of H.R. 5376. Upon adoption of H.Res. 803, the text of H.R. 5376 was further modified by the text of the amendment printed in H.Rept. 117-175. On November 19, 2021, the House passed H.R. 5376, as amended.<sup>16</sup>

The Senate committees instructed to submit reconciliation legislation to the Senate Budget Committee did not formally respond to their instruction; however, many of the committees released legislative text described as being intended for H.R. 5376.<sup>17</sup> Two Senate committees released legislation affecting Medicare, Medicaid, CHIP, and private health insurance:<sup>18</sup>

- The Senate Committee on Finance, which received a reconciliation instruction to reduce the deficit by at least \$1 billion over the period FY2022-FY2031, released legislative text on its website on December 11, 2021.<sup>19</sup>
- The Senate Health, Education, Labor, and Pensions (HELP) Committee, which received a reconciliation instruction to increase the deficit by no more than \$726.38 billion, released legislative text on its website on December 11, 2021.<sup>20</sup>

For more than eight months, Congress took no further formal action on H.R. 5376. On August 6, 2022, the Senate agreed to a motion to proceed to H.R. 5376,<sup>21</sup> after which Senate Majority Leader Chuck Schumer offered an amendment in the nature of a substitute, the text of which was referred to as the Inflation Reduction Act, or IRA, of 2022. On August 7, 2022, the Senate passed H.R. 5376, as amended, after considering more than two dozen amendments and adopting three (including the amendment in the nature of a substitute).<sup>22</sup>

On August 12, 2022, the House adopted H.Res. 1316, which stated that upon the resolution's adoption, it would be in order to consider H.R. 5376, as amended by the Senate.<sup>23</sup> The House then voted to agree to the bill as amended by the Senate. On August 16, 2022, President Joe Biden signed the bill into law.

## Abbreviated Summary of Provisions

**Table 1** provides abbreviated summaries for each of the health provisions in P.L. 117-169, the budget reconciliation legislation often referred to as the Inflation Reduction Act.

<sup>16</sup> H.R. 5376 was considered by the House on November 18-19, 2021, and passed by a vote of 220-213.

<sup>17</sup> See, for example, committees' legislative text and associated Congressional Budget Office (CBO) estimates at Senate Democrats, "Senate Committee CBO Scores for Build Back Better," January 7, 2022, at <https://www.democrats.senate.gov/senate-committee-cbo-scores-for-build-back-better>.

<sup>18</sup> For more information on the contents of Senate committee-released legislative text affecting private health insurance, Medicaid, CHIP, and Medicare, see CRS Report R47056, *Build Back Better Act (BBBA) Health Coverage Provisions: House-Passed and Senate-Released Language*.

<sup>19</sup> U.S. Congress, Senate Committee on Finance, *Finance Committee Build Back Better Text*, 117<sup>th</sup> Cong., 1<sup>st</sup> sess., December 11, 2021, at <https://www.finance.senate.gov/download/finance-committee-build-back-better-text->.

<sup>20</sup> U.S. Congress, Senate Committee on Health, Education, Labor, and Pensions (HELP), "HELP Committee Posts Updated Build Back Better Text Ahead of Bipartisan Parliamentary Discussions," press release, December 11, 2021, at <https://www.help.senate.gov/chair/newsroom/press/help-committee-posts-updated-build-back-better-text-ahead-of-bipartisan-parliamentary-discussions>.

<sup>21</sup> The Senate adopted the motion to proceed on H.R. 5376 by a vote of 51-50.

<sup>22</sup> The Senate passed H.R. 5376 by a vote of 51-50.

<sup>23</sup> The House adopted H.Res. 1316 by a vote of 219-208.



**Table I. Abbreviated Summaries of Health Provisions in the Budget Reconciliation Law Known as the Inflation Reduction Act (P.L. 117-169)**

| Section Number | Section Title                                                                            | Description of Section                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | CRS Contact   |
|----------------|------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| 11001          | Medicare Prescription Drug Price Negotiation                                             | Establishes a Drug Price Negotiation Program covering selected, qualifying single-source drugs dispensed to certain Medicare enrollees, including drugs and biological products with the highest expenditures in Medicare Parts B and D. To be eligible for secretarial negotiation, a chemical drug must have had Food and Drug Administration approval for at least 7 years and a biological product must have been licensed for at least 11 years. In 2023, the Secretary is to designate 10 drugs for negotiation for the initial applicability year (2026). The number of drugs selected for negotiation is to increase to 15 for each of 2027 and 2028 and to 20 in 2029 and subsequent years. | Sue Kirchhoff |
| 11002          | Special Rule to Delay Selection and Negotiation of Biologics for Biosimilar Market Entry | Requires the Secretary to delay, for up to two years, selecting certain biological products for negotiation in the Drug Price Negotiation Program. Allows this delay in cases where a lower-cost biosimilar is poised to enter the market.                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Sue Kirchhoff |
| 11003          | Excise Tax Imposed on Drug Manufacturers During Noncompliance Periods                    | Imposes an excise tax on sales of selected drugs by manufacturers that are not in compliance with the agreement, negotiation, renegotiation, or information submission requirements under Social Security Act Sections 1193 and 1194 (as added by §11001).                                                                                                                                                                                                                                                                                                                                                                                                                                           | Edward Liu    |

| Section Number | Section Title                           | Description of Section                                                                                                                                                                                                                                                                                                                                                                                                              | CRS Contact   |
|----------------|-----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| 11004          | Funding                                 | Appropriates \$3 billion to the Centers for Medicare & Medicaid Services for FY2022 to carry out the provisions of Sections 11001-11003.                                                                                                                                                                                                                                                                                            | Sue Kirchhoff |
| 11101          | Medicare Part B Rebate by Manufacturers | Requires drug manufacturers of most single-source Medicare Part B drugs and biological products to pay quarterly rebates to Medicare for the amount that the price of these “rebutable drugs” exceeds the drugs’ quarterly inflation-adjusted average sales prices (ASPs)—as measured by the CPI-U—beginning January 1, 2023. The Secretary may delay implementation of the rebate for calendar quarters before September 30, 2025. | Cliff Binder  |
| 11102          | Medicare Part D Rebate by Manufacturers | Requires manufacturers of certain Part D-covered drugs to pay a rebate to Medicare if the manufacturers raise the products’ price above an allowable rate of inflation, as measured by the CPI-U from a 2021 benchmark period. The program first applies to the applicable 12-month period starting on October 1, 2022, and continues to apply each following 12-month period.                                                      | Sue Kirchhoff |

| Section Number | Section Title                                                                                                                                            | Description of Section                                                                                                                                                                                                                                                                                                                                                                                                                                                       | CRS Contact   |
|----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| I 1201         | Medicare Part D Redesign                                                                                                                                 | Changes the structure of the Part D standard benefit by, among other modifications, capping annual enrollee out-of-pocket spending for Part D at the catastrophic threshold, beginning in 2024, and reducing the catastrophic threshold to \$2,000 in out-of-pocket spending beginning in 2025 (adjusted annually thereafter). Creates a new program requiring manufacturers of Part D-covered drugs to provide certain discounts, and caps annual Part D premium increases. | Sue Kirchhoff |
| I 1202         | Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans and MA-PD Plans                                                               | Amends Part D prescription cost-sharing requirements to allow any enrollee in a Part D plan to make prescription cost-sharing payments in monthly, capped installments up to the annual out-of-pocket threshold, beginning in 2025.                                                                                                                                                                                                                                          | Sue Kirchhoff |
| I 1301         | Extension of Moratorium on Implementation of Rule Relating to Eliminating the Anti-Kickback Statute Safe Harbor Protection for Prescription Drug Rebates | Prohibits the Secretary from enforcing, prior to 2032, a 2020 final rule to restrict the use of manufacturer drug rebates in Part D plans.                                                                                                                                                                                                                                                                                                                                   | Sue Kirchhoff |
| I 1404         | Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program                                                                      | Expands eligibility for LIS subsidies, which allow Medicare beneficiaries with limited incomes and resources to qualify for assistance with their Part D premiums, cost-sharing, and other out-of-pocket expenses under the LIS.                                                                                                                                                                                                                                             | Sue Kirchhoff |

| Section Number | Section Title                                                                                                    | Description of Section                                                                                                                                                                                                                                                                                                                                                                                         | CRS Contact   |
|----------------|------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| 11402          | Payment for Biosimilar Biological Products During Initial Period                                                 | Establishes an initial period payment rate for Medicare Part B biosimilar products furnished beginning July 1, 2024. The biosimilar product's payment rate during the initial period is the lesser of the biosimilar product's wholesale acquisition cost plus a 3% add-on payment or 100% of the reference biological product's ASP plus a 6% add-on payment based on the reference biological product's ASP. | Cliff Binder  |
| 11403          | Temporary Increase in Medicare Part B Payment for Certain Biosimilar Biological Products                         | Increases for five years the Medicare Part B add-on payment for qualifying biosimilar biological products from 6% to 8% of the reference biological product's ASP beginning October 1, 2022. Depending on when Medicare Part B first paid for the drug, the five-year period for the increased add-on payment begins on the first day of the calendar quarter and ends after five years.                       | Cliff Binder  |
| 11401          | Coverage of Adult Vaccines Recommended by the Advisory Committee on Immunization Practices Under Medicare Part D | Prevents Part D plans from applying a deductible, coinsurance, or other cost-sharing requirement for adult vaccinations recommended by the ACIP that are covered Part D drugs beginning in 2023. <sup>a</sup>                                                                                                                                                                                                  | Sue Kirchhoff |

| Section Number | Section Title                                                                                                                                       | Description of Section                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | CRS Contact       |
|----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| 11405          | Improving Access to Adult Vaccines Under Medicaid and CHIP                                                                                          | Beginning October 1, 2023, expands coverage of ACIP-recommended adult vaccines and vaccine administration, without beneficiary cost sharing, under Medicaid and CHIP by mandating such coverage for (1) enrollees who receive coverage under traditional Medicaid; (2) all Medicaid medically needy enrollees in specified states (i.e., states that offer services in institutions for mental diseases or in “intermediate care facilities for the mentally retarded” [or both] to any medically needy subgroup in the state); and (3) CHIP enrollees who are 19 years of age or older. Over the first eight fiscal quarters, the Federal Medical Assistance Percentage rate associated with such coverage under traditional Medicaid will increase by one percentage point. | Evelyn Baumrucker |
| 11406          | Appropriate Cost Sharing for Covered Insulin Products Under Medicare Part D                                                                         | Caps insulin cost sharing for enrollees in Medicare Part D plans to the “applicable copayment amount,” defined as a copayment no greater than \$35 starting in plan year 2023. Also provides that, starting with plan year 2023, deductibles no longer apply to Part D-covered insulin products.                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Sue Kirchhoff     |
| 11407          | Limitation on Monthly Coinsurance and Adjustments to Supplier Payment Under Medicare Part B for Insulin Furnished Through Durable Medical Equipment | Requires the Secretary to adjust Medicare Part B supplier payment rates to ensure beneficiary coinsurance for a month’s supply of insulin furnished through durable medical equipment does not exceed \$35 beginning July 1, 2023.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Cliff Binder      |

| Section Number | Section Title                                                                    | Description of Section                                                                                                                                                                                                                                                                                                                                                                                                                              | CRS Contact          |
|----------------|----------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| 11408          | Safe Harbor for Absence of Deductible for Insulin                                | Allows HDHPs that qualify for tax-advantaged HSAs to cover the costs of selected insulin products before an enrollee has met the annual deductible and still be considered HSA-qualified HDHPs. Current Internal Revenue Service guidance considers insulin a preventive care service for individuals diagnosed with diabetes in HSA-HDHPs, therefore already allowing insulin coverage pre-deductible. Effective for plan years beginning in 2023. | Katherine Kehres     |
| 12001          | Improve Affordability and Reduce Premium Costs of Health Insurance for Consumers | Expands eligibility for and the amount of the Premium Tax Credit applicable to certain exchange plans for tax years 2021 through 2025. Expands income eligibility to households with annual incomes above 400% of FPL and reduces amounts all eligible households would be required to pay to enroll in certain exchange plans. Eligible individuals and families with incomes at or below 150% of FPL receive full premium subsidies.              | Bernadette Fernandez |

**Source:** Congressional Research Service (CRS) analysis of P.L. 117-169.

**Notes:** References in this table to “the Secretary” are to the Secretary of the Department of Health and Human Services (HHS). ACIP = Advisory Committee on Immunization Practices; ASP = average sales price; CHIP = State Children’s Health Insurance Program; CPI-U = Consumer Price Index for Urban Consumers; FPL = federal poverty level; HDHP = High-Deductible Health Plan; HSA = Health Savings Account; LIS = Low-Income Subsidy; MA-PD = Medicare Advantage plan with a Part D component.

- a. The ACIP provides guidance to HHS and the Centers for Disease Control and Prevention on the use of vaccines, including recommending immunization schedules for the U.S. population, with certain vaccine dosages based on age.

## Detailed Summary of Provisions

The following sections contain detailed summaries for each of the health provisions in P.L. 117-169, the budget reconciliation legislation often referred to as the Inflation Reduction Act of 2022. The summaries are grouped by subject.

## Medicare Prescription Drug Price Negotiation

### Section 11001: Providing for Lower Prices for Certain High-Priced Single-Source Drugs

#### Background

Medicare is a federal program that pays for covered health care services of qualified beneficiaries, including prescription drugs. Medicare was established in 1965 under Title XVIII of the Social Security Act (SSA) to provide health insurance to individuals aged 65 and older. It has been expanded over the years to include permanently disabled individuals under the age of 65.<sup>24</sup>

Medicare Part A (Hospital Insurance, or HI) covers inpatient hospital services, skilled nursing care, hospice care, and some home health services. Part A typically pays providers for drugs as part of a predetermined per episode payment. Under Part A, hospitals also can receive add-on payments for certain new innovator drugs.

Medicare Part B (Supplementary Medical Insurance, or SMI) covers physician services, outpatient services, and some home health and preventive services. Medicare pays most health care practitioners for Part B prescription drugs based on a statutory formula, which is the drug's average sales price (ASP) plus a percentage add-on payment. Medicare pays practitioners separately to administer Part B prescription drugs to beneficiaries.<sup>25</sup> Generally, Medicare beneficiaries pay 20% coinsurance on the Part B payment amount, including the payment for drugs and biological products as well as any applicable administration fees.

The voluntary Medicare Part D retail prescription drug benefit provides coverage of outpatient prescription drugs to Medicare beneficiaries who choose to enroll in standalone private prescription drug plans (PDPs) or Medicare Part C (Medicare Advantage, or MA) managed care plans (which cover Part A and B services) with a Part D component (MA-PDs). The Part D “noninterference” provision generally bars the Secretary of Health and Human Services (HHS; the HHS Secretary is referred to hereinafter as the Secretary) from negotiating Part D drug prices and from requiring a set formulary or pricing structure.<sup>26</sup> Part D plan sponsors (insurers), working with pharmacy benefit managers (PBMs), negotiate prescription drug price discounts and rebates

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<sup>24</sup> CRS Report R40425, *Medicare Primer*.

<sup>25</sup> Generally, in administering Medicare Part B prescription drugs, practitioners infuse, inject, insert, implant, or facilitate inhalation of the drugs and biological products. For more information, see Medicare Payment Access Commission (MEDPAC), “Part B Drugs Payment Systems,” November 2021, at [https://www.medpac.gov/wp-content/uploads/2021/11/medpac\\_payment\\_basics\\_21\\_partb\\_final\\_sec.pdf](https://www.medpac.gov/wp-content/uploads/2021/11/medpac_payment_basics_21_partb_final_sec.pdf).

<sup>26</sup> 42 U.S.C. §1395w-111(i): “Noninterference.—In order to promote competition under this part and in carrying out this part, the Secretary—(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.”

with pharmaceutical manufacturers and dispensing pharmacies. Sponsors must offer enrollees their “negotiated price” for covered drugs. Under the HHS regulatory definition of negotiated prices, sponsors have latitude to decide whether to pass on rebates and certain other price concessions to enrollees at the pharmacy point of sale or to use the rebates instead to reduce premiums for all enrollees.

## Provision

Section 11001 amends SSA Title XI to add a Part E after Section 1184 (42 U.S.C. §1320e–3). The new Part E adds new SSA Sections 1191–1198, which require the Secretary to establish a Drug Price Negotiation Program (referred to throughout this section of the report as the Program) covering selected, qualifying single-source drugs dispensed to certain Medicare enrollees, including covered drugs and biological products with the highest expenditures in Medicare Parts B and D.<sup>27</sup> The provision requires the Secretary to select a specified number of eligible drugs or biological products for price negotiation each year. For the first two years, the Program applies only to Part D drugs. To be eligible for secretarial negotiation, a chemical drug must have had Food and Drug Administration (FDA) approval for at least 7 years and a biological product must have been licensed for at least 11 years. Certain types of drugs or biological products are exempt from negotiation.

The Secretary, acting on behalf of Medicare, is to negotiate maximum fair prices (MFPs) with the manufacturers of the selected drugs. Manufacturers are subject to an excise tax for noncompliance, including failure to enter into an agreement to negotiate an MFP. The section amends the Part D noninterference provision to create an exception allowing for the Program.

An MFP for a selected drug is defined as the price that a manufacturer and the Secretary, following negotiation, agree to for an applicable price year or price period. The Program sets a ceiling for the MFP, which varies based on the type of drug or biological product and the length of time the drug has been on the market.<sup>28</sup> There is a temporary floor for MFPs for drugs manufactured by small biotech firms, as defined in the section.

The Program begins in 2023 for the initial price applicability year of 2026, when the first set of negotiated MFPs go into effect. The Program consists of the following components:

- Annual identification and publication of a list of selected drugs subject to negotiations between manufacturers and the Secretary
- Agreements between the Secretary and manufacturers of selected drugs that set out terms for negotiating MFPs for selected drugs
- Negotiation (and, if applicable, renegotiation) of the MFPs of such selected drugs
- Administrative duties of the Secretary to enable the prescribed negotiation process
- Mechanisms to promote compliance and/or participation in the Program
- Other miscellaneous requirements

<sup>27</sup> P.L. 117-169 defines *maximum fair price individuals* at 1192(c)(2) as Medicare beneficiaries enrolled in Part B or Part D, including Part D standalone and MA-PD plans.

<sup>28</sup> The ceiling price could be based on the nonfederal average manufacturer price (AMP). As defined in 38 U.S.C. §8126(h)(5), the *nonfederal AMP* means “the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during the period.” All manufacturers must calculate and report the nonfederal AMP to the Secretary of Veterans Affairs to be used to calculate the Federal Ceiling Price (FCP).



The process for identifying selected drugs, and the negotiation and application of drug MFPs, occurs annually. In general, negotiations take place yearly for newly selected drugs. However, an MFP resulting from a negotiation generally applies during price applicability periods that begin with the initial price applicability year for a selected drug—the first plan year for which the negotiated MFP would become effective—and continue until the drug is no longer a selected drug (meaning the drug has market competition). The Secretary and manufacturers are required to renegotiate the MFP for a selected drug if there is a specified change in circumstances, including a material change in manufacturer-specific information submitted to the Secretary.

In other words, negotiations and renegotiations, if applicable, take place on an annual basis, while a selected drug may be subject to an MFP for a series of plan years. The MFP is adjusted in each subsequent year based on the rate of consumer inflation as measured by the Consumer Price Index for All Urban Consumers (all items; United States city average) (CPI-U).<sup>29</sup>

There is a special timeline for negotiating drug prices for the 2026 initial price applicability year. The timeline for 2026 is as follows:

- The Secretary publishes a list of selected drugs for negotiation by September 1, 2023.
- The Secretary enters into agreements with manufacturers to negotiate prices no later than October 1, 2023.
- The Secretary and manufacturers negotiate prices for selected drugs during a period that begins October 1, 2023, and ends August 1, 2024.
- During the negotiation period: No later than October 2, 2023, the manufacturer of the drug submits required information to the Secretary. No later than February 1, 2024, the Secretary provides the manufacturer with a written initial offer that contains the Secretary's proposal for the MFP for the drug and a list of the considerations used to develop the MFP. No later than 30 days after the receipt of an initial offer from the Secretary, the manufacturer is to either accept the offer or propose a counteroffer, to which the Secretary is required to respond.
- The Secretary is to publish the negotiated MFPs no later than September 1, 2024, and information on the MFPs and factors that went in to determining the MFPs by March 1, 2025 (subject to confidentiality limits).

For subsequent price applicability years, the annual timeline for negotiation is as follows:

- The Secretary publishes an annual list of selected drugs for negotiation by February 1 of each year beginning two years prior to the next price applicability period (e.g., publication is February 1, 2025, for the applicability year of 2027). (The list also includes previously selected drugs for renegotiation.)
- The Secretary enters into agreements with manufacturers to negotiate prices no later than February 28 following the selected drug publication date of each year beginning two years prior to the next price applicability period (February 28, 2025, for 2027).
- The Secretary and manufacturers negotiate prices for selected drugs during a period that begins on February 28 and ends on November 1 of the year beginning

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<sup>29</sup> The Consumer Price Index (CPI), published by the U.S. Bureau of Labor Statistics in the Department of Labor, is a measure of the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services. See Bureau of Labor Statistics, "CPI," at <https://www.bls.gov/cpi/>. The CPI-U is a broad measure of about 93% of the total U.S. population.

two years prior to the next price applicability period (February 28-November 1, 2025, for 2027).

- During the negotiation period: No later than March 1, the manufacturer of the drug submits required information to the Secretary. No later than June 1, the Secretary provides the manufacturer with a written initial offer that contains the Secretary's proposal for the MFP of the drug and a list of the considerations used to develop the MFP. No later than 30 days after the receipt of an initial offer from the Secretary, the manufacturer either accepts the offer or proposes a counteroffer, to which the Secretary responds in writing.
- The Secretary publishes the negotiated MFPs by November 30 of the year beginning two years prior to the next price applicability period and publishes information on the MFPs and factors that went into determining the MFPs by March 1 of the year prior to the next price applicability period (subject to confidentiality limits).

The subsections that follow describe in further detail the components of the Program as specified in Section 11001.

### ***Selected Drug Identification and Publication***

No later than February 1 of each year beginning two years prior to the next price applicability period (e.g., February 1, 2025, for the initial price applicability year of 2027) the Secretary selects and publishes a list of negotiation-eligible qualifying single-source drugs that are subject to price negotiation for the initial price applicability year. Each *negotiation-eligible* drug on the list is to be considered a *selected drug*. The list of selected drugs includes a specified number of negotiation-eligible drugs or biological products chosen from a larger pool of negotiation-eligible drugs or biological products, subject to the requirements outlined below. (For 2026, the Secretary is to publish the list by September 1, 2023.) In subsequent years, the Secretary's list also includes previously selected drugs subject to renegotiation during a price applicability period.

The Secretary is to designate 10 negotiation-eligible drugs as selected drugs for the initial applicability year of 2026, and the number of selected drugs increases in subsequent years. For each of 2027 and 2028, the Secretary is to select and publish a list of 15 negotiation-eligible drugs as selected drugs. For 2029 and each subsequent year, the Secretary is to select and publish 20 negotiation-eligible source drugs as selected drugs. If the number of negotiation-eligible drugs is less than the designated number in any one year, the Secretary must select and publish a list of all negotiation-eligible drugs.

Negotiation-eligible drugs include products that are (1) among the 50 qualifying single-source drugs with the highest total expenditures under Medicare Part D or (2) among the 50 qualifying single-source drugs with the highest total expenditures under Medicare Part B, as determined by the Secretary based on the most recent period of 12 months for which data were available prior to the selected drug publication date but ending no later than October 31 of the year prior to the publication date. (For 2026, the expenditures are calculated based on the period from June 1, 2022, to May 31, 2023.)

For initial price applicability years of 2026 and 2027, the Secretary includes only the 50 qualifying single-source drugs with the highest total expenditures under Medicare Part D when selecting negotiation-eligible drugs. Starting with initial price applicability year 2028, the Secretary includes drugs with the highest expenditures under either Part D or Part B. Total expenditures under Medicare Part D include ingredient costs; dispensing fees; sales tax; and, if applicable, vaccine administration fees. Total expenditures under Medicare Part B exclude

expenditures for a drug or biological product that is bundled or packaged into a payment for another service.

A *qualifying single-source drug* is defined as follows:

- A covered Part D or Part B drug that is FDA approved and continues to be marketed pursuant to FDA approval, has had at least seven years elapse since FDA approval, and is not the listed drug for any approved and marketed generic drug
- A covered Part D or Part B biological product that is licensed and continues to be marketed pursuant to the license, has had at least 11 years elapse since the date of licensure, and is not the reference product for any approved and marketed biosimilar<sup>30</sup>

An authorized generic drug is to be treated the same as its listed qualifying single-source drug.<sup>31</sup> A biological product is to be treated the same as its qualifying single-source drug if it is licensed and marketed, sold, or distributed directly or indirectly to the retail class of trade under a different label, product code, labeler code, trade name, or trademark than the reference product.

A *qualifying single-source drug* does not include the following:

- Orphan drugs designated as drugs for only one rare disease or condition and for which are the only approved indication (or indications) is for such disease or condition.<sup>32</sup>
- Low-spend Medicare drugs. For the initial price applicability year of 2026, a drug is considered a low-spend drug if spending from June 1, 2022, to May 31, 2023, is less than \$200 million for Medicare Parts B and D. (In making the determination, the Secretary is required to use specific data aggregation rules.) For 2027, the amount is the \$200 million for 2026 adjusted by the CPI-U for June 1, 2023, through September 30, 2024. For a subsequent initial price applicability year, the threshold is the dollar amount for the previous initial price applicability year increased by the annual percentage increase in the CPI-U for the 12-month period ending on September 30 of the year prior to the year of the selected drug publication date, with respect to such subsequent initial price applicability year.
- Plasma-derived products, defined as biological products derived from human whole blood or plasma.

<sup>30</sup> FDA, “Biosimilars,” <https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars>. A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved biological reference product.

<sup>31</sup> According to the FDA, “The term “authorized generic” drug is most commonly used to describe an approved brand name drug that is marketed without the brand name on its label. Other than the fact that it does not have the brand name on its label, it is the exact same drug product as the branded product. An authorized generic may be marketed by the brand name drug company, or another company with the brand company’s permission. In some cases, even though it is the same as the brand name product, a company may choose to sell the authorized generic at a lower cost than the brand name drug.” FDA, “FDA List of Authorized Generic Drugs,” Updated July 1, 2022, <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs>.

<sup>32</sup> An FDA-designated orphan drug treats a disease or condition that affects fewer than 200,000 people in the United States, or affects more than 200,000 people in the United States, but there is no reasonable expectation that the cost of developing and making the drug would be recovered. FDA, “Rare Diseases at FDA,” <https://www.fda.gov/patients/rare-diseases-fda>.

The provision prohibits the Secretary, when compiling the list of negotiation-eligible drugs, from considering or counting drugs that already were selected drugs and, for initial price applicability years 2026-2028, small biotech drugs that meet the exception criteria described below. (In ranking drugs, the Secretary also cannot include data on biological products subject to a listing delay.<sup>33</sup> See “Section 11002: Special Rule to Delay Selection and Negotiation of Biologics for Biosimilar Market Entry.”)

*Negotiation-eligible drugs* are defined as qualifying single-source drugs that meet the criteria (high-spend, single-source drugs) to be placed on the list of selected drugs. The negotiation-eligible drugs with the highest total expenditures are ranked highest. The Secretary selects from the ranked drugs the negotiation-eligible drugs with the highest such rankings based on the annual thresholds described above as selected drugs (e.g., 10 negotiation-eligible drugs in 2026).

Negotiation-eligible drugs included on the selected list for a price applicability year are considered selected drugs for that year and for each subsequent plan year until the first plan year beginning at least nine months after the date the Secretary determines there is at least one drug (generic) or biological product (biosimilar) that was FDA approved or licensed using the selected drug as the listed drug or reference product and is marketed pursuant to the FDA approval or licensure. If the Secretary determines that there is at least one generic or biosimilar for a negotiation-eligible drug that is on the list of selected drugs for an initial price applicability year, then the selected drug is not subject to the negotiation process but continues to be considered a selected drug with respect to the number of negotiation-eligible drugs published for such initial price applicability year.

### **Small Biotech Exception for Initial Price Applicability Years 2026-2028**

Certain qualifying single-source drugs are not considered negotiation-eligible drugs for the initial price applicability years 2026-2028 if the drugs met either of the following criteria:

- Total Medicare Part D expenditures for the drug during 2021 (1) are equal to or less than 1% of total Part D expenditures for all covered Part D drugs and (2) total Part D spending for the drug is equal to at least 80% of total Part D spending for all of the manufacturer’s drugs that were covered by a Part D Medicare Coverage Gap Discount Program agreement for that year.<sup>34</sup>
- Total Medicare Part B expenditures for the drug during 2021 (1) are equal to or less than 1% of total Part B expenditures for all qualifying single-source drugs during that year and (2) total Part B expenditures for the drug are equal to at least 80% of total Part B spending for all of the manufacturer’s qualifying single-source drugs covered under Medicare Part B that year.

When determining whether the small biotech exception applies, an aggregation rule requires that all persons<sup>35</sup> treated as a single employer under subsection (a) or (b) of the Internal Revenue Code (IRC) Section 52 are treated as one manufacturer.

<sup>33</sup> When determining whether a qualifying single-source drug is a negotiation-eligible drug or is excepted under the small biotech drug exception, the Secretary is to use data that are aggregated across dosage forms and strengths of the drug, including new formulations of the drug (such as extended-release formulations), but are not based on the specific formulation or package type of the drug.

<sup>34</sup> See “Medicare Part D Program Changes.”

<sup>35</sup> Under the IRS Code, the word person refers to corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals. See 1 U.S.C. §1.

The exception for small biotech drugs does not apply to the following qualifying single-source drugs:

- A new formulation, such as an extended release formulation, of a qualifying single-source drug.
- A qualifying single-source drug where the manufacturer was acquired after 2021 by another manufacturer that did not meet the definition of a specified manufacturer at SSA1860D–14C(g)(4)(B)(ii), effective at the beginning of the plan year immediately following the acquisition or effective January 1, 2025, for acquisitions before 2025.<sup>36</sup>

### *Agreements Between the Secretary and Manufacturers of Selected Drugs*

Following publication of the list of selected drugs by February 1 each year (September 1, 2023, for 2026), the Secretary enters into agreements with manufacturers of selected drugs by no later than February 28 (no later than October 1, 2023, for 2026). The agreements specify the process and requirements with respect to negotiating, renegotiating, and administering the MFP for a selected drug during the coming applicability period.

Agreements have to encompass the following:

- **Agreement to Negotiate and Provide Access to the Selected Drug at the MFP.** The Secretary and each manufacturer are to negotiate an MFP for a selected drug no later than the end of the negotiation period, which ends on November 1 of the year that begins two years prior to the initial price applicability year. (The negotiation period ends on August 1, 2024, for the 2026 price year.) The manufacturer must agree to make the selected drug available at the MFP during the price applicability period to (1) MFP-eligible individuals enrolled in a Part D PDP or an MA-PD plan under Part C at the point-of-sale at pharmacies, mail-order services, and other dispensers (and to pharmacies, mail-order services, and other dispensers that dispense selected drugs to such individuals) and (2) hospitals, physicians, and other providers of services and suppliers with respect to MFP-eligible individuals enrolled in Part B, including individuals enrolled in MA plans under Part C.
- **Agreement to Renegotiate Under Specified Circumstances.** The Secretary and manufacturers must renegotiate the MFP for a selected drug if there is a material change in manufacturer-specific information regarding a selected drug or another specified change. Much like the initial negotiated MFP, the manufacturer is to make available the selected drug at the renegotiated MFP to MFP-eligible individuals (and to pharmacies, mail-order services, and other dispensers that dispense selected drugs to such individuals) and to hospitals, physicians, and other providers of services and suppliers that administer selected drugs to MFP-eligible individuals.
- **Agreement to Provide Certain Drug Price Information.** Under the agreement, the manufacturer submits, in a form and manner specified by the Secretary, information on the nonfederal average manufacturer price (AMP) for the drug for

<sup>36</sup> Section 11201 of P.L. 117-169 creates a new Part D manufacturer discount program at SSA 1860D-14C, which includes a definition of a Part D specified manufacturer at 1860D–14C(g)(4)(B)(ii).

the applicable year or period and all other information the Secretary requires to carry out the negotiation/renegotiation process.<sup>37</sup>

- **Agreement to Comply with Requirements.** The manufacturer agrees to comply with requirements imposed by the Secretary for administering and monitoring compliance with the Program.

An agreement entered into between a manufacturer and the Secretary is in effect until such time as a drug is no longer considered a selected drug.

If the Secretary determines that manufacturer-submitted information submitted subject to the agreements is proprietary, the Secretary could use or disclose the information only to the Comptroller General for use in carrying out the requirements of the Program.

### **Nonduplication with 340B Ceiling Price**

Drug manufacturers with products subject to MFP-negotiation that also have Public Health Service Act (PHSA) Section 340B Drug Pricing Program (340B Program) agreements are required to provide 340B Program-covered entities the lower of either the 340B Program ceiling price or the MFP. Drug manufacturers are not required to provide both the MFP and the 340B ceiling price on MFP-selected drugs.<sup>38</sup>

### **Price Negotiation and Renegotiation Process and Methodology**

Under the agreements, manufacturers of selected drugs and the Secretary negotiate (or, if applicable, renegotiate) an MFP. The Secretary must to develop and use a consistent methodology for annual MFP negotiations with manufacturers that will achieve the lowest MFP for each selected drug.

### **Negotiation Process**

The negotiation period begins on the sooner of the date on which the manufacturer and the Secretary enter into an agreement to negotiate with respect to a drug or February 28 following the selected drug publication date (e.g., February 28, 2025, for 2027). The deadline for ending negotiations is November 1 following the selected drug publication date for an initial price applicability year (e.g., November 1, 2025, for 2027). (For 2026, the negotiation period begins by October 1, 2023. The deadline for ending negotiations is August 1, 2024.)

After the Secretary and a manufacturer enter into an agreement to negotiate, the manufacturer must submit to the Secretary, not later than March 1 of the year of the selected drug publication date (e.g., March 1, 2025, for 2027), information on the nonfederal AMP for a drug for the applicable year or period and all other information that the Secretary requires to carry out the negotiation process. (The deadline for 2026 is October 2, 2023.)

<sup>37</sup> As defined in 38 U.S.C. §8126(h)(5), the *nonfederal AMP* means “the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during the period.” It does not take into account any prices paid by the federal government or any prices found by the Secretary to be merely nominal in amount. All manufacturers must calculate and report the nonfederal AMP to the Secretary of Veterans Affairs to be used to calculate the FCP.

<sup>38</sup> The Public Health Service Act (PHSA) Section 340B Drug Pricing Program (340B Program): Under the 340B Program, pharmaceutical manufacturers that choose to participate in the Medicaid drug rebate program must enter into pharmaceutical pricing agreements with the Secretary that require provider discounts on covered outpatient drugs purchased by covered entities. Covered entities are nonprofit, safety net organizations such as certain hospitals owned or operated by state or local governments that serve higher percentages of Medicaid beneficiaries as well as federal grantees such as health centers, Ryan White Program grantees, and other specialized clinics. Drug manufacturers must sell their drugs to 340B Program-covered entities at a statutory, discounted *ceiling price*.



After the information has been submitted, not later than June 1 following the selected drug publication date, the Secretary sends an initial offer for an MFP for a selected drug in writing to the drug's manufacturer. The initial offer contains a list of the factors used in developing the offer. (The deadline for 2026 is February 1, 2024.)

No later than 30 days after receipt of the initial offer, the manufacturer must either accept the offer or propose a counteroffer in writing. If the manufacturer makes a counteroffer, it must be in writing and based on the list of factors that the Secretary must consider during the negotiation process. The Secretary must respond in writing to a counteroffer. All negotiations end prior to November 1 of the year of the selected drug publication date (August 1, 2024, for 2026).

When negotiating an MFP with respect to an initial price applicability year or renegotiating an MFP, the Secretary is prohibited from offering or agreeing to a counteroffer for an MFP that exceeds the MFP ceiling determined for a selected drug or is less than the temporary floor for small biotech drugs.

### **Factors to Consider During Negotiation**

During price negotiations or renegotiations, the Secretary is required to consider the following specified factors.

- Manufacturer-Specific Information (including as submitted by the manufacturer)
  - The manufacturer's research and development costs for the drug and the extent to which the manufacturer has recouped those costs
  - Unit costs of production and distribution
  - Prior federal financial support for novel therapeutic discovery and development with respect to the drug
  - Data on patents and on existing and pending exclusivity for the drug
  - Market data and national sales volume data for the drug
- Information on the Drug and Alternative Treatments
  - The extent to which the drug represents a therapeutic advance, as compared to existing therapeutic alternatives and, to the extent such information is available, the costs of such existing therapeutic alternatives
  - Prescribing information approved by the FDA for such drug and therapeutic alternatives of such drug
  - Comparative effectiveness for such products and therapeutic alternatives for such products, taking into consideration the effects of such products and therapeutic alternatives on specific populations, including individuals with disabilities, the elderly, the terminally ill, children, and other populations
  - The extent to which such drug and therapeutic alternatives address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by an available therapy

When considering information on the comparative effectiveness analysis of a drug and therapeutic alternatives for the drug, the Secretary is prohibited from using evidence or findings from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

## Renegotiation Process

For years beginning with 2028, the Secretary is required to provide a renegotiation process with respect to the MFP for negotiated drugs that meet the definition as renegotiation-eligible drugs. The renegotiation process must be consistent, to the extent practical, with the initial negotiation methodology and process, including the MFP ceiling and the temporary floor for small biotech drugs and as further specified in this section.

A selected drug is a *renegotiation-eligible drug* if any of the following apply:

- A new indication has been added for the drug.
- The drug initially was not an extended-monopoly or long-monopoly drug but had a change in status to that of an extended-monopoly drug.<sup>39</sup>
- The drug initially was not a long-monopoly drug but had a change in status to a long-monopoly drug.
- The Secretary determined there had been a material change in any of the factors included in the manufacturer-specific information or the information on the drug and alternative treatments for the drug.

From the group of drugs considered renegotiation-eligible, the Secretary each year must select for renegotiation (1) all renegotiation-eligible drugs based on a change to extended-monopoly status, (2) all renegotiation-eligible drugs based on a change to long-monopoly status, and (3) renegotiation-eligible drugs for which the Secretary expects renegotiation likely will result in a significant change in an MFP already negotiated. The MFP ceiling for a selected drug that is renegotiation-eligible based on a change in status to either an extended-monopoly or a long-monopoly drug is calculated using the applicable percentage reflecting the change in status, as described below (e.g., the applicable percentage for long-monopoly drugs is to be applied for renegotiation-eligible drugs that changed from extended-monopoly to long-monopoly status).

A renegotiation-eligible drug is not subject to the renegotiation process if the Secretary determines before or during a renegotiation period that at least one drug or biological product has been approved or licensed using the renegotiation-eligible drug as the listed drug or reference product.

## Ceilings for Maximum Fair Price

Negotiated MFPs are subject to price ceilings for the first year of the price applicability period for a drug. The general MFP ceilings cannot exceed the *lower* of the following:

- **For a Part D-Covered Drug.** The sum of plan-specific enrollment weighted amounts for each PDP or MA-PD. The specific enrollment weighted amount for a Part D plan is the product of (1) the Part D negotiated price of the drug, net of all price concessions received by a Part D plan or a PBM on behalf of a Part D plan for the most recent year for which data were available, and (2) a fraction, with the numerator being the total number of enrollees in the plan for the year and the denominator being the total number of individuals enrolled in a Part D PDP or MA-PD during the year.

<sup>39</sup> *Extended-monopoly drugs* are selected drugs that were drugs or biological products that had been FDA-approved or licensed for at least 12 years but fewer than 16 years prior to the initial price applicability year. The definition excludes vaccines licensed and marketed under the license or drugs that were covered under an agreement with the Secretary under the Drug Price Negotiation Program prior to the initial price applicability year 2030. *Long-monopoly drugs* are defined as selected drugs that were drugs or biological products that had been FDA-approved or licensed for at least 16 years. The definition excludes vaccines licensed and marketed under the license.



- **For a Part B Drug or Biological Product.** The ASP payment amount for a single-source drug or biological product at SSA Section 1847A(b)(4) for the year prior to the year of the selected drug publication date with respect to the initial price applicability year for the drug or biological product.

**OR**

- **For a Drug with an Initial Price Applicability Year of 2026.** The average nonfederal AMP for the selected drug for 2021 (or in the case there was not an average nonfederal AMP for 2021, the nonfederal AMP for the first full year following the market entry of the drug) increased by the percentage increase in the CPI-U from September 2021 (or December of the first full year following market entry for such drug) to September of the year prior to year of the publication of the drug as a selected drug for the initial price applicability year.
- **For a Drug with an Initial Price Applicability in 2027 and Subsequent Years.** The *lower* of (1) the average nonfederal AMP for 2021 (or in the case where there was not an average nonfederal AMP available in 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the CPI-U from September 2021 (or December of the first full year following market entry), as applicable, to September of the year prior to the year of selected drug publication date for the initial price applicability year, OR (2) the average nonfederal AMP for the selected drug for the year prior to the publication date of the drug as a selected drug for the initial price applicability year.

### **Maximum MFP Based on Monopoly Designation**

The allowable MFP ceiling for a short-monopoly drug (any drug that is not an extended-monopoly or long-monopoly drug) is 75% of the average nonfederal AMP. The ceiling for an extended-monopoly drug is 65% of the average nonfederal AMP, and the ceiling for a long-monopoly drug is 40%.

An extended-monopoly drug with respect to an initial price applicability year is a selected drug or biological product that had been FDA approved or licensed for at least 12 years but fewer than 16 years. A drug is excluded from being considered an extended-monopoly drug if it is a vaccine licensed and marketed under the license or if it has been covered under an agreement with the Secretary under the Program for an initial price applicability year prior to 2030.

A long-monopoly drug is a drug or biological product that has been FDA approved or licensed for at least 16 years. A vaccine that was licensed and marketed under the license is excluded from being defined as a long-monopoly drug. Being a selected drug under an agreement for an initial price applicability period prior to 2030 does not limit the transition of a short-monopoly drug to a long-monopoly drug if a drug meets the long-monopoly definition.

The average nonfederal AMP means the average of the price for the four calendar quarters of the year involved.

### **Temporary MFP Floor for Small Biotech Drugs for 2029-2030**

P.L. 117-169 includes a special MFP floor for qualifying single-source drugs of small biotech firms that meet a definition as specified small manufacturers. For qualifying drugs with an initial price applicability year of 2029 or 2030, the negotiated MFP cannot be less than 66% of the average nonfederal AMP for such drug for 2021 (or, if there is not an average nonfederal AMP for such drug for 2021, for the first full year following the market entry for such drug) increased by the percentage increase in the CPI-U from September 2021 (or December of such first full year

following the market entry), as applicable, to September of the year prior to the selected drug publication date for the initial price applicability year.

### **Publication of Maximum Fair Prices**

No later than November 30 of the year that is two years prior to the initial price applicability year for a drug (e.g., November 30, 2025, for 2027), the Secretary is to publish the MFP for a selected drug that has been negotiated with the manufacturer. (For 2026, the deadline is September 1, 2024.) The Secretary is to publish information on the MFP and factors used to determine the MFP by March 1 of the year prior to the initial price applicability year (e.g., March 1, 2026, for 2027; for 2026, the deadline is March 1, 2025). Publication is subject to confidentiality limits.

For subsequent-year MFPs (after the first initial price applicability year), the Secretary is to publish, not later than November 30 of the year that is two years prior to such subsequent year (e.g., November 30, 2025, for 2027), updated MFPs for selected drugs that equal the MFP for the selected drug for the previous year increased by the annual percentage increase in the CPI-U, for the 12-month period ending with the July immediately preceding such November 30. If a selected drug had an MFP that was renegotiated, the renegotiated price is to be published as the selected drug's MFP for the first year such a renegotiated price would apply.

If the MFP for a selected drug for an initial price applicability year was agreed upon after the MFP publication deadline, the Secretary is required to publish the MFP no later than 30 days after the MFP has been determined.

### ***Administrative Duties of the Secretary***

The Secretary is to carry out certain administrative duties related to the Program, including establishing the following:

- Procedures to ensure the MFP for a selected drug is applied before (1) any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of MFP-eligible individuals and (2) any other discounts
- Procedures to compute and apply the MFP across a selected drug's strengths and dosage forms that are not based on specific formulation, package size, or package type
- Procedures to carry out the provisions with respect to MFP-eligible individuals enrolled in Medicare Part D coverage through a PDP or an MA-PD and MFP-eligible individuals enrolled in Medicare Part B, including those enrolled in an MA plan
- A drug price negotiation and renegotiation process
- A process for manufacturers to submit information, including information on the nonfederal AMP for a drug and all other information required by the Secretary to carry out negotiations
- A process to share with the Secretary of the Treasury such information as is necessary to determine the tax imposed by IRC Section 4192 (relating to enforcement of the Program)
- Procedures for applying the aggregation rule that requires all persons treated as a single employer under subsection (a) or (b) of IRC Section 52 to be treated as

one manufacturer for the purposes of the small biotech drug exception to the definition of negotiation-eligible drug

## ***Mechanisms to Promote Participation in and/or Compliance with the Program***

### **Civil Monetary Penalties**

A manufacturer of a selected drug that enters into an agreement with respect to a plan year during a price applicability period is subject to a civil monetary penalty (CMP) if the manufacturer fails to make available a drug at a price that is the MFP, or less, to MFP-eligible individuals (and to pharmacies, mail-order services, and other dispensers that dispense such drug to such individuals) or to hospitals, physicians, and other providers of services to MFP-eligible individuals. The CMP for a failure to provide access is 10 times the amount that is equal to the product of the number of units of the drug furnished, dispensed, or administered during a year to MFP-eligible individuals and the difference between the MFP and the price actually made available to the individual or hospital, physician, or other provider that administered the drug.

Any manufacturer of a selected drug that enters into an agreement with respect to a plan year during the price applicability period and that violates the requirements under the agreement for administering the Program, including the requirement to submit information, is subject to a CMP of up to \$1 million for each day of such violation.

Any manufacturer that knowingly provides false information related to the procedures for applying the aggregation rule described above is subject to a CMP equal to \$100 million for each item of false information.

The procedures for enforcing the CMPs under SSA Section 1128A apply to the enforcement of CMPs established under this section.

### **Information Sharing with the Secretary of the Treasury**

For the purposes of the excise tax described in Section 11003 (see “Section 11003: Excise Tax Imposed on Drug Manufacturers During Noncompliance Periods”), the Secretary must share with the Secretary of the Treasury information necessary to determine the applicable excise tax to impose on manufacturers, producers, or importers of any selected drug for noncompliance.

### **Monitoring Compliance**

The Secretary is required to monitor manufacturer compliance with the terms of an agreement and establish a mechanism through which agreement violations are reported to the Secretary.

### **Limitation on Judicial and Administrative Review**

Section 11001 deems the following determinations and selections under the Program not to be subject to administrative and judicial review:

- Determination of whether a drug is a qualifying single-source drug
- Determination of whether a drug is a negotiation-eligible drug
- Selection of drugs for publication as selected drugs
- Determination of the MFP for a selected drug
- Determination of whether a drug is eligible for renegotiation
- Selection of renegotiation-eligible drugs
- Determination of units of a drug or biological product

## ***Conforming Amendments***

To conform the Program to existing SSA Medicare and Medicaid requirements, Section 11001 does the following:

- Amends Medicare Part B requirements to substitute the MFP for the ASP when calculating reimbursement for selected drugs, with respect to a price applicability period, that are covered outpatient drugs under Medicare Part B
- Amends Medicare Part C requirements to require that cost sharing for selected Medicare Part B drugs be based off of the negotiated MFP
- Exempts the new Program from existing restrictions on the Secretary's involvement in the Medicare Part D drug negotiation process (pursuant to the Medicare Part D noninterference provision)
- Clarifies that under Medicare Part D, the negotiated price, which must be passed on to drug plan enrollees, can be no greater than the MFP for selected drugs for each plan year during the price applicability period
- Amends Medicare Part D access requirements for 2026 and subsequent years to require Part D plan sponsors that use formularies to include each covered Part D drug that would be a selected drug and for which there would be a manufacturer agreement with the Secretary to negotiate and offer an MFP in effect for such drug for such year
- Amends Medicare Part C and Part D contracting requirements to require plan sponsors to provide information to the Secretary, as requested by the Secretary in accordance with SSA Section 1194(g) established under P.L. 117-169
- Amends the Medicaid prescription drug rebate program to require drug manufacturers to exclude any selected drugs' MFPs from the rebate period calculation of those drugs' AMPs
- Amends the Medicaid statute to require that drug manufacturers include the MFP of covered outpatient drugs selected for negotiation during a rebate period in the determination of the selected drug's best price
- Requires that manufacturers report information regarding any termination of their participation in the Medicare Part D Coverage Gap Discount Program and the new manufacturer discount program created in SSA Section 11201 or in the Medicaid rebate program. P.L. 117-169 also amends Part D conditions for coverage of drugs in the manufacturer Coverage Gap Discount Program at SSA Section 1860D-43(c). SSA Section 1860D-43(c) allows drugs to be covered under Medicare Part D even if the manufacturer has not entered into a coverage gap discount agreement, if the drugs are essential to the beneficiary's health or there are extenuating circumstances. That exception does not apply to a Part D drug during the time that the excise tax in Section 11003 of the act is suspended. (Under Section 11003, the excise tax is suspended if none of a manufacturer's drugs is covered by a Medicaid Drug Rebate Program agreement, a Medicare Part D Coverage Gap Discount agreement, or a Medicare Part D Manufacturer Discount Program agreement.)

## Section 11002: Special Rule to Delay Selection and Negotiation of Biologics for Biosimilar Market Entry

### Background

A *biological product*, or *biologic*, is a term that can refer to a number of large, complex molecules derived from natural sources used to treat various medical conditions. Products considered biologics include vaccines, gene therapies, and tissues, among others. These products may be produced through the use of biotechnology in a living system, such as a cell. A *biosimilar*, which is sometimes referred to as a *follow-on biologic*, is a therapeutic product that is highly similar and has no clinically meaningful difference to an existing FDA-approved biologic reference product. Before a biologic or biosimilar may be marketed in the United States, it must be licensed (i.e., approved) by FDA. To obtain licensure of a new biologic, the sponsor (generally the manufacturer of the product) submits to FDA a biologics license application (BLA) with data demonstrating that the biologic—and the facility in which it is manufactured, processed, packed, or held—meets standards to assure the product is safe, pure, and potent. To obtain licensure of a biosimilar, the sponsor submits to FDA a BLA that provides information demonstrating, among other things, that the product is both highly similar to the reference product (based on data from analytical studies [structural and functional tests]) and not clinically meaningfully different from the reference product (based on animal studies [toxicity tests], and/or a clinical study or studies [tests in human patients]).<sup>40</sup>

### Provision

Section 11002 amends certain provisions in SSA Title XI, Part E, created by P.L. 117-169, which establishes a Drug Price Negotiation Program (referred to in this report as the Program) covering selected qualifying single-source drugs dispensed to certain Medicare enrollees, including drugs and biological products with the highest expenditures in Medicare Parts B and D (See “Section 11001: Providing for Lower Prices for Certain High-Priced Single-Source Drugs”).<sup>41</sup> The newly amended provisions delay, for up to two years, the selection of certain biological products for negotiation.

Under the Program, no later than February 1 of each year beginning two years prior to the next price applicability year, the Secretary is required to publish a list of selected drugs that will be subject to price negotiation. (A biological product must be FDA licensed for 11 years before it can be selected for negotiation.)

The Secretary, acting on behalf of Medicare, negotiates an MFP with the manufacturers of the selected drugs and biologics. The Program sets a ceiling on the MFP for the first year a drug has a negotiated MFP. In subsequent years, the MFP increases based on the CPI-U.

A selected drug is considered an extended-monopoly drug with respect to an initial price applicability year if it has been FDA approved or licensed for at least 12 years but fewer than 16 years. Long-monopoly drugs are selected drugs or biological products that have been FDA approved or licensed for at least 16 years.

<sup>40</sup> For additional information, please see CRS In Focus IF11083, *Medical Product Regulation: Drugs, Biologics, and Devices*.

<sup>41</sup> Section 11002 of P.L. 117-169 amends Section 1192 of SSA Title 11, Part E. (Part E was created by Section 11001 of P.L. 117-169.) Section 1192 governs the selection of drugs for annual price negotiation by the HHS Secretary.

Section 11002 adds new provisions to the Program that require the Secretary to delay, for up to two years, selecting certain biological products for negotiation of an MFP. The delay applies in cases where the Secretary determines there is a high likelihood that a biosimilar (for which the biological product would be the reference product) would be licensed and marketed within two years from the date the selected drug list for an initial applicability year is published. The delay applies to biological products that otherwise would have been considered selected extended-monopoly products and would have met the criteria to be included on the list of selected drugs for an initial applicability year.

The Secretary may provide for a delay *only* in cases where (1) for an initial one-year delay, a manufacturer of a biosimilar product made a request for a delay prior to the publication date of the selected drug list for the initial price applicability year on which the reference biological product otherwise would have been included or (2) for a second one-year delay, if the manufacturer of a biosimilar product made a request prior to the publication date of the selected drug list for the initial price applicability year that was one year after the initial price applicability year for which the reference biological product otherwise would have been included.

If the Secretary delays including a biological product on a selected drug list for a price applicability year, the drug is not included in the ranked spending list of Part D and Part B drugs, which is used to develop the selected drug list for that year.

A manufacturer must submit a request for a delay to the Secretary at a time and in a form and manner specified by the Secretary. The request is to contain the following:

- Information and documents necessary for the Secretary to make determinations required by the provision, as specified by the Secretary
- All agreements related to the biosimilar product filed with the Federal Trade Commission or the assistant attorney general pursuant to subsections (a) and (c) of Section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; P.L. 107-173)
- Any additional information and documents the Secretary deems necessary to make determinations after reviewing the initial request and materials

### **Criteria for Determining a High Likelihood of a Biosimilar Being Licensed and Marketed**

There is a high likelihood that a biosimilar product would be licensed and marketed within the specified timeframe if the Secretary finds that

- an application for licensure under PHSA Section 351(k) for the biosimilar product has been accepted for review or approved by the FDA; and
- information from documents submitted by the manufacturer requesting a delay, to the extent available, provide clear and convincing evidence that such biosimilar product would be marketed within the specified period.

Information used to demonstrate high likelihood includes, to the extent available,

- the manufacturing schedule for a biosimilar product submitted to the FDA during its review of the application under PHSA Section 351(k); and
- Disclosures in filings by the manufacturer of the biosimilar product with the Securities and Exchange Commission required under the Securities Exchange Act of 1934 Sections 12(b), 12(g), 13(a), or 15(d) about capital investment, revenue expectations, and manufacturer actions that are typical of the normal course of business in the year (or the two years, as applicable) before marketing



of a biosimilar product that pertain to the marketing of such biosimilar product, or comparable documentation that is distributed to the shareholders of privately held companies.

### **First One-Year Delay**

If the Secretary determines that a new biosimilar is highly likely to be licensed and marketed within the specified time frame, the Secretary approves the manufacturer's request and delays inclusion of the reference biological product as a selected drug until publication of the initial price applicability list that is one year after the initial price applicability year for which the biological product would have been included as a selected drug. If the manufacturer's biosimilar product is not licensed and marketed during the period between the publication date of the selected drug list that originally would have included the biological product and the publication of the selected drug list for the following initial price applicability period one year later, the Secretary is to, at the request of such manufacturer,

- reevaluate whether there is a high likelihood that such biosimilar biological product will be licensed and marketed before the selected drug list publication date that is two years after the publication of the selected drug list from which the product was excluded; and
- evaluate whether, on the basis of clear and convincing evidence, the manufacturer of the biosimilar product has made a significant amount of progress (as determined by the Secretary) toward both the licensure and the marketing of the biosimilar product since the manufacturer's request for delay, including the same range of documents and information used in the initial request for the delay.

If the Secretary determines (1) there is not a high likelihood the biosimilar product will be licensed and marketed or (2) there had not been a significant amount of progress, then

- the Secretary includes the reference biological product as a selected drug on the selected drug list published with respect to the initial price applicability year that is one year after the initial price applicability year for which such biological product originally would have been included as a selected drug; and
- the manufacturer of the reference biological product pays a rebate with respect to the year for which the manufacturer would have provided access to an MFP for the biological product, but for the delay.

### **Second One-Year Delay**

If, after the initial one-year delay, the Secretary determines that (1) there is a high likelihood that the biosimilar product will be licensed and marketed before the selected drug list publication date that is two years after the publication of the selected drug list from which the product was excluded and (2) the manufacturer of the biosimilar product has made a significant amount of progress toward such licensure and marketing, the Secretary would delay inclusion of the reference biological product as a selected drug. The delay would last until the publication of the selected drug list with respect to the initial price applicability year that occurs two years after the initial price applicability year for which the biological product was excluded.

If the Secretary determines the biosimilar was not marketed and licensed during the time period between (1) the publication date of the selected drug list that originally would have included the biological product as a selected drug and (2) the publication date of the selected drug list for the initial price applicability that is two years after, then

- the Secretary is required to include the reference biological product as a selected drug for the initial price applicability year that is two years after the initial year; and
- the manufacturer of the reference biological product is required to pay a rebate for the years the biological product would have been subject to an MFP.

### ***Limitations on Delay in Listing a Biological Product***

The provision includes certain limitations on delaying the inclusion of the biological product on the selected drug list.

- There is no case in which the Secretary may delay inclusion of a biological product as a selected drug for more than two years. The Secretary may provide a second one-year delay for a biological product that had received an initial one-year delay if, during the delay, the biological product had a change in status from an extended-monopoly drug to a long-monopoly drug if it had been a selected drug.
- There is no case in which the Secretary could delay the inclusion of a biological product on the selected drug list if more than one year elapsed since the biosimilar product was licensed under PHSA Section 351(k) and marketing for the biosimilar product had not commenced.

The provision also includes limitations on the delay of certain manufacturers that produce biosimilar products. *There is no case* in which the Secretary may delay the inclusion of a biological product on the selected drug list if the manufacturer of the biosimilar product

- is the same as the manufacturer of the biological reference product or is treated as being the same;
- has entered into any agreement (pursuant to MMA Section 1112, subsections (a) and (c), which relate to agreements between makers of biological and biosimilar drugs using the same reference product) with the manufacturer of the reference product that requires or incentivizes the manufacturer of the biosimilar product to submit a request to delay listing of the biological reference product; and
- in cases where agreements between makers of biological and biosimilar drugs using the same reference product restrict, directly or indirectly, the amount of the biosimilar sold in the United States over a period of time.

The Secretary is required to inform the public within 30 days of making a determination to delay a listing under this provision, in a form and manner determined by the Secretary.

If the Secretary determines that a biological reference product no longer qualifies for a delay, the product is to be included on the selected drug list for the applicable year and would count toward meeting the specified number of selected drugs for that applicable year.

### ***Manufacturer Definition***

All persons treated as a single employer under subsection (a) or (b) of IRC Section 52, or in a partnership, are treated as one *manufacturer*. The term *partnership* means a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on by the manufacturer of the biological product and the manufacturer of the biosimilar product.



## **Rebate**

The amount of any required rebate is equal to the estimated amount of the following.

For a biological product that is a covered Part D drug, the product of

- 75% of the amount by which the AMP for the biological product that, with respect to each of the calendar quarters of the price applicability period, would have applied but for delay, exceeds the following: (1) for an initial one-year delay, the MFP for the product or (2) in the case of a two-year delay, the MFP increased by the annual percentage increase in the CPI-U for the 12-month period ending with September of such previous year; and
- the number of units dispensed under Part D for such covered drug during each such quarter of such price applicability period.

For a biological product that is a covered Part B drug, the rebate is be the product of

- 80% of the amount by which the biological product's ASP for each of the calendar quarters of the price applicability period that would have applied, but for this delay, exceeded (1) for an initial one-year delay, the MFP for the product or, (2) in the case of a two-year delay, the MFP increased by the annual percentage increase in the CPI-U for the 12-month period ending with September of such previous year; and
- the number of units (excluding units packaged into the payment amount for an item or service and not separately payable under Part B) of the billing and payment code of such biological product administered or furnished through Part B during each calendar quarter of such price applicability period.

In the case of a biological product that qualified as a long-monopoly drug at the time of its inclusion on the selected drug list, the following amount would be substituted for the MFPs in the rebate formulas above for Part D and Part B: 65% of the average nonfederal AMP for the biological product for 2021 (or, in the case that there is not an average nonfederal AMP available for 2021, for the first full year following the market entry for such biological product), increased by the percentage increase in the CPI-U from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the selected drug publication date with respect to the initial price applicability year that would have applied, but for the delay.

Rebates for Part B drugs and for Part D drugs are to be deposited in the Federal Supplementary Medical Insurance Trust Fund.<sup>42</sup> Any manufacturer that fails to comply with the rebate requirements is subject to a CMP equal to 10 times the amount of the rebate the manufacturer failed to pay.

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<sup>42</sup> For more information on the Medicare Insurance Trust Fund, see CRS Report R40425, *Medicare Primer*.

## Section 11003: Excise Tax Imposed on Drug Manufacturers During Noncompliance Periods

### Background

IRC Subtitle D imposes various excise taxes on different entities, including public charities, private foundations, and pension plans that fail to meet certain requirements imposed elsewhere in federal law.

### Provision

Section 11003 amends IRC Subtitle D to add Section 5000D. The new section imposes an excise tax on selected drug sales by manufacturers, producers, or importers during the following noncompliance periods:

- The period beginning on the March 1 immediately following the selected drug publication date and ending on the first date during which the selected drug manufacturer enters into an agreement with the Secretary to negotiate a drug's MFP. For the 2026 initial price applicability year, the period is to begin on October 2, 2024.
- The period beginning on the November 2 immediately following the March 1 date referenced in the first noncompliance period above and ending on the first date during which the manufacturer and the Secretary agreed on an MFP. For the 2026 initial price applicability year, the period would begin on August 2, 2025.
- In the case of a selected drug for which the Secretary specified a renegotiation period under an agreement, the period beginning on the first date after the last date of the renegotiation period and ending on the first date during which the manufacturer agreed to a renegotiated MFP.
- With respect to information that must be submitted to the Secretary, the period beginning on the date on which the Secretary certified the required information was overdue and ending when the information was submitted.

The amount of excise tax imposed on the sale of a selected drug is calculated as a percentage of the sum of the sales price and the tax imposed under this section. (This differs from some other excise taxes in which the amount of the tax is a percentage of the sales price alone.) The applicable percentage for the excise tax would increase as the noncompliance period continues, with an applicable percentage of 65% during the first 90 days, 75% during days 91-180, 85% during days 181-270, and 95% for sales subsequent to the 270<sup>th</sup> day of the noncompliance period. Periods of noncompliance also end once a generic version of the selected drug becomes available.

### Excise Tax Example

For example, assume that a selected drug is subject to this excise tax with an applicable percentage of 65%. Furthermore, assume that the price of the drug, exclusive of tax, is \$100. In that case, the amount of the tax imposed under this section would be approximately \$186 because  $\$186 / (\$100 + \$186) = 65\%$ . The excise tax imposed per dollar of the sales price of drugs subject to the tax at the four applicable percentages are presented below:

- Days 1-90 of noncompliance: 65% applicable percentage results in an excise tax of \$1.86 per dollar of the drug sales price;
- Days 91-180 of noncompliance: 75% applicable percentage results in an excise tax of \$3.00 per dollar of the drug sales price;
- Days 181-270 of noncompliance: 85% applicable percentage results in an excise tax of \$5.67 per dollar of the drug sales price; and
- Days 271 and after of noncompliance: 95% applicable percentage results in an excise tax of \$19.00 per dollar of the drug sales price.

**Note:** See Joint Committee on Taxation, Description of Subtitle J—Drug Pricing Budget Reconciliation Legislative Recommendations, September 14, 2021, p. 7, at <https://www.jct.gov/CMSPages/GetFile.aspx?guid=157edf71-4c4a-4704-b50a-ed5a2f8abcb0> (describing similar excise tax language in an earlier version of these drug pricing provisions).

Section 5000D also applies several special rules to this excise tax. For sales that were timed to avoid the excise tax, the Secretary of the Treasury may treat the sale as occurring during a day in a noncompliance period. The excise tax does not apply to drugs sold for export. The excise tax is suspended during any period in which none of the drugs made by a selected drug's manufacturer is covered by a Medicaid Drug Rebate Program agreement, a Medicare Part D Coverage Gap Discount agreement, or a Medicare Part D Manufacturer Discount Program agreement.

Manufacturers are prohibited from deducting excise tax payments for federal income tax purposes. The Secretary is directed to prescribe necessary and appropriate regulations and guidance to carry out Section 5000D.

The new excise tax under Section 5000D is to apply to sales during a noncompliance period after the date of this act's enactment.

## Section 11004: Funding

### Background

There is no applicable current funding.

### Provision

Section 11004 appropriates \$3 billion dollars to the Centers for Medicare & Medicaid Services (CMS) for FY2022 to carry out the provisions of Sections 11001-11003 of P.L. 117-169. The funding is to remain available until expended.

# Medicare Inflation Drug Rebates

## Section 11101: Medicare Part B Rebate by Manufacturers

### Background

Medicare pays providers and suppliers for certain covered outpatient drugs and biologic products under Part B rather than under Medicare's Part D prescription drug benefit. Part B covers physician, outpatient, and some home health and preventive services. Throughout the discussion of Section 11101 in this report, unless otherwise specified, *drugs* refers to drugs and biological products, including biosimilar biologic products. Part B covers certain drugs that health practitioners purchase; these practitioners then bill Medicare after administering the drugs to beneficiaries. Generally, Part B drugs are separately payable and administered "incident to physician services." Part B also covers certain non-separately payable drugs when they are included as part of a procedure or treatment, such as end-stage renal disease dialysis, certain vaccines, and new drugs included in the outpatient hospital new technology transitional pass-through payments.<sup>43</sup>

With some exceptions, for most Part B drugs, Medicare pays providers and suppliers the drug's quarterly Average Sales Price (ASP) plus a 6% add-on payment. Drug manufacturers determine each drug's ASP based on the drug's quarterly sales to most U.S. purchasers, after deducting price concessions and other adjustments and dividing quarterly sales by the total units of the drug sold during the calendar quarter.

To encourage development of lower-priced biosimilar substitutes for biological products, Medicare Part B pays providers and suppliers the biosimilar product's ASP plus a 6% add-on payment based on the typically more expensive reference biological product's ASP. For most Part B services, after meeting an annual deductible, Medicare beneficiaries are responsible for coinsurance of 20% of the cost of the item or service. For Part B drugs, beneficiaries pay 20% coinsurance on the Medicare payment amount, including the drug's ASP, the applicable add-on payment, and the payment to the health care practitioner to administer the drug.

The Secretary sets Part B drug payment amounts by aggregating ASP data for individual drugs into Medicare billing codes. The payment for each billing code is the volume-weighted average of the ASPs for all drugs grouped into the billing code, plus a 6% add-on payment. Generally, biological, biosimilar, and single-source brand-name products have individual billing codes, whereas multiple-source brand-name and generic drugs grouped together have one billing code.

Section 11101 refers to prescription drug payments under other federal health programs, including Medicaid and the 340B Program. As a condition for access to the Medicaid market, Medicaid statute requires drug manufacturers to agree to provide rebates to state Medicaid programs for covered outpatient drugs dispensed to Medicaid beneficiaries. Medicaid statute also requires drug manufacturers to provide discounts to the following other federal health programs: Veterans Administration, Coast Guard, Department of Defense, and 340B Program.

<sup>43</sup> The Centers for Medicare & Medicaid Services (CMS) is required to adjust Medicare outpatient payment rates to ensure beneficiary access to new technology. During an interim period when certain new drugs, biological products, and devices first are approved, but before data to set payments are available, Medicare pays providers based on the product's cost.

## Provision

Section 11101 amends the SSA Section 1847A (42 U.S.C. §1395w-3a) by adding a new subsection (i). For calendar quarters beginning on or after January 1, 2023, SSA Section 1847(i) as added by P.L. 117-169 Section 11101 requires drug and biologic manufacturers to pay the federal government a rebate if the ASP of certain single-source Medicare Part B drugs, referred to as *Part B rebatable drugs*, exceeds those drugs' inflation-adjusted ASP.

Section 11101 also amends SSA Section 1833 (42 U.S.C. §13951) to specify that Medicare beneficiaries' coinsurance for Part B rebatable drugs is 20% of the inflation-adjusted Part B drug payment amount. This section further amends SSA Section 1847A to prohibit the Secretary from making specified administrative and judicial determinations. Section 11101 also amends SSA Section 1927 (42 U.S.C. §1396r-8(k)(1)(B)(i)) to add the Part B rebatable drug inflation rebate to the drug price disclosure prohibition and to exclude the Medicare Part B rebatable drug inflation rebate from the calculation of the AMP for the Medicaid drug rebate program.

### Rebatable Drug Definition

With a few exceptions, *Part B rebatable drugs* are Medicare Part B-covered single-source drugs, including applicable biosimilar drugs but excluding certain “qualifying biosimilar biologic products.”<sup>44</sup> Part B rebatable drug exceptions are drugs the Secretary determines have annual average total Part B allowed charges per individual of less than \$100 and Part B-covered vaccines, which include the following vaccines: influenza, hepatitis virus B (under specified conditions), pneumonia, Coronavirus Disease 2019 (COVID-19), and other vaccines only when administered to a beneficiary who is treated for the vaccine's underlying condition.<sup>45</sup>

The \$100 threshold for the annual average total allowed charges per individual is adjusted yearly for inflation using the percentage increase in the CPI-U for the 12-month period ending with June of the previous year (rounded to the nearest \$10) starting in 2024. In 2024, the threshold for the annual average total allowed charges per individual is the \$100 threshold for 2023 adjusted by the percentage increase in the CPI-U for the 12-month period ending June 30, 2023.

### Inflation Rebate Determination

The amount of the inflation rebate owed by drug manufacturers is determined by multiplying (1) the total Medicare Part B rebatable drug billing units sold by the manufacturer under Medicare during a calendar quarter by (2) the amount each Part B rebatable drug's quarterly billing-code payment exceeded the inflation-adjusted payment.

In determining the rebate amount, the Secretary is required to exclude certain sales from the drug manufacturer's calendar quarter Medicare Part B units. Section 11101 directs the Secretary to exclude units paid by state Medicaid programs, including Medicaid state plan waivers, units subject to a discount under the PHSA Section 340B Drug Pricing Program, and Medicare Part B units not separately payable but packaged into the payment amount for an item or service.

The inflation-adjusted payment amount is the billing code payment amount for a Part B rebatable drug in the payment amount benchmark quarter increased by the percentage by which the rebate period CPI-U exceeded the benchmark period CPI-U.

<sup>44</sup> SSA Section 1847A(b)(8)(iii) defines *qualifying biosimilar biologic products* as biosimilar biologic products eligible for a five-year temporary increase in the Part B add-on payment from 6% to 8% of the reference biological product.

<sup>45</sup> Under law prior to the P.L. 117-169 amendments, Medicare Part B did not cover most vaccines unless the vaccines directly related to treatment of an injury or direct exposure to a disease or condition, such as anti-rabies treatment or tetanus antitoxin vaccine.

The payment amount benchmark quarter is the calendar quarter beginning July 1, 2021. The benchmark period CPI-U is January 2021. The rebate period CPI-U is the greater of either (1) the benchmark period CPI-U (January 2021) or (2) the CPI-U for the first month of the calendar quarter that is two calendar quarters prior to the rebate period calendar quarter.

### Special Treatment and Exemption

Certain drugs are subject to the following special treatment or exemption from the Part B inflation rebate requirements:

- For Part B rebatable drugs that were FDA approved or licensed after December 1, 2020, the payment amount benchmark quarter is the third full calendar quarter after the day the drugs first were on the market. For subsequently approved or licensed drugs, the benchmark period CPI-U is the CPI-U in the first month of the first calendar quarter after the day the drug first was on the market. The Part B rebate is applied to these subsequently approved or licensed drugs beginning on the later of the first day of the sixth full calendar quarter after the drug was first on the market or January 1, 2023.
- Under certain circumstances, the Secretary is required to reduce or waive the calendar-quarter rebate for Part B rebatable drugs. These circumstances include the following: (1) if a drug appears on the Federal Food, Drug, and Cosmetic Act shortage list at any time during the calendar quarter; or, (2) for a biosimilar biological product, if the Secretary determines there is a severe supply chain disruption during the calendar quarter, such as a natural disaster or other unique or unexpected event.<sup>46</sup>
- For Part B rebatable drugs previously selected for an MFP negotiation under SSA Title XI, Part E, as added by P.L. 117-169 Section 11001 that no longer are subject to an MFP negotiation, the payment amount benchmark quarter is the calendar quarter that began January 1 of the last year during the drug's MFP applicability period. The benchmark period CPI-U for the drug is the CPI-U for July of the year preceding the last year that began during the drug's MFP applicability period.

### Beneficiary Coinsurance

If the payment amount for the calendar quarter exceeds the inflation-adjusted payment amount for a Part B rebatable drug furnished on or after April 1, 2023, then Medicare beneficiaries' coinsurance is 20% of the inflation-adjusted payment amount. Specifically, if a separately payable Part B rebatable drug payment amount or the rebatable drug's MFP were to exceed the quarterly inflation-adjusted payment amount, the Secretary may set the quarterly beneficiary coinsurance at 20% of the rebatable Part B drug's inflation-adjusted price. In addition, the Secretary is required to base the quarterly coinsurance for separately payable rebatable Part B drugs, administered on or after April 1, 2023, in hospital outpatient departments and ambulatory surgery facilities, on the inflation-adjusted rebate price.

<sup>46</sup> The Federal Food, Drug, and Cosmetic Act defines a *drug shortage* as a period of time when the demand or projected demand for a drug product within the United States exceeds the supply of the drug. The Food and Drug Administration tracks shortages at the national level and receives information from manufacturers about their ability to supply the market. For more information see, U.S. Food and Drug Administration, "Frequently Asked Questions About Drug Shortages," at <https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages>.



### **Rebate Payment Requirement**

SSA Section 1847(i) as added by P.L. 117-169 Section 11101 requires the Secretary to provide drug manufacturers specified information on each Part B rebatable drug before six months after the end of each calendar quarter beginning on or after January 1, 2023. The Secretary is required to provide drug manufacturers the total number of specified billing units for each Part B rebatable drug billing and payment code during the calendar quarter. The Secretary also is required to determine the Part B rebatable drug's quarterly excess rebate amount owed by the drug manufacturer. The Secretary may delay reporting the required information to drug manufacturers for calendar quarters beginning in 2023 and 2024 until no later than September 30, 2025.

Drug manufacturers are required to provide to the Secretary the Part B rebatable drug rebates within 30 days after receiving the specified information. The rebates are to be deposited into the Medicare Supplementary Medical Insurance Trust Fund.

### **Civil Monetary Penalties**

Drug manufacturers that do not comply with the quarterly Part B rebate requirements are subject to a CMP of at least 125% of the rebate amount for that calendar quarter. In addition, procedural provisions for enforcing CMPs under SSA Section 1128A apply to the enforcement of these CMPs.

### **Judicial and Administrative Review**

Judicial or administrative review is prohibited for the following: determining the number of rebatable Part B drug units, identifying which drugs are Part B rebatable drugs, calculating the Part B inflation rebate, determining the beneficiary coinsurance percentage, and setting the adjusted Medicare Part B payment percentage.

### **Conforming Amendments**

Section 11101 made conforming amendments to the Part B ASP calculation and Medicaid best price and AMP to exclude the Part B inflation rebates. Section 11101 also amended Medicaid prescription drug statute to add the Medicare Part B inflation rebate to the prohibition on disclosing drug prices.

### **Funding**

P.L. 117-169 appropriated \$80 million to CMS for FY2022, including \$12.5 million for FY2022 and \$7.5 million for each of FY2023-FY2031, to carry out provisions of Section 11101. Amounts are available until expended.

## **Section 11102: Medicare Part D Rebate by Manufacturers**

### **Background**

Medicare Part D plan sponsors submit annual bids to CMS to offer Part D benefits in set regions of the country. Part D sponsors, and the PBMs they own or contract with, seek to control costs, in part, by negotiating price concessions with manufacturers. Part D manufacturer price concessions primarily take the form of rebates (price reductions after the point of sale) from a list price for a brand-name drug. Drug manufacturers are not required to participate in Part D and are not required to provide rebates. However, manufacturers that choose to participate in Part D must provide a 70% manufacturer discount on brand-name drugs, biologics, and biosimilars purchased by Part D enrollees in the coverage gap. The *coverage gap* (or *doughnut hole*) is a period in the



Part D standard benefit where individuals have spending sufficient to reach the initial coverage limit but do not have enough out-of-pocket spending to reach the annual catastrophic threshold.

More generally, pharmaceutical manufacturers are required to report certain price information to HHS for purposes of federal health care program administration. One such reporting requirement is data used to compile a price measure for the Medicaid program, known as the AMP. The AMP, defined at SSA Section 1927(k)(1), is the average price a manufacturer receives in the United States for sales to wholesalers that supply retail community pharmacies and for sales directly to retail community pharmacies. The AMP does not include manufacturer rebates or discounts to PBMs and health plans, certain manufacturer prompt pay discounts, sales to other government programs, and consumer coupons. Certain other types of sales are exempt for purposes of calculating the AMP.

## Provision

Section 11102 creates a new SSA Section 1860D-14B (after Section 1860D-14A, 42 U.S.C. §1395w-114a), establishing a Part D rebate program that applies to manufacturers of certain Part D-covered drugs, defined as *rebatable drugs* (see definition below), with annual price increases above an allowable rate of inflation during an applicable period, as measured by the CPI-U. The program first applies to the applicable 12-month period starting on October 1, 2022, and continues to apply to each following 12-month period.

## Rebatable Drug Definition

*Part D rebatable drugs* are defined as certain Part D-covered drugs or biological products that meet a specified cost threshold.

## Drugs Subject to Rebate

P.L. 117-169 defines drugs or biological products that could be subject to a rebate (if they meet the cost threshold, below). In general, the definitions refer to (1) new chemical drugs approved under Federal Food, Drug, and Cosmetic Act Section 505(c); (2) generic drugs that lack competition (i.e., the brand-name drug that the generic is a copy of is not being marketed and no other generic versions are being marketed) and that are not covered by the specified 180-day generic drug-exclusivity periods; and (3) biologic drugs licensed under PHSA Section 351.

## Cost Threshold

A drug could qualify as a rebatable drug if its average total cost per individual were more than \$100 per applicable period, as determined by the Secretary. The Secretary is to determine whether a Part D drug meets the cost threshold based on the “most recent data available.” If data are not available, the Secretary must estimate whether a drug meets the threshold. The threshold for the applicable period beginning October 1, 2023, is to be set at the amount (\$100) specified for the applicable period beginning October 1, 2022, increased by the percentage increase in the CPI-U for the 12-month period beginning in October 2023.<sup>47</sup> For following years, the threshold is the dollar amount for the previous applicable period adjusted by the percentage increase in the CPI-U for the 12-month period beginning with October of that previous year. Any dollar amount that is not a multiple of \$10 is rounded to the nearest multiple of \$10.

<sup>47</sup> As specified in this section, the starting month for the inflation period of October 2023 would be during the same year as the applicable period of 2023.

## Inflation Rebate Determination

HHS determines the price of a rebatable drug using AMP data. Under the rebate program, the Secretary calculates an annual AMP for each dosage form and strength of a drug by averaging quarterly reported AMP price data for each drug unit, weighted by the number of units used to calculate the AMP each quarter. A *drug unit* is defined as the lowest dispensable quantity of a Part D-rebatable drug, including data reported under the statutory AMP calculation. HHS is to determine whether a manufacturer owes an annual rebate for each dosage form and strength of a rebatable drug, and the amount of such rebate, using a formula that compares the annual AMP for the applicable year with an inflation-adjusted payment amount.

The inflation-adjusted payment amount is defined as the AMP for each dosage form and strength of the drug in the payment amount benchmark period (which will begin on January 1, 2021, and will end in the month immediately prior to October 1, 2021), increased by the percentage by which the applicable period CPI-U (CPI-U in the first month of an applicable period, which is to be a 12-month period beginning with October 1 of a year) exceeds the benchmark period CPI-U (i.e., CPI-U for January 2021).

The estimated amount of any rebate for a dosage form and strength of a rebatable drug is the amount by which the annual price exceeds the allowable price. The rebate applies to all units of a drug dispensed under Part D during the applicable period. Starting in 2026, the rebate calculation excludes drug units covered by a Medicaid National Drug Pricing Agreement. To carry out the rebate provisions, the Secretary is to use information submitted by manufacturers and states in calculating the AMP and information submitted by sponsors or Medicare Part D PDPs and MA-PD plans.

## Exceptions

Defined exceptions to the Part D rebate requirements include the following:

- For drugs approved or licensed by the FDA after October 1, 2021, the payment amount benchmark period for determining the rebate is the first calendar year beginning after the day the drug was first marketed by any manufacturer. The benchmark period CPI-U is the CPI-U for January of the first year beginning after the date the drug was first marketed by any manufacturer.
- The Secretary is required to reduce or waive the rebate amount for a generic or a biosimilar if the Secretary determines there was a severe supply chain disruption during the applicable period, such as that caused by a natural disaster or other unique or unexpected event.
- The Secretary is required to reduce or waive the rebate amount in the case of a Part D rebatable drug described as currently in shortage on an FDA shortage list at any point during the applicable period.
- The Secretary is required to reduce or waive the rebate amount for a generic Part D rebatable drug, if the Secretary determines that without such a reduction or waiver, the drug is likely to be described as in shortage on such shortage list during a subsequent applicable period.
- In the case of Part D rebatable drugs that lose their status as selected drugs under SSA Title XI, Part E,<sup>48</sup> the payment amount benchmark period is to be the last year that begins during the drug's negotiated price applicability period. The

<sup>48</sup> Section 11001 of P.L. 117-169 creates a new Part E under SSA Title XI, authorizing the HHS to negotiate prices for certain drugs. The provision refers selected drugs for price negotiation at Part E, Section 1192(c).

benchmark period CPI-U in this case is to be the CPI-U for January of the last year that begins during the drug's negotiated price applicability period. The change is effective in the following applicable period.

- For a Part D drug that is a line extension of a Part D rebatable drug that was in an oral solid dosage form (i.e., a capsule or tablet), the Secretary is required to establish a formula for calculating rebate and payment amounts, consistent with the formula applied under Medicaid best price requirements. A line extension does not include an abuse-deterrent formulation of a drug.

### **Rebate Payment Requirement**

No later than nine months after the end of an applicable period, the Secretary is required to report the following to the manufacturer of a Part D rebatable drug: (1) information on the amount, if any, of the excess AMP increase for each dosage form and strength for such drug and such year and (2) the rebate amount for each dosage form and strength of such drug for the year.

For each applicable period, manufacturers are required to pay the required rebates to the Secretary no later than 30 days after receiving the Secretary's report. The Secretary is allowed to delay reporting for the applicable periods beginning in October 2022 and October 2023 until no later than December 31, 2025.

### **Judicial and Administrative Review**

There is no allowable administrative or judicial review of (1) the determination of drug units under the rebate program, (2) the determination of whether a drug was a Part D rebatable drug, and (3) the calculation of the rebate amount.

Rebates are to be deposited into the Federal Supplementary Medical Insurance Trust Fund.

### **Conforming Amendments**

Conforming amendments require drug manufacturers to exclude the Part D inflation rebates from the following: (1) the Medicaid best price determination, (2) the AMP calculation, and (3) the Medicare Part B ASP calculation. Conforming amendments also authorize the Secretary to disclose the confidential Part D inflation rebates as necessary to carry out the outpatient Medicare Part B and Medicare Part D drug programs.

### **Civil Monetary Penalties**

If a manufacturer of a Part D rebatable drug fails to comply with the requirements for an applicable year, the manufacturer is subject to (in accordance with a process established by the Secretary pursuant to regulations) CMPs equal to 125% of the required rebate amount for the drug. In addition, procedural provisions for enforcing CMPs under SSA Section 1128A apply to the enforcement of these CMPs.

### **Funding**

P.L. 117-169 provides to CMS \$80 million for FY2022, including \$12.5 million for FY2022 and \$7.5 million for each of FY2023-FY2031, to carry out provisions of the section. Amounts are available until expended.

The Secretary provides for a reconciliation process in the case where a Part D plan sponsor submits revised data regarding Part D dispensed drugs.

# Medicare Part D Program Changes

## Section 11201: Medicare Part D Redesign

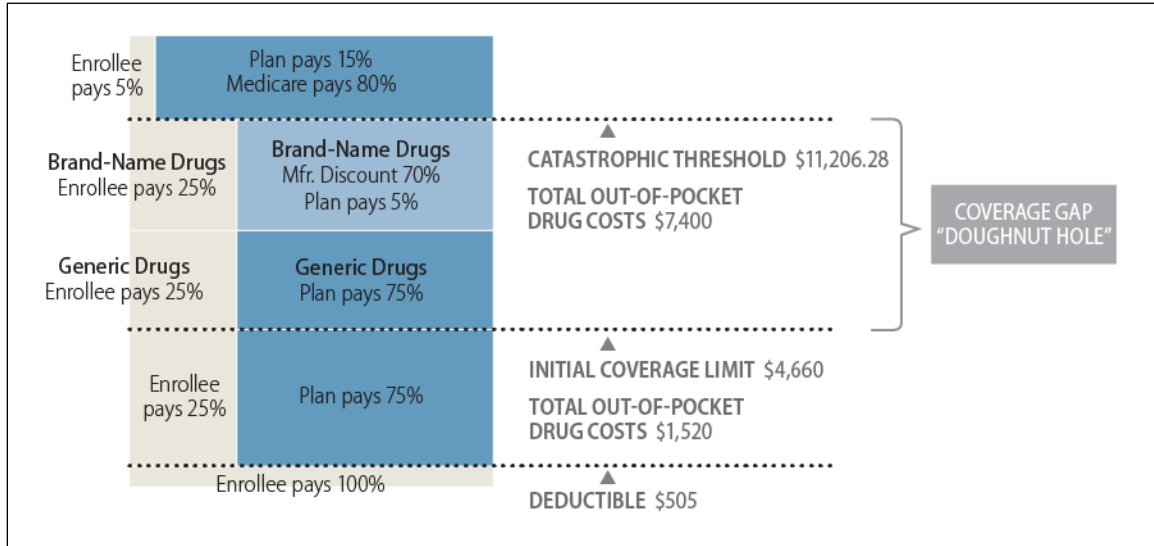
### Background

Medicare Part D provides a voluntary, outpatient prescription drug benefit for Medicare beneficiaries and is the primary source of drug coverage for dual-eligible individuals covered by both Medicare and the state-federal Medicaid program. Part D coverage is provided by private insurers, or *plan sponsors*, that submit annual bids approved by CMS for either PDPs or MA-PDs. Congress designed Part D as a market-oriented program in which sponsors compete for enrollees based on plan premiums and scope of benefits, including cost-sharing requirements. Private drug plans participating in Part D bear some financial risk, although federal subsidies cover most program costs in an effort to encourage participation and keep benefits affordable. Part D plans are offered on a calendar year basis, and enrollees may change plans during an annual enrollment period.

At a minimum, Part D sponsors must offer plans with “standard” benefits as defined in law. Plan sponsors also may offer alternative or enhanced coverage that is at least actuarially equivalent to a standard plan. Medicare provides subsidies to plan sponsors for each enrollee in a Part D plan; on average, these subsidies equal 74.5% of the value of standard coverage. Part D subsidies include direct subsidies, under which Medicare pays drug plans a risk-adjusted per enrollee payment, and reinsurance, under which Medicare subsidizes 80% of a plan’s drug spending above a catastrophic threshold. Medicare covers a greater portion of costs for low-income individuals through the Low-Income Subsidy (LIS), which varies by specified income and assets thresholds.

In 2023, under the Part D standard benefit, an enrollee first pays a deductible (\$505). After the deductible has been met, the enrollee is responsible for 25% of the cost of prescription drugs (with the plan covering the remaining 75%) up to the initial coverage limit (\$4,660). (See **Figure 1.**)

**Figure I. 2023 Medicare Part D Standard Benefit**



**Source:** Figure based on data from Centers for Medicare & Medicaid Services, “Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies,” Attachments IV and V, at <https://www.cms.gov/files/document/2023-announcement.pdf>.

**Notes:** Beneficiaries with out-of-pocket drug spending above the catastrophic threshold pay the greater of a \$4.15 co-payment for generic drugs and a \$10.35 co-payment for brand-name drugs or 5% cost sharing in 2023. Low Income Subsidy beneficiaries pay less out of pocket than other beneficiaries do. For example, full-benefit dual-eligible beneficiaries pay no deductible, have minimal cost sharing in the coverage gap, and have no cost sharing above the catastrophic threshold. *Mfr. Discount* means *manufacturer discount*.

After reaching the initial coverage threshold, a beneficiary enters the coverage gap, or *doughnut hole*. Manufacturers that choose to sell their drugs through the Part D program are required to participate in the Coverage Gap Discount Program, which provides a 70% discount for brand-name, biologic, and biosimilar drugs purchased by non-LIS enrollees in the doughnut hole. Enrollees count the coverage gap discount as part of their own out-of-pocket spending. Enrollees exit the doughnut hole if they reach the catastrophic threshold, which is set at \$7,400 in total out-of-pocket spending in 2023 (for those not receiving the LIS). Enrollees above the catastrophic threshold have a maximum 5% coinsurance.

The dollar level of beneficiary cost sharing for Part D drugs dispensed by network pharmacies in a standard plan is based on each Part D plan sponsor’s negotiated price for a drug (e.g., 25% coinsurance on a drug with a \$100 negotiated price).<sup>49</sup> Part D plan sponsors have some latitude to decide what price concessions to include in the negotiated price at the point of sale and generally do not include the value of manufacturer rebates (price reductions calculated after the point of sale), which effectively makes Part D negotiated prices more akin to list prices than to a plan’s net price.<sup>50</sup>

<sup>49</sup> As defined at 42 C.F.R. §423.100.

<sup>50</sup> By law, Part D sponsors must provide beneficiaries with access to negotiated prices for covered drugs at the point of sale that “take into account” any rebates, discounts, or other direct and indirect price concessions obtained by the plans. According to CMS, the statutory language gives plan sponsors latitude to decide what price concessions to include in the negotiated price. Plan sponsors may instead choose to pass price concessions through to beneficiaries outside of negotiated prices, such as in the form of lower monthly plan premiums. However, all aggregate price concessions that plan sponsors obtain for Part D covered drugs—whether included in the negotiated price at the point of sale or passed on to enrollees outside the negotiated price—must be reported to CMS for use in annual plan payment and administration. See 42 C.F.R. §423.100.

There is no annual cap on Part D enrollee prescription out-of-pocket spending, with the exception of LIS beneficiaries with the lowest income and assets, who have no cost sharing once they reach the catastrophic threshold. Part D coverage parameters based on dollar amounts generally are updated each plan year based on changes in average per capita spending for covered Part D drugs during the 12-month period ending in July of the previous year. In addition, Part D enrollees pay monthly premiums, which are based on a rate equal to 25.5% of the annual nationwide average of plan bids for standard benefits; however, actual premiums vary widely by the plan selected.

## **Provision**

Section 11201 amends SSA Section 1860D–2(b) (42 U.S.C. §1395w–102(b)) and Section 1860D–15(b) (42 U.S.C. §1395w–115(b)) to change the structure of the Part D standard benefit. Among other modifications, the section (1) caps annual enrollee out-of-pocket spending for Part D at the catastrophic threshold, beginning in 2024, and reduces the catastrophic threshold to \$2,000 in out-of-pocket spending beginning in 2025 (adjusted annually thereafter); and (2) reduces to 20% from 80% the federal reinsurance subsidy to Part D sponsors for catastrophic coverage for applicable drugs and to 40% from 80% for non-applicable drugs, beginning in 2025.

Under the redesigned standard benefit, all enrollees have zero cost sharing above the catastrophic threshold, beginning in 2024. In 2025, the catastrophic threshold is lowered to \$2,000 and is then adjusted in subsequent years for Part D drug inflation, using the current-law formula. Also beginning in 2025, there is no initial coverage limit or coverage gap in the redesigned benefit and the range of third-party payments that enrollees may count as their own out-of-pocket spending is expanded to include reimbursement through insurance, a group health plan, or certain other third-party payment arrangements. Starting in 2025, enrollees will no longer be allowed to count the manufacturer discount as their own out-of-pocket spending, as is the case in the current Part D manufacturer discount program. The current manufacturer discount program sunsets at the end of 2024 and a new manufacturer discount program takes effect in 2025.

Non-LIS enrollees continue to pay 25% coinsurance up to the catastrophic threshold and LIS beneficiaries continue to have low, set cost sharing. (Section 11404 of the act makes changes to allow more enrollees to qualify for higher LIS subsidies.)

## **Premium Stabilization Program**

The legislation creates a Part D premium stabilization program. Under law prior to the amendments in P.L. 117-169 becoming effective, at SSA Section 1860D–13(a)(2), the base beneficiary premium is set at 25.5% of the weighted average of Part D plan bids submitted to CMS for a program year. For 2024-2029, the base premium for each year is to be equal to the lesser of (1) the base premium for the previous year (e.g., 2023 for the applicable year 2024) increased by 6%, or (2) the base premium for the applicable year (in this case, 2024) as computed under SSA Section 1860D–13(a)(2).

For 2030 and subsequent years, the premium is set based on the percentage of plan bids that the Secretary determines is necessary to ensure the base premium in 2030 is equal to the lesser of (1) the base premium for 2029 increased by 6% or (2) the base premium that would have been computed for 2030 under SSA Section 1860D–13(a)(2). (For example, the percentage amount could continue to be 25.5% of plan bids if the lower premium amount for 2030 were the base premium as calculated under SSA Section 1860D–13(a)(2).) P.L. 117-169 further specifies that the base premium for 2030 and subsequent years cannot be set at less than 20% of the weighted average of all plan bids.



Under the premium stabilization provision, Medicare’s direct subsidies to Part D plan sponsors would increase in any year from 2024 to 2029 in which the base premium had risen by more than 6% from the previous year, absent the cap.<sup>51</sup> After 2030, the direct subsidy level could be adjusted, if the act’s formula for setting the base beneficiary premium from 2030 on produces a different percentage than the 25.5% in SSA Section 1860D-13(a)(2).

### **Manufacturer Discount Program**

Section 11201 creates a new SSA Section 1860D-14C, under which the Secretary is to establish a new manufacturer discount program, effective in 2025. Manufacturers that choose to participate in Part D are required to enter into annual discount agreements not later than March 1, 2024, for the period from January 1, 2025, to December 31, 2025. For each subsequent year, the Secretary establishes a deadline for an agreement. The existing Coverage Gap Discount Program sunsets after 2024.

Under the new program, manufacturers provide a 10% discount off the negotiated price for applicable drugs purchased by enrollees who have exceeded the annual Part D deductible but have not reached the catastrophic threshold. Manufacturers provide a 20% discount off the negotiated price on applicable drugs purchased by enrollees who reach the catastrophic threshold. The discounted prices are to be provided to enrollees at the pharmacy or through mail order at the point of sale. Enrollees will no longer be allowed to count the manufacturer discount as their own out-of-pocket spending. (Manufacturer discounts under the existing Coverage Gap Discount Program continue to count as out-of-pocket spending under Part D until the new manufacturer discount program takes effect in 2025.)

The new manufacturer discount program applies to *applicable drugs*, defined as brand-name drugs, biosimilars, and biologics on the formulary of a Part D plan or otherwise covered by a Part D plan, including through an enrollee exception or appeal.

Single-source drugs selected by the Secretary for price negotiation under Section 11001 are not subject to the manufacturer discount program, so long as the drugs are covered under a negotiation price applicability period. If such a single-source drug is dispensed to a Part D enrollee who had not met the annual out-of-pocket threshold, the Secretary is required to provide the Part D plan sponsor with a subsidy equal to 10% of the plan’s negotiated price.

*Applicable beneficiaries* are enrollees with incurred costs above the annual deductible, including LIS enrollees, who are not covered under the existing manufacturer coverage gap discount program. Part D plan sponsors are required to include the expected value of manufacturer discounts when submitting annual bids to CMS each June to offer Part D plans for the following year.

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<sup>51</sup> See CBO Letter to Rep. Jason Smith, August 4, 2022, at <https://www.cbo.gov/system/files/2022-08/58355-Prescription-Drug.pdf>. For example, if the base premium would have risen more than 6% for a year absent the cap, P.L. 117-169 would adjust the direct subsidy to Part D plans (set to average 74.5% of the average cost of a Part D standard benefit) to compensate, basically holding plans harmless. After 2030, the direct subsidy level would be equal to 100% minus the percentage amount of the base premium for 2030, which is to be derived under the formula in P.L. 117-169. According to the CBO letter,

That subsidy and subsequent reduction in premiums would increase federal spending by roughly \$40 billion over the 2024-2031 period, CBO estimates. Beneficiaries’ spending on premiums would be lower under the premium-stabilization provision than it would be without it. That estimate is an average effect among the possible paths of premiums that CBO considered when modeling the uncertainty of future outcomes. Under some of those paths, premiums would grow by less than 6 percent a year, and the provision would have no cost; under others, premiums would grow faster, and the provision would generate costs. (p. 3).



The Secretary is to administer the program and may impose CMPs on manufacturers that fail to provide required discounts.

The provision provides two separate special phase-ins of the manufacturer discount for manufacturers that account for a smaller share of Medicare drug spending: one for manufacturers of drugs sold to LIS beneficiaries and one for manufacturers of drugs sold to all applicable beneficiaries in cases where most of the manufacturer's Medicare revenue is derived from sales of just one drug.

### **Phase-In for Drugs Dispensed to LIS Beneficiaries**

The manufacturer discount is phased in over a period of years for applicable drugs, produced by specified manufacturers that are dispensed to LIS beneficiaries. Specified manufacturers are defined as manufacturers of applicable drugs, for which in 2021

- a Part D coverage gap discount agreement with HHS was in effect;
- total spending for all the manufacturer's specified drugs covered by Part D discount agreement(s) was less than 1% of total Part D drug spending; and
- total spending for all the manufacturer's specified drugs that were single-source drugs and biological products covered under Medicare Part B during such year represented less than 1% of total expenditures under Part B for all drugs or biological products during such year.

*Specified drugs* are defined, for 2021, as applicable drugs produced, prepared, propagated, compounded, converted, or processed by a specified manufacturer. All persons treated as a single employer under subsection (a) or (b) of IRC Section 52 are treated as one manufacturer for purposes of determining a specified manufacturer. A specified manufacturer does not fall under the provision if it was acquired after 2021 by another manufacturer that was not a specified manufacturer, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.

For an applicable drug of a specified manufacturer (1) marketed as of the date of enactment and (2) dispensed to an applicable LIS beneficiary, the discounted price is as follows:

- For an applicable drug dispensed to an LIS enrollee who had not incurred costs equal to or greater than the annual out-of-pocket threshold for the year, the 10% manufacturer discount would be phased in at 1% for 2025; 2% for 2026; 5% for 2027; 8% for 2028; and 10% for 2029 and each subsequent year.
- For an applicable drug dispensed for an LIS enrollee who had incurred costs for covered part D drugs that were equal to or exceeded the annual out-of-pocket threshold, the 20% manufacturer discount would be phased in at 1% for 2025; 2% for 2026; 5% for 2027; 8% for 2028; 10% for 2029; 15% for 2030; and 20% for 2031 and each subsequent year.

### **Phase-In for Small Manufacturers**

The manufacturer discount is phased in over a period of years for applicable drugs produced by specified small manufacturers. The provision applies to drugs marketed as of the date of enactment of P.L. 117-169 and dispensed to applicable beneficiaries.

*Small manufacturers* are defined as specified manufacturers (see above) in 2021 where total spending for any one of the manufacturer's drugs covered by a Part D manufacturer discount agreement is equal to more than 80% of total spending for all of the manufacturer's specified drugs covered by such agreements. *Specified small manufacturer drugs* are defined, for 2021, as

applicable drugs produced, prepared, propagated, compounded, converted, or processed by a specified manufacturer. (Small manufacturers are subject to the same requirements as specified manufacturers, above, regarding aggregation and acquisition by another manufacturer.)

The specified small manufacturer discount phase-in is as follows:

- For applicable drugs dispensed to Part D enrollees who had not incurred costs equal to or greater than the annual out-of-pocket threshold for the year, the 10% manufacturer discount would be phased in at 1% for 2025; 2% for 2026; 5% for 2027; 8% for 2028; and 10% for 2029 and each subsequent year.
- For applicable drugs dispensed to enrollees who had incurred costs equal to or above the annual out-of-pocket threshold, the 20% manufacturer discount would be phased in at 1% for 2025; 2% for 2026; 5% for 2027; 8% for 2028; 10% for 2029; 15% for 2030; and 20% for 2031 and each subsequent year.

### **Funding**

The section appropriates to CMS a total of \$341 million for FY2022, including \$20 million and \$65 million to carry out the provisions in FY2022 and FY2023, respectively, and \$32 million to carry out the provisions in each of FY2024-FY2031. The funds remain available until expended.

## **Section 11202: Maximum Monthly Cap on Cost-Sharing Payments Under Prescription Drug Plans and MA-PD Plans**

### **Background**

Prior to the amendments in P.L. 117-169 becoming effective, there is no monthly cap on cost-sharing payments for dispensed prescriptions for enrollees in Medicare Part D plans. Cost sharing for specific drugs varies among plans and can range from zero cost sharing for a generic drug to 50% coinsurance for certain brand-name drugs.

### **Provision**

Section 11202 amends Part D prescription cost-sharing requirements at SSA Section 1860D-2(b) (42 U.S.C. §1395w-102(b)) to allow any enrollee in a Part D plan, including an LIS enrollee, to elect to make prescription cost-sharing payments in monthly, capped installments up to the annual out-of-pocket threshold. Part D enrollees can elect capped cost sharing for plan years beginning in 2025 and may opt in prior to, or at any time during, a plan year. Plan sponsors are required to provide information to enrollees and pharmacies regarding the new option.

The maximum monthly payment for the first month is derived by taking the dollar amount of the annual out-of-pocket threshold (to be set at \$2,000 in 2025 under Section 11201 and adjusted annually thereafter), subtracting an enrollee's already-incurred costs (if any), and dividing the difference by the number of months remaining in the plan year. For a subsequent month, the cap is adjusted based on the amount of enrollee spending in previous months. Enrollees are to be billed a monthly amount that reflects incurred costs. The amount may be less than the monthly cap, depending on enrollee spending.

Enrollees who fail to make required monthly payments lose the right to participate in the capped payment option and must pay any amount owed up to the out-of-pocket threshold. Part D plan sponsors can ban enrollees who failed to make a monthly payment from using the capped cost-sharing option in a subsequent plan year.

The section appropriates \$10 million to CMS for FY2023, to remain available until expended, to carry out the program.

## **Section 11301: Extension of Moratorium on Implementation of Rule Relating to Eliminating the Anti-Kickback Statute Safe Harbor Protection for Prescription Drug Rebates**

### **Background**

The federal anti-kickback statute makes it a felony for a person to knowingly and willfully offer, pay, solicit, or receive anything of value in return for a referral or to induce generation of business reimbursable under a federal health care program. There are certain statutory exceptions to the anti-kickback statute. In addition, the HHS Office of Inspector General (OIG) has promulgated regulations that contain several *safe harbors* to prevent common business arrangements from being considered kickbacks. On November 30, 2020, the HHS OIG published a final rule that would alter an anti-kickback regulatory safe harbor to restrict the use of manufacturer drug rebates to Part D plans.<sup>52</sup> Implementation of the rule was delayed until 2026 as part of the Infrastructure Investment and Jobs Act (P.L. 117-158) and subsequently was delayed until 2027 as part of the Bipartisan Safer Communities Act (P.L. 117-159).

### **Provision**

Section 11301 amends Division I of the Infrastructure Investment and Jobs Act (42 U.S.C. §1320a–7b note), Section 90006, as amended by Division A of the Bipartisan Safer Communities Act, Section 13101, to prohibit the Secretary from enforcing the rebate rule prior to 2032.

## **Section 11404: Expanding Eligibility for Low-Income Subsidies Under Part D of the Medicare Program**

### **Background**

Medicare beneficiaries with limited incomes and resources may qualify for assistance with their Part D premiums, cost sharing, and other out-of-pocket expenses under the LIS. There are two categories of LIS beneficiaries, full and partial. The designation is based on meeting set income and asset tests.

Certain groups of Medicare beneficiaries automatically qualify and are deemed eligible for the full LIS. So-called *full-benefit dual-eligibles* who qualify for Medicaid benefits based on income and assets are automatically deemed eligible for the full Medicare prescription drug LIS. Additionally, those who receive Medicare premium and/or cost-sharing assistance from Medicaid through the Medicare Savings Program plus those eligible for Supplemental Security Income cash assistance are automatically deemed eligible for the full LIS. These three categories include all eligible persons who (1) have countable incomes below 135% of the federal poverty level (FPL) and (2) have countable resources up to set limits, which are adjusted annually for inflation.

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<sup>52</sup> HHS, Office of Inspector General, “Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service,” 85 *Federal Register* 76666, November 30, 2020, at <https://www.govinfo.gov/app/details/FR-2020-11-30/2020-25841>.

Full-subsidy LIS beneficiaries do not pay monthly plan premiums if they enroll in certain lower-cost Part D plans. They also do not pay a deductible and face minimal cost sharing during the initial coverage period and coverage gap and no cost sharing above the catastrophic threshold.

Other individuals with limited incomes and resources who do not automatically qualify may apply for the LIS and have their eligibility determined by either the Social Security Administration or their state Medicaid agency. This group includes non-deemed individuals who may be eligible for the full LIS. It also includes individuals who may qualify for the partial LIS because they (1) are enrolled in a Part D PDP or MA-PDP; (2) have countable incomes below 150% of the FPL; and (3) have countable resources up to an annual amount that is set at a higher level than for the limit used to determine qualification for a full-subsidy LIS designation. Partial LIS beneficiaries receive Part D premium assistance based on an income sliding scale, pay a partial deductible (\$99 in 2022), pay an average 15% coinsurance for drugs up to the out-of-pocket threshold, and pay set co-payments for drugs above the out-of-pocket threshold (\$3.95 for generic drugs and \$9.85 for brand drugs in 2022).

### Provision

Section 11404 amends SSA Section 1860D-14(a) (42 U.S.C. §1395w-114(a)) to alter the LIS program to sunset the partial LIS designation for plan years beginning in 2024. From 2024 on, there is to be only one category of LIS, and it will provide the maximum subsidies now available to enrollees who qualify for the full LIS. Eligibility for this single LIS benefit is to be based on the higher income (150% of the FPL) and resource limits in effect prior to P.L. 117-169; these limits are to continue to be used in 2023 to determine eligibility for the partial LIS subsidy.

## Payment for Medicare Part B Biosimilar Biological Products

### Section 11402: Payment for Biosimilar Biological Products During Initial Period

#### Background

Biological products are medical products derived from living organisms, which can include animal cells and microorganisms (e.g., yeast, bacteria), whereas drug manufacturers derive conventional drugs from chemicals.<sup>53</sup> In contrast to generic drugs, which are bioequivalent to brand-name drugs, biosimilar biological products are similar to but structurally may differ slightly from brand-name biological products, known as reference products.

Biosimilar biological manufacturers may apply to the FDA for market approval of products that are *interchangeable* with the reference biological product. Pharmacists may substitute biosimilar biological products for reference biological products without intervention by the prescribing health care practitioner.

Federal law authorizes FDA to approve drugs and license biological products for periods of market exclusivity. For instance, the first generic drug manufacturer that applies to market a drug

<sup>53</sup>For additional biological product information, see CRS In Focus IF11083, *Medical Product Regulation: Drugs, Biologics, and Devices*.

based on a brand-name drug can be approved by FDA for a 180-day period of market exclusivity. During the exclusivity period, FDA cannot approve another generic manufacturer's marketing application based on the same brand-name product. In contrast, FDA licensure of the first biosimilar product based on a reference biological product does not include an exclusivity period.

The first interchangeable biosimilar biological product licensed by FDA is eligible for an exclusivity period of up to 42 months, which depends on market introduction and patent litigation. During the exclusivity period, FDA cannot license another biosimilar biological as interchangeable with the same reference product. In July 2021, FDA licensed the first interchangeable biosimilar biological product.<sup>54</sup>

Medicare reimburses Part B providers and suppliers for prescription drugs and biological products after the provider has purchased the drug or biological product and administered or furnished it to a beneficiary. With exceptions, Medicare generally reimburses providers and suppliers for most Part B drugs and biological products at the rate of the product's ASP plus a 6% add-on payment. Under Medicare statute, ASP is the average price, net of discounts, for all units of a drug sold during a rebate period—a calendar quarter—to all purchasers except sales subject to Medicaid best price and nominal price sales. Medicare statute requires that biosimilar biological products are paid 100% of their ASP plus an add-on payment equal to 6% of the reference biological product's ASP.

Medicare statute does not specify the payment rate for biosimilar biological products during the initial product introduction period, when pricing data may be insufficient to calculate the product's ASP. By statute, the initial period payment rate is limited to the first full calendar quarter after the drug or biological product is first marketed.

Generally, when prescription drug and biological sales data are insufficient to calculate a product's ASP, such as during the initial period the drug or biological product is marketed, Medicare statute directs the Secretary to determine the Medicare Part B reimbursement rate based on the following:

- If the drug or biological product was furnished to beneficiaries prior to January 1, 2019, the payment rate is based on the wholesale acquisition cost (WAC) or Medicare Part B payment methodologies for drugs and biological products in effect November 1, 2003.
- If the drug or biological product was furnished to beneficiaries on or after January 1, 2019, the payment rate is based on an amount not to exceed 103% of the WAC or the Medicare Part B payment methodologies for drugs and biological products in effect November 1, 2003.

WAC is a drug manufacturer's list price for the most recent month to U.S. wholesalers or direct purchasers excluding prompt payment discounts or other discounts, rebates, or price reductions, as published in drug pricing compendia.<sup>55</sup> As a list or published price, WAC usually exceeds ASP. Generally, the Medicare Part B drug payment methodology in effect November 1, 2003, was 95% of the average wholesale price (AWP).<sup>56</sup> AWP is a list price used by wholesalers and distributors when selling to pharmacies and usually exceeds WAC.

<sup>54</sup>For additional information, see CRS Report R44620, *Biologics and Biosimilars: Background and Key Issues*

<sup>55</sup> *Wholesale acquisition cost* is defined in Medicare statute (SSA Section 1847A(c)(6)(B)).

<sup>56</sup> SSA Section 1842(o)(1)(G).

## **Provision**

Section 11402 amends SSA Section 1847A(c) (42 U.S.C. §1395w-3a(c)) to establish an initial period Medicare Part B payment rate for separately payable biosimilar biological products furnished to beneficiaries on or after July 1, 2024. The biosimilar biological payment rate during the statutory initial period is the lesser of the following: (1) the biosimilar product's WAC plus a 3% add-on payment or (2) 100% of the reference biological product's ASP plus a 6% add-on payment based on the reference biological product's ASP. The initial-period Medicare Part B payment rate for biosimilar biological products furnished on or after January 1, 2019, but before July 1, 2024, is an amount not to exceed 103% of the product's WAC or the Part B payment methodologies for drugs and biological products in effect November 1, 2003.

## **Section 11403: Temporary Increase in Medicare Part B Payment for Certain Biosimilar Biological Products**

### **Background**

Medicare pays for many biological products under Part B as drugs dispensed “incident to physician services” or physician administered drugs (PADs). Many PADs are products used in treating cancer, arthritis, and other chronic conditions that are more common among elderly individuals, including Medicare beneficiaries.

Medicare reimburses Part B providers and suppliers for prescription drugs and biological products after the provider purchases the drug or biological product and administers it to the patient. With exceptions, Medicare generally reimburses providers and suppliers for most Part B drugs and biological products at the rate of the product's ASP plus a 6% add-on payment. To encourage development of lower priced biosimilar biological products, Medicare statute requires that biosimilar biologics are paid 100% of their ASP plus an add-on payment of 6% of the reference biological product's ASP.

### **Provision**

Section 11403 amends SSA Section 1847A(b) (42 U.S.C. §1395w-3a(b)) to authorize the Secretary to temporarily (for five years) increase the Medicare Part B add-on payment for qualifying biosimilar biological products from 6% to 8% of the reference biological products' ASP. The five-year period for the increase in Medicare Part B payments for qualifying biosimilar products begins on the first day of a calendar quarter between October 1, 2022, and December 31, 2027, based on when payment was first made for the product under Part B.

For biosimilar biological products paid under Medicare Part B as of September 30, 2022, the Medicare payment includes the additional add-on payment for five years beginning October 1, 2022, unless the biosimilar biological products' ASP exceeded the reference biological product's ASP. For biosimilar biological products first paid between October 1, 2022, and December 31, 2027, the Medicare Part B payment includes the 8% add-on payment for five years beginning on the first day of the first calendar quarter Medicare Part B first paid for the product, unless the product's ASP exceeded the reference biological product's ASP.



# Vaccines Under Medicare Part D, Medicaid, and CHIP

## Section 11401: Coverage of Adult Vaccines Recommended by the Advisory Committee of Immunization Practices Under Medicare Part D

### Background

The Advisory Committee on Immunization Practices (ACIP) provides guidance to HHS and the Centers for Disease Control on the use of vaccines, including recommending immunization schedules for the U.S. population, with certain vaccine dosages based on age.

Medicare coverage for vaccines is divided between Part B and Part D. Part B covers vaccines for influenza, pneumonia, Hepatitis B (for beneficiaries at increased risk from the disease), and COVID-19. Part B also covers vaccines administered directly in relation to treatment of an injury or direct exposure to a disease or condition, such as tetanus shots.

Medicare Part D covers all commercially available vaccines, except for vaccines covered under Part B, or in cases where the vaccine manufacturer has chosen not to participate in the Part D Coverage Gap Discount Program. The shingles vaccine (herpes zoster), which the ACIP recommends for adults aged 50 and older, is an example of a vaccine covered under Part D.

Medicare Part B beneficiaries have no cost sharing (co-payment and annual deductible) for covered vaccines, except when the vaccine is administered for the treatment of an injury or direct exposure to a disease or condition, in which case beneficiaries would be responsible for 20% of the Medicare-approved amount for the vaccine and its administration. By comparison, Medicare Part D plans may impose cost sharing for vaccines. Cost sharing may vary across plans, and enrollees can face substantial cost sharing for vaccines, particularly the shingles vaccine, if beneficiaries are in the deductible phase of the benefit or if the vaccine has been placed on a formulary tier with high cost sharing. The shingles vaccine accounts for more than 80% of Part D vaccine claims and more than 90% of all Part D spending on vaccinations, according to the Medicare Payment Advisory Commission (MedPAC).<sup>57</sup>

### Provision

Section 11401 amends SSA Section 1860D-2 (42 U.S.C. §1395w-102) to specify that, for plan years beginning in 2023, Part D plans may no longer apply a deductible, coinsurance, or other cost-sharing requirement for adult vaccinations recommended by the ACIP that are covered Part D drugs.

In addition to amounts otherwise payable under this section to a Part D PDP or MA-PD sponsor, for plan year 2023, the Secretary is to provide additional subsidies equal to the aggregate reduction in cost sharing and deductible payments due to the provision governing ACIP vaccines. The subsidies qualify as incurred costs (i.e., as out-of-pocket spending) for Part D enrollees. The

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<sup>57</sup> MedPAC, Chapter 7 in *Report to the Congress: Medicare and the Health Care Delivery System*, June 2021, p. 251, at <https://www.medpac.gov/recommendation/medicare-vaccine-coverage-and-payment-june-2021/>.



subsidies are to be provided not later than 18 months following the end of the applicable plan year.

## **Section 11405: Improving Access to Adult Vaccines Under Medicaid and CHIP**

### **Background**

#### *Medicaid*

Federal law provides two primary benefit packages for state Medicaid programs: (1) traditional Medicaid and (2) alternative benefit plan (ABP) coverage. Each of these packages has its own federal requirements, including which service categories are considered mandatory (i.e., services the state must cover) and which are available at state option. For certain subgroups, states may offer a targeted benefit package (e.g., enrollees eligible only for family planning services). In addition, states can use waiver authority to tailor benefit packages to specified Medicaid subgroups or to offer services outside of those permitted under the Medicaid statute.

#### **Traditional Medicaid Coverage**

In general, Medicaid coverage of ACIP-recommended adult vaccines is available at state option for enrollees who receive services under traditional Medicaid. However, states may cover vaccines and vaccine administration under certain traditional state plan mandatory service categories (e.g., inpatient hospital services, outpatient hospital services, rural health clinic services, Federally Qualified Health Centers, physicians' services), depending on how the state defines the amount, duration, and scope of this coverage. In another example, state coverage of vaccine and vaccine administration is required for persons aged 19 and 20 under Medicaid's Early and Periodic Screening Diagnostic and Treatment program. Adult vaccines and vaccine administration also may be a covered service via an optional state plan benefit category (e.g., preventive services, other licensed practitioners, or clinic services). In addition, for medically needy subgroups,<sup>58</sup> states may offer a more restrictive benefit package than is available to other enrollees that could include such coverage. States may impose enrollee cost sharing on adult vaccines and vaccine administration, when cost sharing is otherwise permitted under Medicaid program rules.

A state may receive a one percentage point increase in its Federal Medical Assistance Percentage (FMAP) rate for providing coverage of adult vaccines (and vaccine administration), as well as other preventive services, if the state meets certain specified requirements. For example, the state must cover, without enrollee cost sharing, (1) any clinical preventive services that are assigned a grade of A or B by the United States Preventive Services Task Force and, (2) for adult beneficiaries, it must cover all ACIP-recommended vaccines and their administration.

#### **Medicaid Alternative Benefit Plan Coverage**

Medicaid coverage of ACIP-recommended vaccines and vaccine administration, without enrollee cost sharing, is mandated for enrollees who receive coverage under Medicaid ABPs regardless of the enrollee's age.

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<sup>58</sup> States are permitted to extend coverage to medically needy individuals (e.g., children, pregnant women, aged, blind, or disabled) who are otherwise eligible for Medicaid but who have incomes too high to qualify. Medically needy enrollees spend down their income on medical care to meet the state's income eligibility threshold.

### ***State Children's Health Insurance Program***

CHIP provides health insurance coverage to low-income, uninsured children (through the age of 18) in families with incomes above applicable Medicaid income standards as well as to certain pregnant individuals, through an expansion of Medicaid, a separate CHIP program, or a combination of both. There are certain circumstances under which CHIP coverage may be available to an adult aged 19 and older, as in the case where states provide CHIP coverage to pregnant individuals by extending coverage to unborn children as permitted through federal regulation. Vaccines are not statutorily required for pregnant individuals covered through a separate CHIP program, although all states that cover pregnant individuals through a separate CHIP program currently cover vaccines and their administration without cost sharing for this population.<sup>59</sup>

### **Provision**

#### **Medicaid**

Section 11405(a) amends SSA Sections 1902(a)(10)(A) (42 U.S.C. §1396a(a)(10)(A)) in the matter preceding clause (i), 1902(a)(10)(C)(iv) (42 U.S.C. §1396a(a)(10)(C)(iv)), 1916 (42 U.S.C. §1396o), and 1916A(b)(3)(B) (42 U.S.C. §1396o-1(b)(3)(B)) to expand coverage of ACIP-recommended adult vaccines and vaccine administration, without enrollee cost sharing, under Medicaid by mandating such coverage for (1) enrollees who receive coverage under traditional Medicaid and (2) all Medicaid medically needy enrollees in specified states (i.e., states that offer services in institutions for mental diseases or in an “intermediate care facility for the mentally retarded” [or both] to any medically needy subgroup in the state). The FMAP rate associated with such coverage under traditional Medicaid is increased by one percentage point during the first eight fiscal quarters on or after the date of enactment (i.e., from October 1, 2023, through September 30, 2025).

#### **State Children's Health Insurance Program**

Section 11405(b) amends SSA Section 2103(c) (42 U.S.C. §1397cc(c)) to mandate coverage of ACIP-recommended adult vaccines and vaccine administration, without beneficiary cost sharing, for CHIP enrollees who are 19 years of age or older.

#### **Effective Date**

Section 11405(c) defines the effective date for the Medicaid and CHIP changes made under this provision as the first fiscal quarter that begins on or after one year after enactment (i.e., October 1, 2023).

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<sup>59</sup> CMS, Coverage and Reimbursement of COVID-19 Vaccines, Vaccine Administration, and CostSharing under Medicaid, the Children's Health Insurance Program, and Basic Health Program, May 6, 2022, available at <https://www.medicaid.gov/state-resource-center/downloads/covid-19-vaccine-toolkit.pdf>.

# Insulin

## Section 11406: Appropriate Cost-Sharing for Covered Insulin Products Under Medicare Part D

### Background

The standard Medicare Part D benefit sets average enrollee prescription cost sharing at 25% of a plan's negotiated drug price. Most Part D plan sponsors offer alternative or enhanced plans that instead offer tiered cost sharing, where enrollees pay less for low-cost drugs and more for expensive medications. (All Part D plans must be at least as generous as the standard Part D plan.) Most Part D plans have deductibles, a period in the benefit where an enrollee pays 100% of costs (the maximum deductible is \$480 in 2022). Prior to the amendments in P.L. 117-169 becoming effective, there is no annual out-of-pocket cap on spending for most enrollees. Starting in 2024, the act will cap annual Part D out-of-pocket spending.

According to CMS, about 3.3 million Part D enrollees use insulin, including 2 million who were LIS enrollees with reduced cost sharing or enrollees in special employer-based Part D plans referred to as Employer Group Waiver Plans (EGWPs); these plans often provide more generous benefits, according to MedPAC.<sup>60</sup> Other Part D enrollees may face high or variable insulin cost sharing, including paying 100% of the cost of the drug in the deductible.

To improve insulin adherence, CMS initiated a pilot program in 2021 known as the Part D Senior Savings Model, which caps monthly co-payments for certain insulins at \$35 throughout the benefit, including in the deductible phase.<sup>61</sup> Insurers offering enhanced stand-alone Part D plans and qualifying MA-PD plans that choose to participate in the model must offer the \$35 co-payment to enrollees. (The pilot does not apply to LIS recipients or EGWPs.) Specifically, participating plans must offer \$35 cost sharing for one vial dosage and one pen form of a rapid-, short-, intermediate-, and long-acting insulin. In 2022, about 106 Part D sponsors are in the program, covering more 17 million total enrollees, including more than 800,000 enrollees who use insulin.<sup>62</sup>

### Provision

Section 11406 amends SSA Section 1860D-2 (42 U.S.C. §1395w-102) to cap insulin cost sharing for enrollees in Part D PDP and MA-PD plans. Starting with plan year 2023, PDP and MA-PD deductibles no longer apply to Part D-covered insulin products. During each plan year, starting with 2023, a Part D plan sponsor is required to provide insulin at cost sharing equal to the “applicable copayment amount,” which is defined as a co-payment no greater than \$35 for 2023-2025. For 2026 and subsequent years, the co-payment amount is the lesser of

- \$35;
- an amount equal to 25% of the MFP for the covered insulin product under the Drug Price Negotiation Program in Section 11001; or

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<sup>60</sup> MedPAC, Chapter 13 in *Report to the Congress: Medicare Payment Policy*, March 2022, p. 496, at <https://www.medpac.gov/document/chapter-13-the-medicare-prescription-drug-program-part-d-status-report-march-2022-report/>.

<sup>61</sup> CMS, “Part D Senior Savings Model,” at <https://innovation.cms.gov/innovation-models/part-d-savings-model>.

<sup>62</sup> Ibid., see heading “CY 2022 Participating Part D Plan Sponsors.”

- an amount equal to 25% of the negotiated price of the covered insulin product under the PDP or MA-PD plan.

From January through March 2023, a Part D plan sponsor is required to reimburse an enrollee for any cost-sharing payments in excess of the \$35 cap.

In addition to regular Part D program subsidies to plan sponsors for the 2023 plan year, the Secretary is to provide additional subsidies equal to the aggregate reduction in enrollee cost-sharing and deductible payments that are due to the new \$35 insulin cap. The additional, temporary subsidies are to count as incurred costs (i.e., enrollee out-of-pocket spending) for purposes of plan administration.

For plan years prior to 2025, the applicable co-payment amount applies regardless of whether an enrollee reaches the initial coverage limit or the catastrophic threshold. For 2025 and subsequent plan years, Part D plans provide coverage for insulin products at the applicable co-payment amount up to the catastrophic threshold. The maximum \$35 co-payment applies to both LIS and non-LIS enrollees.

The provision appropriates \$1.5 million to CMS for FY2022, to remain available until expended, to carry out the provisions of this section.

## **Section 11407: Limitation on Monthly Coinsurance and Adjustments to Supplier Payment Under Medicare Part B for Insulin Furnished Through Durable Medical Equipment**

### **Background**

Medicare covers reasonable and necessary durable medical equipment (DME) for Medicare Part B beneficiaries, including external insulin infusion pumps. Some beneficiaries whose diabetic conditions meet certain specified criteria benefit from receiving insulin through an external ambulatory insulin infusion pump. Medicare Part B covers insulin pumps and the insulin used in the pump in “the home setting” when prescribed by a health care practitioner.

With exceptions for some services and supplies, Medicare Part B beneficiaries generally are financially responsible for an annual deductible and a monthly premium. In addition, Part B beneficiaries pay 20% coinsurance for the Medicare payment amount for each service or item furnished by providers and suppliers.

Most Medicare Part B beneficiaries have additional health insurance coverage, such as private supplemental health insurance through a former employer, Medigap coverage, or Medicare managed care, that pays most Part B coinsurance.<sup>63</sup> Medicare pays DME suppliers and pharmacies for the insulin furnished through insulin pumps in the same way it pays for other separately payable Medicare Part B drugs.

### **Provision**

Section 11407 amends SSA Section 1833(b) (42 U.S.C. §1395l(b)) to waive the Medicare deductible when a Medicare Part B beneficiary receives insulin through an item of DME on or after July 1, 2023. In addition, Section 11407 amends SSA Section 1833(a) (42 U.S.C.

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<sup>63</sup> MedPAC, *A Data Book: Health Care Spending and the Medicare Program*, July 2022. In 2019, 89% of Medicare beneficiaries had supplemental coverage or participated in Medicare managed care.

§1395l(a)(1)(S)) to set the Medicare Part B payment amount to suppliers for insulin furnished through DME on or after July 1, 2023, at 80% of the Medicare Part B drug payment amount. Section 11407 further amended the SSA Section 1833(a) (42 U.S.C. §1395l(a)) by directing the Secretary to adjust the Medicare supplier payment for insulin furnished through DME on or after July 1, 2023, so that Medicare beneficiaries' coinsurance for a month's supply of insulin does not exceed \$35.

## Section 11408: Safe Harbor for Absence of Deductible for Insulin

### Background

A health savings account (HSA) is a tax-advantaged account that individuals can use to pay for unreimbursed medical expenses (e.g., deductibles, co-payments, coinsurance, and services not covered by insurance).<sup>64</sup>

Individuals are eligible to establish and contribute to an HSA if they have coverage under an HSA-qualified High Deductible Health Plan (HDHP), do not have disqualifying coverage, and cannot be claimed as a dependent on another person's tax return.

To be considered an HSA-qualified HDHP, a health plan must meet several criteria: (1) it must have a deductible above a certain minimum level, (2) it must limit out-of-pocket expenditures for covered benefits to no more than a certain maximum level, and (3) it can cover only preventive care services and (for limited time periods) telehealth services before the deductible is met.

For example, if a health plan satisfied the first two of these criteria and provided coverage for preventive care services and prescription drugs before the deductible was met, that health plan would not be considered an HSA-qualified HDHP because it provided prescription drug benefits before the deductible was met.

According to current IRS guidance, insulin is considered a preventive care service for individuals diagnosed with diabetes.<sup>65</sup>

### Provision

Section 11408 amends IRC Section 233(c)(2) to allow HSA-qualified HDHPs to cover the costs associated with selected insulin products before the deductible is met and still be considered an HSA-qualified HDHP. This section defines *selected insulin products* as "any dosage form (such as vial, pump, or inhaler dosage forms) of any different type (such as rapid-acting, short-acting, intermediate-acting, long-acting, ultra-long acting, and premixed) of insulin."<sup>66</sup>

Similar to preventive care services and telehealth services (for limited time periods), this provision adds selected insulin products to items and services that may be covered before the deductible is met.

This section applies to plan years that begin on or after December 31, 2022.

<sup>64</sup> For more information on health savings accounts, see CRS Report R45277, *Health Savings Accounts (HSAs)*.

<sup>65</sup> Internal Revenue Service, "Additional Preventive Care Benefits Permitted to Be Provided by a High Deductible Health Plan Under §223," *Notice 2019-45*, at <https://www.irs.gov/pub/irs-drop/n-19-45.pdf>.

<sup>66</sup> See §11408(a) of the P.L. 117-169.

## Premium Tax Credit

### Section 12001: Improve Affordability and Reduce Premium Costs of Health Insurance for Consumers

#### Background

Individuals (and families) may receive federal financial assistance in the form of a *premium tax credit* (PTC) if they meet income eligibility criteria, are not eligible for subsidized health coverage (e.g., Medicaid), and meet other requirements. A PTC reduces the cost of purchasing certain health insurance offered through exchanges (or *marketplaces*).<sup>67</sup> As authorized under the Patient Protection and Affordable Care Act (ACA; P.L. 111-148, as amended), the PTC was available to individuals whose annual household incomes were at or above 100% of FPL but no more than 400% of FPL.<sup>68</sup> The American Rescue Plan Act of 2021 (ARPA; P.L. 117-2) made temporary changes to the income eligibility criteria. For taxable years 2021 and 2022, the ARPA eliminated the income eligibility phaseout at 400% of FPL, requiring individuals to meet only the minimum threshold to be income eligible for the PTC (such individuals must still meet the applicable non-income eligibility criteria to receive the credit).<sup>69</sup>

Individuals who are eligible for the PTC may still be required to pay an amount toward the premium. Under the ACA, the required premium contribution is capped at a dollar amount that is equivalent to a percentage of annual household income (*applicable percentage*), with income measured relative to the FPL.<sup>70</sup> The cap requires lower-income individuals to contribute a smaller share of income toward the premium, compared with the contribution requirement for higher-income individuals; applicable percentages are adjusted on an annual basis. Prior to enactment of the ARPA, the 2021 applicable percentages varied from 2.07% to 9.83% for incomes within the original range of 100%-400% of FPL.<sup>71</sup> The ARPA temporarily reduced the percentage of income used in the credit formula. For taxable years 2021 and 2022, applicable percentages ranged from 0.0% to 8.5% of income, effectively reducing the amounts that eligible individuals paid to enroll in certain exchange plans (compared with the amounts they would have paid without the ARPA PTC provisions).<sup>72</sup> Eligible individuals with incomes between 100% and 150% of FPL received full premium subsidies (toward benchmark exchange plans) in 2021 and 2022; eligible individuals with higher incomes received partial subsidies for such plans. For all eligible households with annual incomes at or above 400% of FPL, each household was required to spend up to 8.5% of its income (prorated monthly) before receiving any credit. For some higher-income households, this provision resulted in receiving no credit despite being eligible.

<sup>67</sup> 26 U.S.C. §36B.

<sup>68</sup> 26 U.S.C. §36B(c)(1)(A) and (d)(2).

<sup>69</sup> 26 U.S.C. §36B(c)(1)(E).

<sup>70</sup> 26 U.S.C. §36B(b)(3)(A).

<sup>71</sup> Internal Revenue Service, “Examination of Returns and Claims for Refund, Credit, or Abatement; Determination of Correct Tax Liability,” Revenue Procedure 2020-36, at <https://www.irs.gov/pub/irs-drop/rp-20-36.pdf>.

<sup>72</sup> 26 U.S.C. §36B(b)(3)(A)(iii).

## **Provision**

Section 12001 amends 26 U.S.C. §36B to extend the PTC changes enacted under the ARPA. For taxable years 2021 through 2025, the provision (1) eliminates the eligibility phaseout for households with annual incomes above 400% of FPL and (2) uses the ARPA applicable percentages (0.0% to 8.5% of annual household income) to calculate the credit amount. As is the case under the ARPA, this provision provides the largest benefit to those with incomes at or below 150% of FPL; such individuals would receive full subsidies to cover benchmark plan premiums.



## Appendix A. Common Insurance and Prescription Drug Terms

### Common Insurance and Prescription Drug Terms

**Biologics (Biological Products):** Products derived from living organisms, which can include animal cells and microorganisms, often produced through the use of biotechnology in a living system, such as a cell, for the treatment of various medical conditions.

**Brand-Name Drug:** The Food and Drug Administration (FDA) defines a *brand-name drug* as a drug marketed under a proprietary, trademark-protected name.

**Coinsurance:** The percentage share that an enrollee in a health insurance plan pays for a product or service covered by the plan. An insurer could charge 10% coinsurance for a \$100 prescription drug, meaning the consumer's out-of-pocket cost would be \$10.

**Co-payment:** A fixed dollar amount that an enrollee in a health insurance plan pays for a product or service covered by the plan. For example, an insurer could charge a \$20 co-payment for a physician visit or a \$5 co-payment for a prescription drug.

**Cost Sharing:** Refers generally to health plan deductibles, coinsurance, or co-payments for drugs or services. Does not include plan premiums.

**Deductible:** The amount an enrollee is required to pay for health care services or products before his or her insurance plan begins to provide coverage. An enrollee in an insurance plan with a \$500 deductible would be responsible for paying for the first \$500 in health care services. In some insurance plans, the deductible does not apply to certain services, such as preventive care. Insurance plans vary regarding whether beneficiaries must meet a deductible for prescription drug coverage.

**Formulary:** A list of prescription drugs covered by an insurance plan. In an effort to control costs, insurers are imposing closed or partially closed formularies, which include a more limited number of drugs than traditional formularies.

**Generic:** A generic drug is identical to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price.

**Out-of-Pocket Costs:** The total amount an insured consumer pays each year for covered health care services that are not reimbursed by an insurance plan. Out-of-pocket costs can include deductibles, co-payments, and coinsurance.

**Out-of-Pocket Maximum:** The maximum amount an enrollee must pay before his or her health insurance plan covers 100% of health benefits. Certain costs, such as premiums, generally do not count toward an out-of-pocket maximum, or cap.

**Pharmacy Benefit Managers (PBMs):** Intermediaries between health plans and pharmacies, drug wholesalers, and manufacturers. PBMs perform functions such as designing drug formularies, negotiating prices, and administering prescription drug payment systems on behalf of health plans.

**Pharmacy Network:** A group of retail, mail-order, and specialty pharmacies that contract with PBMs and health insurers to dispense covered drugs at set prices. Network pharmacies also may provide other services under contract, such as monitoring patient adherence to drugs.

**Premium:** The amount an enrollee pays for health insurance coverage. Many plans charge monthly premiums, but premiums also can be assessed on a quarterly or annual basis.

**Specialty Drug:** There is no one set definition of specialty drugs, although insurers and other health care payers often characterize them as prescription products requiring extra handling or administration that are used to treat complex diseases, such as cancer. High cost can trigger a specialty drug designation. Biologics, or drugs derived from living cells, often are deemed specialty drugs.

**Tiered Pricing:** Insurers use tiered cost sharing for formulary drugs, meaning patients face lower co-payments or coinsurance for less expensive generic drugs and certain brand-name drugs designated by the plan as preferred drugs, based on the price the plan has negotiated with the manufacturer and the product's effectiveness. At the same time, patients are charged higher co-payments or coinsurance for more expensive drugs (including specialty drugs) or drugs the plan deems to be less effective.

## **Drug Price Terms**

**Average Manufacturer Price (AMP):** The AMP is a statutorily defined price (Social Security Act [SSA] §1927) used in the state-federal Medicaid program. The AMP is the average price paid by wholesalers for drugs distributed to the retail class of trade, net of customary prompt pay discounts and other adjustments. Manufacturers are required to report AMP data for Medicaid-covered drugs each quarter under the Medicaid drug rebate program.

**Average Sales Price (ASP):** The ASP is a statutorily defined price (SSA §1847A) used to set payment rates for Medicare Part B physician-administered drugs. For most separately payable Part B drugs, Medicare pays practitioners the product's ASP plus a 6% add-on payment. Drug manufacturers calculate each drug's ASP from quarterly sales of a drug to most U.S. purchasers, net of price concessions, such as rebates and discounts, and other adjustments, divided by the total units of the drug sold to those purchasers in the quarter.

**Average Wholesale Price (AWP):** The AWP is a market-derived approximation of a drug's list price. The AWP is available from private publishers, such as Red Book and Medispan. It is not a regulated price measure.

**Medicare Part D Negotiated Price:** Under law, Part D sponsors must provide beneficiaries with access to negotiated prices for covered drugs at the point of sale that "take into account" any rebates, discounts, or other direct and indirect price concessions obtained by the plans (SSA §1860D-2(d)(1)(B)). According to the Centers for Medicare & Medicaid Services (CMS), the statutory language gives plan sponsors latitude to decide what price concessions to include in the negotiated price at the point of sale. Plan sponsors may instead choose to pass price concessions through to beneficiaries outside of negotiated prices, such as in the form of lower monthly plan premiums. However, all aggregate price concessions that plan sponsors obtain for Part D covered drugs—whether included in the negotiated price at the point of sale or passed on to enrollees outside the negotiated price—must be reported to CMS for use in annual plan payment and administration (see 42 C.F.R. §423.100).<sup>73</sup> Currently, most Part D plans do not count the value of

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<sup>73</sup> Under final regulations published in July 2022, beginning in 2024, Part D plans must pass on fees imposed on network pharmacies, which have the effect of reducing the cost for dispensing a drug, as part of the negotiated price at

rebates and pharmacy fees in the negotiated price at the point of sale, making it more akin to a list price than a net price. Under final rules published in May 2022, starting in 2024, Part D plan sponsors must pass on fees imposed on network pharmacies (which reduce the cost of dispensing a drug) as part of the negotiated price at the point of sale.

**Wholesale Acquisition Cost (WAC):** WAC, as defined in Medicare statute (SSA §1847A(c)(6)(B)), is a drug manufacturer’s most recent monthly list price to U.S. wholesalers or direct purchasers, excluding prompt payment discounts or other discounts, rebates, or price reductions, as published in drug pricing compendia. As a list or published price, WAC usually exceeds ASP. Generally, the Medicare Part B drug payment methodology in effect November 1, 2003 was 95% of the AWP.

**Nonfederal AMP:** The nonfederal AMP is defined in statute as “the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during the period” (38 U.S.C. §8126(h)(5)). The nonfederal AMP does not take into account any prices paid by the federal government or any prices found by the Secretary to be merely nominal in amount. All manufacturers must calculate and report the nonfederal AMP to the Secretary of Veterans Affairs to be used to calculate the Federal Ceiling Price.

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the point of sale. Centers for Medicare & Medicaid Services, “Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency,” 87 Federal Register 27883, May 9, 2022, at <https://www.federalregister.gov/d/2022-09375/page-27833>.

## Appendix B. Abbreviations Used in the Report

This report uses a number of abbreviations, listed in the table below.

**Table B-1. Abbreviations Used in Report**

| Acronym  | Meaning                                              |
|----------|------------------------------------------------------|
| ABP      | Alternative Benefit Plan                             |
| ACA      | Affordable Care Act                                  |
| ACIP     | Advisory Committee on Immunization Practices         |
| AMP      | Average Manufacturer Price                           |
| ARPA     | American Rescue Plan Act                             |
| ASP      | Average Sales Price                                  |
| AWP      | Average Wholesale Price                              |
| BLA      | Biological License Application                       |
| CBO      | Congressional Budget Office                          |
| CHIP     | State Children's Health Insurance Programs           |
| CMP      | Civil Monetary Penalty                               |
| CMS      | Centers for Medicare & Medicaid Services             |
| CPI-U    | Consumer Price Index for all Urban Consumers         |
| DME      | Durable Medical Equipment                            |
| EGWP     | Employer Group Waiver Plan                           |
| FDA      | Food and Drug Administration                         |
| FMAP     | Federal Medical Assistance Percentage                |
| FPL      | Federal Poverty Level                                |
| HDHP     | High Deductible Health Plan                          |
| HELP     | Health, Education, Labor, and Pensions               |
| HHS      | Health and Human Services                            |
| HI       | Hospital Insurance                                   |
| HSA      | Health Savings Account                               |
| HSA-HDHP | Health Savings Account – High Deductible Health Plan |
| IRA      | Inflation Reduction Act                              |
| IRC      | Internal Revenue Code                                |
| LIS      | Low Income Subsidy                                   |
| MA       | Medicare Advantage                                   |
| MA-PD    | Medicare Advantage plans with a Part D component     |
| MedPAC   | Medicare Payment Advisory Commission                 |
| MFP      | Maximum Fair Price                                   |
| MMA      | Medicare Modernization Act                           |
| OIG      | Office of Inspector General                          |

|      |                                 |
|------|---------------------------------|
| PAD  | Physician Administered Drug     |
| PBM  | Pharmacy Benefit Managers       |
| PDP  | Prescription Drug Plans         |
| PHSA | Public Health Service Act       |
| PTC  | Premium Tax Credit              |
| SMI  | Supplementary Medical Insurance |
| SSA  | Social Security Act             |
| WAC  | Wholesale Acquisition Cost      |

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## Acknowledgments

CRS Research Assistant John Gorman assisted with this report.

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