



**Congressional
Research Service**

Informing the legislative debate since 1914

Medicare Part D Prescription Drug Benefit

Updated November 14, 2023

Congressional Research Service

<https://crsreports.congress.gov>

R40611



R40611

November 14, 2023

Suzanne M. Kirchhoff
Analyst in Health Care
Financing

Medicare Part D Prescription Drug Benefit

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; P.L. 108-173) established a voluntary, outpatient prescription drug benefit under Medicare Part D, effective January 1, 2006. Medicare Part D provides coverage through private prescription drug plans (PDPs) that offer only drug coverage, or through Medicare Advantage (MA) prescription drug (MA-PD) plans that offer coverage as part of broader, managed care plans. 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.

At a minimum, Medicare drug plans must offer a legislatively specified “standard” package of benefits or alternative coverage that is actuarially equivalent to a standard plan. Plans also may offer enhanced benefits. Although all plans must meet certain minimum requirements, there can be significant differences among offerings in terms of benefit design, specific drugs included in formularies (i.e., lists of covered drugs), cost sharing for particular drugs, or the level of monthly premiums.

In general, beneficiaries can enroll in a plan, or change plan enrollment, when they first become eligible for Medicare or during open enrollment periods each October 15 through December 7. Beneficiaries also have some options to change enrollment during a plan year due to special circumstances. Because sponsors are allowed to change plan offerings from year to year, beneficiaries annually face the need for careful review of their choices to select the plans that best meet their needs.

A key element of the Part D program is enhanced coverage for low-income individuals. Medicare beneficiaries with incomes up to 150% of the federal poverty level (FPL) and assets below set limits are eligible for extra assistance with Medicare Part D premiums and cost sharing. Individuals enrolled in both Medicare and Medicaid (so-called *dual eligibles*) and certain other low-income beneficiaries are automatically enrolled in no-premium plans, which are Part D plans that have premiums at or below specified levels.

Of the 65 million Medicare beneficiaries in 2022 who were eligible for Part D, 49.8 million (about 77%) were enrolled in a Part D plan and another 1.3 million (about 2%) had prescription drug coverage through a former employer that received a Part D subsidy for a portion of the coverage. Of the remaining roughly 21% of Medicare beneficiaries, nearly half had drug coverage as generous as Part D through another source, while about 12% of all beneficiaries had either less generous coverage than Part D or no drug coverage at all.

Total Part D expenditures were approximately \$125.7 billion in 2022. Spending is expected to moderate in the next 10 years due in part to a redesign of the Part D benefit under the 2022 law known as the Inflation Reduction Act (IRA; P.L. 117-169). The 2022 IRA phases in a number of significant Part D changes from 2023 to 2025, including an annual out-of-pocket cap on Part D enrollee cost sharing, enhanced low-income subsidies, a \$35 monthly cap on insulin cost sharing, and an annual limit on premium increases from 2024 to 2029. The law also imposes a penalty on drug manufacturers that takes the form of a rebate to Medicare if drug manufacturers raise prices of most Part D-covered drugs above an annual inflation measure. These rebates are deposited in the Federal Supplementary Medical Insurance Trust Fund that funds Part D. The law requires the Secretary of Health and Human Services (HHS) to negotiate the prices of certain single-source drugs with the highest total expenditures under Medicare Part D.

Contents

Overview	1
Eligibility for Medicare Part D.....	2
Eligibility for Low-Income Assistance	3
Full-Subsidy-Eligible Individuals	4
Partial-Subsidy-Eligible Individuals	6
Changes in LIS Status.....	7
Medicare Part D Enrollment Periods	7
Initial Enrollment Period.....	7
Annual Open Enrollment Period.....	8
Special Enrollment Periods.....	8
Late Enrollment Penalty.....	8
Plan Selection.....	9
Low-Quality Plans	10
Plan Marketing.....	11
Enrollment Process.....	11
LIS Enrollment.....	12
Auto-Enrollment	12
Facilitated Enrollment.....	13
Reassignment of Certain LIS Beneficiaries	13
Part D Benefit Structure	13
Qualified Drug Coverage	14
Standard Prescription Drug Coverage.....	14
Actuarially Equivalent and Enhanced Plans	15
The Coverage Gap.....	16
True Out-of-Pocket Costs.....	17
IRA Changes to the Medicare Part D Benefit in 2023	19
Part D Standard Benefit For 2024	19
Medicare Part D Standard Benefit in 2025	21
Part D Premiums	23
Premium Surcharge for Higher-Income Enrollees	24
IRA Premium Stabilization Program.....	25
Low-Income Subsidies	26
Premium Assistance	26
Full-Subsidy-Eligible Individuals in 2023	26
Partial-Subsidy-Eligible Individuals	27
Cost-Sharing Subsidies	27
LIS Changes Starting in 2024	28
Employer Subsidies for Retiree Drug Coverage	29
Retiree Drug Subsidy	29
Employer Group Waiver Plans.....	30
Formulary Requirements.....	31
Drugs Covered by Other Parts of Medicare	32
Formularies	32
Formulary Categories and Classes.....	33
Six Classes of Clinical Concern.....	33

Vaccines	34
Plan-Year Formulary Changes	35
Transition Policies.....	36
Drug Utilization Management Programs.....	36
Tiered Formularies	36
Other Drug Utilization Controls	37
Part D Opioid Overutilization Monitoring	38
Medication Therapy Management	38
Part D Plans: Payment and Participation.....	39
Approval of PDPs	39
Noninterference Provision	40
Plan Availability	40
Availability of Low-Income Plans	40
Plan Payments	41
Direct Subsidies	41
Reinsurance Subsidies	41
Beneficiary Cost Sharing/Direct and Indirect Remuneration	42
Risk Corridor Payments.....	43
Reconciliation	44
Reduction of Part D Plan Payments Under Sequestration	45
Expected Shifts in Part D Sponsor Reimbursement Due to the IRA	45
Pharmacy Access and Payment	45
Any Willing Pharmacy	45
Preferred Pharmacy.....	46
Retail Pharmacy Access	46
Mail-Order Pharmacy Access	47
Specialty Pharmacy Access.....	47
Long-Term Care Pharmacy Access.....	47
Home Infusion Pharmacy Access.....	47
Out-of-Network Access.....	48
Payments to Pharmacies.....	48
Coverage Determinations, Appeals, and Grievances.....	49
Coverage Determination	50
Appeals.....	51
Redetermination.....	51
Reconsideration by an Independent Review Entity	51
Additional Levels of Appeal	52
Standard Hearing	52
Grievances.....	52
Quality of Care Complaints	53
Program Spending and Financing	53
Expenditures.....	53
Revenues	53
Beneficiary Premiums.....	54
General Revenues	54
State Contributions	55
Estimated Future Part D Expenditures	55

Figures

Figure 1. Overview of 2023 Low-Income Subsidy (LIS)	6
Figure 2. 2023 Standard Medicare Prescription Drug Benefit	15
Figure 3. 2024 Medicare Part D Standard Benefit	19
Figure 4. 2025 Medicare Part D Standard Benefit	21
Figure 5. Annual Part D Base Beneficiary Monthly Premium	23

Tables

Table 1. Total Medicare Beneficiaries with Prescription Drug Coverage, 2022	3
Table 2. Medicare Part D Low-Income Subsidy Enrollment	4
Table 3. 2023 Monthly Medicare Part D High-Income Surcharge.....	24
Table 4. Sliding-Scale Premium for Partial-Subsidy-Eligible Individuals	27
Table 5. Part D Standard Benefit Cost Sharing, 2023	28
Table 6. Part D Standard Benefit Cost Sharing, 2024	29
Table 7. Plan Liability Under Part D Risk Corridor Provisions	43
Table 8. Medicare Part D Risk Corridor Payments	44
Table 9. Statement of Operations of Part D Account, CY2022	54
Table 10. Historical and Projected Growth in Part D Benefits.....	55

Appendixes

Appendix A. Drug Rebates and PBMs in Medicare Part D.....	57
Appendix B. IRA Drug Price Negotiation in Part D	60

Contacts

Author Information.....	61
-------------------------	----

Overview

On January 1, 2023, the Medicare outpatient prescription drug benefit (Medicare Part D) began its 18th year of operation. Congress created the voluntary Part D program in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA; P.L. 108-173), effective January 1, 2006. The law also made Part D the primary source of drug coverage for individuals covered under both Medicare and Medicaid (also called *dual eligibles*). Part D has been modified by a series of statutes since its enactment including, most recently, the 2022 budget reconciliation measure referred to as the Inflation Reduction Act of 2022 (IRA; P.L. 117-169). The IRA includes some of the most significant changes to the Part D benefit since the program was created, including an annual cap on enrollee out-of-pocket spending, beginning in 2024. (See “Standard Benefit” and “**Appendix B**. IRA Drug Price Negotiation in Part D.”)

Part D coverage is provided through stand-alone prescription drug plans (PDPs), which offer only drug coverage, or through Medicare Advantage (MA) prescription drug (MA-PD) plans, which offer drug coverage as part of a broader Medicare Part C managed care benefit that also includes medical services. Commercial insurers that offer Part D plans bear some financial risk, although federal subsidies cover most program costs in an effort to encourage participation and keep benefits affordable. All Part D plans must meet certain minimum requirements, but there are significant variations among plans in terms of premiums and benefit design, including differences in drug formularies (i.e., lists of covered drugs) and cost sharing for particular drugs.

Most Part D plans are individual products, but a number of employers and unions offer retirees Part D benefits through special employer group waiver plans (EGWPs). (See “Employer Group Waiver Plans.”) In addition, the MMA provides separate subsidies for employers that agree to provide retiree drug benefits outside of Medicare, as an incentive for employers to continue offering retiree health benefits. (See “Retiree Drug Subsidy.”)

The Part D program provides additional subsidies to low-income enrollees. Individuals with incomes up to 150% of the federal poverty level (FPL) and limited assets are eligible for a low-income subsidy (LIS) that reduces their out-of-pocket spending by paying for all, or some, of the Part D monthly premium and annual deductible and that limits co-payments or coinsurance.¹ An estimated 14.2 million beneficiaries received the LIS in 2023.²

¹ The federal poverty guidelines, referred to as the *federal poverty level* (FPL), are issued annually by the Department of Health and Human Services (HHS) for administrative purposes such as determining eligibility for certain federal programs. See HHS, “Poverty Guidelines,” at <https://aspe.hhs.gov/poverty-guidelines>.

² Centers for Medicare & Medicaid Services (CMS), *The 2023 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, March 31, 2023, Table IV.B7, p. 147, available at <https://www.cms.gov/oact/tr>. (Hereinafter, 2023 Medicare Trustees Report.)

Monthly enrollment numbers are available for 2023.³ For 2023, a total of 801 PDPs were offered nationwide, a slight increase from 2022. On average, Medicare beneficiaries have 24 PDPs and 35 MA-PD plans to choose from in their geographic area.⁴

During the next several years, the Centers for Medicare & Medicaid Services (CMS) is to phase in wide-ranging changes to Part D, as required by the IRA. Effective in 2023, the IRA eliminated enrollee cost sharing for certain Part D vaccines and set a \$35 cap on enrollee cost sharing for insulin.⁵ Effective in 2024, the IRA caps annual enrollee out-of-pocket spending at \$8,000. In 2025, the IRA reduces the Part D out-of-pocket spending cap to \$2,000 (and then adjusts the cap based on drug price inflation in subsequent years). The IRA also expands LISs (effective in 2024) and limits annual premium increases from 2025 to 2029, among other changes.⁶

This report provides information about the current Part D benefit structure and describes the IRA changes to the Part D standard benefit that are to be phased in through 2025. For a more detailed description of the IRA, including information about provisions (1) requiring the Secretary of the Department of Health and Human Services to negotiate prices for certain Part D drugs and (2) requiring that manufacturers pay mandatory rebates to CMS if they increase Part D drug prices faster than consumer inflation, see CRS Report R47396, *Health Care Provisions of the Budget Reconciliation Measure P.L. 117-169*.⁷

Eligibility for Medicare Part D

In general, anyone who is entitled to Medicare Part A and/or enrolled in Part B is eligible to enroll in a Medicare Part D drug plan. In addition, an individual must be a U.S. citizen or qualified alien and must permanently reside within one of the 34 designated PDP regions in the United States; anyone who is living abroad or is incarcerated is not eligible.⁸

³ CMS, “Monthly Contract Summary Report,” August 2023, <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenrolldata/monthly/contract-summary-2023-10>. Figures are based on enrollment data for the Part D component of Medicare plans including Medicare Advantage prescription drug (MA-PD) plans, the PACE (Program of All-inclusive Care for the Elderly), 1876 Cost Plans, and certain employer/union only group plans (EGWPS). Figures are updated monthly and are the most recent available, so may vary from projected enrollment figures from other sources. As of October 2023, about 52 million Medicare beneficiaries were enrolled in Part D plans. Of that total, about 22.5 million were in prescription drug plans (PDPs), about 29 million were in MA-PD plans, and about 408,000 were in other types of plans.

⁴ Juliette Cubanski and Anthony Damico, “Medicare Part D: A First Look at Prescription Drug Plans in 2023,” Kaiser Family Foundation, November 10, 2022, at <https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-medicare-drug-plans-in-2023/>.

⁵ See CRS In Focus IF12203, *Selected Health Provisions of the Inflation Reduction Act*.

⁶ The 2022 budget reconciliation measure referred to as the Inflation Reduction Act of 2022 (IRA; P.L. 117-169), requires the HHS Secretary to negotiate prices for high-spending drugs in Medicare Part D and in Medicare Part B, which covers physician-administered prescription products. The first negotiated prices take effect in 2026. For more information on price negotiation, see CRS Report R47396, *Health Care Provisions of the Budget Reconciliation Measure P.L. 117-169*.

⁷ The rebates are deposited in the Federal Supplementary Medical Insurance Trust Fund, which helps fund the Part D program.

⁸ In February 2015, CMS issued final rules for the Medicare Advantage and Part D programs for calendar year (CY) 2016. Under the rules, going forward, to be eligible for Medicare prescription drug benefits a potential enrollee had to be a U.S. citizen or qualified alien who is lawfully present in the United States. The rules also require involuntary disenrollment of individuals from Part D plans when they lose eligibility due to unlawful presence status. CMS, “CMS Finalizes Program Changes for Medicare Advantage and Prescription Drug Benefit Programs for Contract Year 2016,” February 6, 2015, at <https://www.cms.gov/newsroom/fact-sheets/cms-finalizes-program-changes-medicare-advantage-and-prescription-drug-benefit-programs-contract>.

For most people, joining Part D is voluntary, although Medicare-Medicaid dual-eligible beneficiaries are automatically enrolled. Medicare beneficiaries cannot be turned down for Part D coverage due to preexisting health conditions or high utilization of prescription drugs.

Of the 65 million Medicare beneficiaries who were eligible for Part D, in 2022, 49.8 million (about 77%) were enrolled in a Part D plan and another 1.3 million (about 2%) had prescription drug coverage through a former employer that received a Part D subsidy for a portion of the coverage. Of the remaining roughly 21% of Medicare beneficiaries, nearly 10% of total beneficiaries had drug coverage as generous as Part D through another source, such as the Federal Employees Health Benefits program (FEHB), TRICARE coverage for the military, or private coverage; about 12% of beneficiaries had either less generous coverage than Part D or no drug coverage at all.⁹ (See **Table 1.**)

Table 1. Total Medicare Beneficiaries with Prescription Drug Coverage, 2022

Description	Number of Medicare Beneficiaries (in millions)	Percentage of Eligible Beneficiaries
Medicare Beneficiaries Eligible for Part D	65.0	100.0%
Medicare Part D	49.8	77%
<i>Stand-Alone PDP</i>	23.3	47%
<i>MA with Drug Coverage</i>	26.5	53%
Medicare Retiree Drug Subsidy (RDS)	1.3	2%
Other Creditable Drug Coverage	6.5	10%
Total Beneficiaries with Drug Coverage	57.6	89%
Beneficiaries Without Equivalent Coverage	7.4	12%

Source: Based on Medicare Payment Advisory Commission (MedPAC), *Report to Congress, Medicare Payment Policy*, March 2023, Table 12-1 and report text. Based on monthly Part D enrollment data.

Note: Totals may not add due to rounding.

Eligibility for Low-Income Assistance

Beneficiaries with limited incomes and resources may qualify for assistance with Part D premiums, cost sharing, and other out-of-pocket expenses. In 2023, a forecast estimated that 14.2 million Medicare beneficiaries are expected to receive LISs. (See **Table 2** below.) In addition to financial assistance, LIS beneficiaries have other added benefits, such as the right to change plans more frequently than other Part D enrollees.

For 2023, there are two categories of LIS beneficiaries: (1) those with the lowest income and assets who are eligible for the full LIS and (2) those with slightly higher income and assets who qualify for a partial LIS. Individuals may be automatically deemed eligible for the full LIS if they are dually eligible for Medicaid.

The IRA requires that the two LIS categories be merged into one LIS classification starting in 2024. The new LIS program will provide the more generous benefits of the previous full LIS and will allow individuals to qualify based on the higher income and resource allowances previously used to determine the partial LIS. (See “Low-Income Subsidies.”)

⁹ Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Medicare Payment Policy*, March 15, 2023, Chapter 12, Table 12-1, p. 394, <https://www.medpac.gov/document/march-2023-report-to-the-congress-medicare-payment-policy/>.

Table 2. Medicare Part D Low-Income Subsidy Enrollment
(in millions)

Year	Medicaid, Full-Benefit Dual Eligible	Other, with Full Subsidy	Other, with Partial Subsidy	Total
2006	5.7	2.3	0.2	8.3
2007	5.9	3.0	0.3	9.2
2008	6.3	3.2	0.3	9.7
2009	6.4	3.3	0.3	10.0
2013	7.2	4.0	0.3	11.5
2014	7.4	4.1	0.3	11.8
2015	7.6	4.2	0.3	12.1
2016	7.8	4.3	0.3	12.4
2017	8.0	4.4	0.3	12.7
2018	8.1	4.5	0.3	12.9
2019	8.2	4.5	0.3	13.1
2020	8.2	4.7	0.3	13.2
2021	8.3	4.7	0.3	13.2
2022	8.7	4.7	0.2	13.6
2023	9.1	4.8	0.2	14.2

Source: Centers for Medicare & Medicaid Services (CMS), *The 2023 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, March 31, 2023, Table IV.B7, available at <https://www.cms.gov/oact/tr>.

Notes: Figures are for calendar years. Totals may not add due to rounding.

Full-Subsidy-Eligible Individuals

Certain groups of Medicare beneficiaries automatically qualify and are *deemed eligible* for the full LIS. The *full-benefit dual eligibles* who qualify for Medicaid benefits based on income and assets are automatically eligible for the full Part D LIS. Additionally, those who receive Medicare premium and/or cost-sharing assistance from Medicaid through the Medicare Savings Program (MSP),¹⁰ plus those eligible for Supplemental Security Income (SSI) cash assistance,¹¹ are automatically deemed eligible for full LIS. These three categories include all eligible persons who (1) have incomes below 135% of the FPL, or \$19,683 for an individual and \$26,622 for a couple in 2023;¹² and (2) have resources below \$9,090 for an individual and \$16,630 for a couple in

¹⁰ The Medicare Savings Program includes the Qualified Medicare Beneficiary program (QMB), Specified Low-Income Medicare Beneficiary program (SLMB), and Qualifying Individual program (QI). These programs help Medicare beneficiaries of modest means pay all or some of Medicare's cost-sharing amounts (i.e., premiums, deductibles, and co-payments). To qualify, an individual must be eligible for Medicare and meet certain annual income limits.

¹¹ Supplemental Security Income (SSI) is a federal income supplement program funded by general tax revenues (not Social Security taxes). It is designed to help aged, blind, and disabled people who have little or no income, and it provides cash to meet basic needs for food, clothing, and shelter.

¹² Social Security benefits, veterans' benefits, public and private pensions, annuities, and in-kind support are counted as (continued...)

2023.¹³ The limits are increased annually by the percentage increase in the Consumer Price Index for urban consumers (CPI-U) as of September of the previous year.¹⁴ (See **Figure 1**.)

CMS deems individuals automatically eligible for the LIS effective as of the first day of the month that they attain qualifying status (e.g., become eligible for Medicaid or SSI). The end date is, at a minimum, through the end of the calendar year within which the individual becomes eligible. Beneficiaries who are deemed LIS-eligible for any month during the period of July through December of one year are deemed eligible through the end of the following calendar year. CMS changes an individual's deemed status in mid-year only when such a change qualifies the beneficiary for lower cost sharing.

Eligibility for the LIS is not always continuous from year to year. For example, LIS beneficiaries who lose eligibility for Medicaid or SSI during a year are not automatically qualified to receive the LIS the next year. Each September, CMS notifies such individuals that their LIS-deemed status will end on December 31 of that year. Such individuals may reapply for the LIS and might qualify for the LIS through the application process. (See "LIS Enrollment.")

At the end of each plan year, CMS reassigns LIS beneficiaries to a new Part D plan if their Part D plan has terminated. CMS also reassigns full LIS beneficiaries who are enrolled in PDPs if their plan raises its monthly premiums to a level above a set LIS benchmark premium for the plan region.¹⁵ (See "Reassignment of Certain LIS Beneficiaries.")

income. HHS sets separate poverty levels for Alaska and Hawaii. See Social Security Administration (SSA) Program Operations Manual, "HI 03001.020 Eligibility for Extra Help (Prescription Drug Low-Income Subsidy)," at <https://secure.ssa.gov/poms.nsf/lnx/0603001020>. See also SSA, "HI 03001.005 Medicare Part D Extra Help (Low-Income Subsidy or LIS)," at <https://secure.ssa.gov/poms.nsf/lnx/0603001005>; and SSA, "Understanding the *Extra Help* with Your Medicare Prescription Drug Plan," at <https://www.ssa.gov/pubs/EN-05-10508.pdf>. HI 03001.020 Eligibility for Extra Help (Prescription Drug Low-Income Subsidy), <https://secure.ssa.gov/poms.nsf/lnx/0603001020>.

¹³ In addition, program resource limits provide for a \$1,500 burial allowance. SSA, "HI 03030.025, Resource Limits for Subsidy Eligibility," at <https://secure.ssa.gov/poms.nsf/lnx/0603030025>.

¹⁴ 42 C.F.R. §423.773(b)(2). The CPI-U, published by the U.S. Department of Labor, is a measure of consumer inflation for urban consumers.

¹⁵ The low-income benchmark premium is the weighted average of monthly premiums for basic PDPs, enhanced PDPs, and MA-PD plans in a Part D region. CMS, *Medicare Part D Prescription Drug Manual*, Chapter 13, "Premium and Cost-Sharing Subsidies for Low-Income Individuals," Section 50.2.1, Rev. October 1, 2018, at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter-13-Premium-and-Cost-Sharing-Subsidies-for-Low-Income-Individuals-v09-14-2018.pdf>. See also, *Medicare Part D Prescription Drug Manual*, Chapter 3, "Eligibility, Enrollment and Disenrollment," Section 40.1.4, Rev. August 12, 2020, at <https://www.cms.gov/files/document/cy2021-pdp-enrollment-and-disenrollment-guidance.pdf>. CMS will attempt to reassign beneficiaries within the same organization wherever possible. If the organization does NOT offer another qualifying PDP, CMS would randomly reassign affected beneficiaries to other PDP sponsors that have at least one qualifying PDP in that region.

Figure 1. Overview of 2023 Low-Income Subsidy (LIS)

	Full LIS Subsidy	Partial LIS Subsidy
 Qualification criteria	Individuals are automatically deemed eligible if they receive one of the following: • Full Medicaid and Medicare benefits (Dual Eligibles) • Medicare Savings Program assistance • SSI benefits Individuals may apply and may be determined eligible if they*: • have income below 135% of FPL, and • have assets below level specified by regulation and statute. <i>*Individuals who meet these criteria may also qualify for Medicaid and SSI benefits, which would change their status to “automatically deemed.”</i>	Individuals can apply and may be determined eligible if they: • have income below 150% of FPL; and • have assets below level specified by statute and regulation.
 Data used to determine eligibility	• SSA records • State files	• SSA records (almost all states) • State files
 Potential changes during the year	• Qualification is for a full calendar year and will not change during the year. • Subsidy could change within the year, but generally only favorable changes (increases) will occur.	• Qualification may change during the year, if income or assets change. • Subsidies can increase, decrease, or terminate during the year.

Source: CRS table based on Social Security Administration (SSA) and CMS data.

Note: Beginning in 2024 there will be one LIS category. The new LIS program will provide the more generous benefits of the previous full LIS and will allow individuals to qualify based on the higher income and resource allowances previously used to determine the partial LIS.

Partial-Subsidy-Eligible Individuals

Individuals with limited incomes and resources who do not automatically qualify for the LIS may apply and have their eligibility determined by either the Social Security Administration (SSA) or their state Medicaid agency. This group includes all other persons who (1) are enrolled in a PDP or MA-PD plan; (2) have incomes below 150% of the FPL, which is \$21,870 for an individual and \$29,580 for a couple in 2023;¹⁶ and (3) have assets below \$15,160 for an individual and \$30,240 for a couple in 2023 (increased in future years by the percentage increase in the CPI-U).¹⁷

An individual who applies, and is determined eligible for the LIS, can begin receiving benefits on the first day of the month in which the application was submitted. In most cases, this means that LIS status is applied retroactively. For example, if an LIS beneficiary was enrolled in a Part D plan prior to a determination of LIS eligibility, the Part D plan sponsor must ensure that the

¹⁶ CMS, “2023 Medicare Part D Low-Income Subsidy (LIS) Income and Resource Standards,” October 25, 2022, <https://www.cms.gov/files/document/lis-memo.pdf>.

¹⁷ See SSA, “HI 03001.020 Eligibility for Extra Help (Prescription Drug Low-Income Subsidy),” at <https://secure.ssa.gov/poms.nsf/lnx/0603001020>; SSA, “HI 03001.005 Medicare Part D Extra Help (Low-Income Subsidy or LIS),” at <https://secure.ssa.gov/poms.nsf/lnx/0603001005>; and SSA, “HI 03030.025, Resource Limits for Subsidy Eligibility,” at <https://secure.ssa.gov/poms.nsf/lnx/0603030025>. See also SSA, “Understanding the Extra Help with Your Medicare Prescription Drug Plan,” at <https://www.ssa.gov/pubs/EN-05-10508.pdf>. Also see HHS, “Poverty Guidelines for 2023,” <https://aspe.hhs.gov/topics/poverty-economic-mobility/poverty-guidelines>.

beneficiary is reimbursed for any premiums or cost sharing that should have been covered by the subsidy. If a person was not already eligible for Medicare, the LIS takes effect on the first day of the month when his or her Medicare eligibility begins.¹⁸

Initial LIS eligibility determinations are for no longer than 12 months. If the SSA or a state Medicaid agency later decides that an individual is no longer eligible for the LIS, that same entity also decides when the LIS benefits end. The end date is always the last day of a calendar month, though it may occur in any month of the year.

Changes in LIS Status

Throughout each plan year, CMS uses SSA data and state files of individuals dually eligible for Medicare and Medicaid to initiate the LIS eligibility process for new recipients and to look for changes in LIS eligibility status for current LIS beneficiaries.¹⁹ Part D law allows forbearance in some instances. For example, in the case of a death, the surviving spouse of an LIS-eligible couple receives a grace period for a redetermination of benefits.²⁰

Medicare Part D Enrollment Periods

A Medicare beneficiary who is signing up for Part D for the first time may do so in one of three specified enrollment periods,²¹ depending on the individual's circumstances:

- Initial Enrollment Period for Part D;
- Annual Open Enrollment Period (or Annual Coordinated Election Period, AEP);
or
- Special Enrollment Period (SEP).

Individuals who qualify for the LIS may enroll at any time.

Initial Enrollment Period

The initial enrollment period is the time during which an individual is first eligible to enroll in a Part D plan.²² Beneficiaries not yet enrolled in Medicare may join a drug plan at any time during their seven-month initial Medicare enrollment period. The Part D initial enrollment period is the same as the initial enrollment period for Medicare Part B.²³ Coverage for new enrollees begins on

¹⁸ CMS, *Medicare Part D Prescription Drug Manual*, Chapter 13, "Premium and Cost-Sharing Subsidies for Low-Income Individuals," Rev. October 1, 2018, at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter-13-Premium-and-Cost-Sharing-Subsidies-for-Low-Income-Individuals-v09-14-2018.pdf>.

¹⁹ CMS Informational Bulletin, "Annual Redetermination of Medicare Part D Low-Income Subsidy Deemed Status (Re-deeming)," July 25, 2017, available at <https://www.hhs.gov/guidance/document/annual-re-determination-medicare-part-d-low-income-subsidy-deemed-status-re-deeming-0>.

²⁰ The extension is for one year from the date upon which the couple's next scheduled redetermination would have occurred. CMS, *Medicare Part D Prescription Drug Manual*, Chapter 13, "Premium and Cost-Sharing Subsidies for Low-Income Individuals," Section 40, Rev. October 1, 2018, at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter-13-Premium-and-Cost-Sharing-Subsidies-for-Low-Income-Individuals-v09-14-2018.pdf>.

²¹ CMS, "Understanding Medicare Part C & D Enrollment Periods," January 2023, at <https://www.medicare.gov/Pubs/pdf/11219-Understanding-Medicare-Part-C-D.pdf>.

²² CMS, *Medicare & You 2023*, Section 1, at <https://www.medicare.gov/pub/medicare-you-handbook>.

²³ CRS Report R40082, *Medicare Part B: Enrollment and Premiums*.

the first day of the month following the month of enrollment, but no earlier than the first month they are entitled to Medicare.

Individuals who become eligible for Medicare but have *creditable coverage*, which is prescription drug coverage that CMS estimates will provide at least the same level of benefits as the Part D standard prescription drug benefit, may choose not to sign up for Part D during their initial enrollment period. Sources of possible creditable coverage include some employer-based prescription drug coverage, including FEHB; qualified State Pharmaceutical Assistance programs (SPAPs); and military-related coverage (e.g., VA, TRICARE). However, these individuals could face a late enrollment penalty if they let their creditable coverage lapse before enrolling in Part D. (See “Late Enrollment Penalty.”)

Annual Open Enrollment Period

In general, an individual who does not sign up for Part D during his or her initial enrollment period may enroll only during the annual open enrollment period, held from October 15 to December 7 each year. Coverage then begins the following January 1. Beneficiaries already enrolled in Part D may change plans during the annual open enrollment period.

Beneficiaries may want to change plans for a variety of reasons, including changes in their health status and prescription drug needs or in response to plan modifications. Generally, sponsors make changes to plan benefits effective at the start of each calendar year. After the open enrollment period closes, most beneficiaries are locked into their Part D plans for the upcoming benefit year.

Special Enrollment Periods

There are limited occasions outside the annual open enrollment period when an individual may enroll in, or disenroll from, a Part D plan or switch from one Part D plan to another. In general, special enrollment periods (SEPs) are open to individuals who (1) move to a new geographic area,²⁴ (2) involuntarily lose creditable coverage, (3) receive inadequate information about their creditable coverage status, (4) are subject to a federal error, or (5) are enrolled in a PDP that has failed or has been terminated.²⁵

Late Enrollment Penalty

A Part D late enrollment penalty is assessed on persons who go without creditable drug coverage for 63 continuous days or more after the close of their initial enrollment period, and then sign up for Part D. The penalty is intended to encourage wider enrollment and prevent adverse selection, which can occur when healthy people put off buying insurance while those with a real or perceived need immediately enroll. If Part D enrollees are mainly those who are ill or have higher prescription drug spending, per capita program costs can rise. Higher premiums and/or cost sharing, in turn, may cause other enrollees (presumably healthier, less costly ones) to end coverage. Over time, if more persons drop out, program costs could become prohibitive.

²⁴ This includes being released from jail or out of an institution.

²⁵ CMS, “Understanding Medicare Part C & D Enrollment Periods,” January 2023, at <https://www.medicare.gov/Pubs/pdf/11219-Understanding-Medicare-Part-C-D.pdf>. The publication includes other examples of SEPs. See also CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 3, “Eligibility, Enrollment and Disenrollment,” Section 30.3, Rev. August 12, 2020, at <https://www.cms.gov/files/document/cy2021-pdp-enrollment-and-disenrollment-guidance.pdf>.

The Part D late enrollment penalty is based on the number of months an individual does not have creditable coverage and is applied to premiums on a monthly basis thereafter.²⁶ The penalty is calculated by multiplying 1% of the national base premium (\$32.74 per month for 2023)²⁷ by the number of full months an individual has been eligible but has gone without coverage. The final amount is rounded to the nearest \$0.10. For example, if a beneficiary was eligible for Part D in June 2020 but did not sign up until the 2023 open enrollment period, (with coverage effective January 2023), and did not have creditable coverage during the 30-month interim period, the individual would pay an additional \$9.80 per month.²⁸

The late enrollment penalty is applied permanently to Part D premiums. Because the national base premium is recalculated annually, and the penalty is based on the base premium, the penalty amount would increase in subsequent years if the base premium rises. Generally, LIS beneficiaries are not subject to the late enrollment penalty.

Plan Selection

Sponsors may alter a plan benefit package at the beginning of a new program year, including changing the mix of drugs in a formulary and/or modifying required cost sharing for certain drugs. Sponsors must mail an Annual Notice of Change (ANOC) to plan enrollees, to be delivered by September 30. The document describes any modifications to the plan's premiums, drug coverage, cost sharing, and other features for the coming benefit year. The delivery deadline is designed to ensure that beneficiaries have at least two weeks to review the information prior to October 15, the first day of the annual enrollment period.

Sponsors are required to send plan enrollees other enrollment-related materials and information such as the Summary of Benefits and Evidence of Coverage documents.²⁹ These documents offer information about a plan's formulary, general utilization management and pricing policies, information on beneficiary rights, and other information.

Each year, Medicare beneficiaries have an opportunity to review the cost of their current drug and health plans, (if in MA) including premiums, co-payments, and deductibles, and compare the cost and coverage to other plans in their area. Additionally, beneficiaries can examine whether plans have price tiers that increase or decrease cost sharing for the drugs they use, whether the plans offer preferred pharmacy options, and what utilization management requirements the plans impose for drugs, such as prior authorization. (See "Drug Utilization Management Programs.")

CMS posts information on Medicare.gov to help beneficiaries compare Part D plan information. Beneficiaries, and persons assisting them, can also use the Medicare drug plan finder to search for

²⁶ The late enrollment penalty is calculated based on the national base beneficiary premium, not the premium of the enrollee's plan. Therefore, the penalty is billed to an applicable enrollee even if the enrollee is in a Part D plan with a \$0 premium.

²⁷ CMS, "Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information," July 29, 2022, at <https://www.cms.gov/files/document/july-29-2022-parts-c-d-announcement-pdf.pdf>.

²⁸ CMS, "Part D Late Enrollment Penalty?," at <http://www.medicare.gov/part-d/costs/penalty/part-d-late-enrollment-penalty.html>. (To calculate, $1\% \times 30$ months equals 0.30, and $\$32.74 \times 0.30$ equals \$9.822. The amount is then rounded to \$9.80.)

²⁹ Starting in 2019, the time frame for delivery of the annual Evidence of Coverage (EOC) information was moved to the first day of the Annual Election Period (AEP), rather than fifteen days prior to that date. In addition, Part D plans were allowed to deliver more documents, including the EOC, by notifying enrollees that the documents have been posted on the Internet. Enrollees have the right to request hard copies. CMS, "Medicare Program: Contract Year 2019 Policy and Technical Changes to Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, Medicare Prescription Drug Benefit Programs, and the PACE Program," 83 *Federal Register* 16440, April 16, 2018, p. 16621; at <https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf>.

information on individual drugs.³⁰ After a beneficiary enters information into the plan finder regarding prescribed medications, the dosages, and specific pharmacy to be used, the plan finder displays applicable Part D plans in the area. The plan finder also provides information on quality ratings to make it easier to compare plans based on cost, quality, and performance ratings.³¹ CMS sends annual notices to beneficiaries in low-quality plans encouraging them to look at other, higher rated plans. (See “Low-Quality Plans.”)

Information on plan availability and characteristics can be obtained from a number of additional sources, including the Medicare toll-free information number (1-800-MEDICARE), State Health Insurance Assistance Programs (SHIPs),³² and other local organizations.

Low-Quality Plans

CMS uses a star-rating system to assess the quality of Part D plans. MA-PD plan sponsors are rated on up to 40 quality and performance measures, while PDP sponsors are assessed on up to 12 measures.³³ Plans are ranked on a scale of one to five stars, with five stars considered excellent. Part D sponsors must provide star rating information to beneficiaries through a standard document distributed with enrollment information and prominently posted on plan websites.

CMS has determined that three stars is the lowest acceptable quality rating for a plan. Plans must display a special icon if they have an aggregate star rating of 2.5 or lower for three years of data. Plans with star ratings of less than three stars for three consecutive years may be terminated by CMS. In addition, CMS may disable the online enrollment function for plans with a low-rating icon, and beneficiaries would have to contact the plan directly if they want to enroll.³⁴ Plans that receive five-star ratings may display a special icon recognizing them as high-performing plans. All Part D enrollees qualify for a special enrollment period during which they can switch from their current plan to a five-star plan, provided they meet other enrollment requirements.³⁵

³⁰ Medicare Plan Finder, at <http://www.medicare.gov/find-a-plan/questions/home.aspx>.

³¹ The plans are rated on how well they perform in different categories, including (1) drug plan customer service; (2) member complaints and number of beneficiaries staying with the same drug plan; (3) member satisfaction with drug plans; and (4) drug pricing and patient safety, including how often drug plans update their prices and formulary information on the Medicare website and how similar a drug plan’s estimated prices on the Medicare website are to prices members pay at the pharmacy.

³² SHIPs are state-based programs that use community-based networks to provide Medicare beneficiaries with local personalized assistance on a wide variety of Medicare and health insurance topics. SHIPs receive federal funding for their activities. See “Contact Medicare,” <http://www.medicare.gov/contacts>.

³³ CMS, “Medicare 2023 Part C & D Star Ratings Technical Notes,” p. 4. Available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData>. Only a portion of the quality measures for MA-PD plans are directly targeted at the administration of the prescription drug benefit. Other measures are targeted at other non-drug related health care quality and delivery performance.

³⁴ Beginning in 2016, CMS began to exercise its authority to terminate Part D plans that had received three years of low ratings. CMS issues contract nonrenewal notices for the affected plans each February, with an effective date of December 31 of the same year. See CMS, “Advance Notice of Methodological Changes for Calendar Year (CY) 2017 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and Call Letter,” February 19, 2016, p.101, at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2017.pdf>. For definitions see 42 C.F.R. §423.186 and 42 C.F.R. §423.509.

³⁵ *Medicare Part D Prescription Drug Manual*, Chapter 3, “Eligibility, Enrollment and Disenrollment,” Section 30.3.8, subsection 12, Rev. August 12, 2020, at <https://www.cms.gov/files/document/cy2021-pdp-enrollment-and-disenrollment-guidance.pdf>.

Plan Marketing

Plan sponsors must provide timely and accurate information in their marketing materials. For example, a plan that has received a four-star rating for one of the categories on which it is assessed but has an aggregate three-star quality rating across all the CMS measures cannot create promotional material stating that the plan is a four-star plan.³⁶ Plans are not allowed to market via unsolicited contacts, such as door-to-door sales, and also face limits on marketing and sales events. All plan sponsors must have interpreters in their call centers.³⁷

Plans must provide certain documents upon request or enrollment, such as a summary of benefits, the plan formulary, and a directory of contracting pharmacies. Plan sponsors may offer nominal gifts (worth \$15 or less per item or \$75 in the aggregate per person, per year) to potential enrollees, though they may not take the form of cash or rebates.³⁸

In 2022, CMS issued new rules increasing federal oversight of third-party marketing organizations, which are outside firms hired to drum up enrollees for Part D plan sponsors. CMS issued the rule to protect Medicare beneficiaries from what it termed “confusing and potentially misleading activities” by the marketing organizations.³⁹

Enrollment Process

Beneficiaries can join a Part D plan in a variety of ways,⁴⁰ including (1) filling out a paper application; (2) visiting a plan’s website and enrolling online; (3) using the Medicare online information site and enrollment center at <http://www.medicare.gov>;⁴¹ (4) calling the company offering the drug plan; or (5) calling 1-800-MEDICARE. In general, a plan sponsor may not deny a valid enrollment request from any Part D-eligible individual residing in its service area.

An individual (or his/her legal representative) must complete an enrollment request, and include all information required to process the enrollment. Upon receiving an enrollment request, a plan sponsor must provide, within 10 calendar days, (1) a notice of acknowledgement of receipt of the beneficiary’s application, (2) a request for more information in cases of incomplete applications, or (3) a notice that the application has been denied, along with an explanation as to why.

³⁶ CMS, “Medicare Communications and Marketing Guidelines (MCMG,” February 9, 2022, <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines>. Plans may provide provider and/or pharmacy directories electronically without prior consent from an enrollee. Part D plans may (1) send enrollees the plan formulary in hard copy, which may be abridged, or (2) send a distinct and separate notice (in hard copy) describing where enrollees can find the formulary online and how enrollees can request a hard copy.

³⁷ CMS call center requirements at 42 C.F.R. §422.111(h)(1)(iii) and §423.128(d)(1)(iii) require that interpreter services be provided to non-English speaking and limited English proficient (LEP) individuals at no cost.

³⁸ CMS, “Medicare Communications and Marketing Guidelines (MCMG),” February 9, 2022, <https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines>.

³⁹ CMS Fact Sheet, “CY 2023 Medicare Advantage and Part D Final Rule (CMS-4192-F),” April 29, 2022, <https://www.cms.gov/newsroom/fact-sheets/cy-2023-medicare-advantage-and-part-d-final-rule-cms-4192-f>. See also CMS, “Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; etc.,” May 9, 2022, <https://www.regulations.gov/document/CMS-2022-0012-4335>. In addition, under the new rule, Part D plans must provide a multi-language insert in the top 15 languages used in the United States, as well as in any additional non-English language that is the primary language of at least 5% of the individuals in a plan benefit area, informing individuals that interpreter services are available for free.

⁴⁰ *Medicare Part D Prescription Drug Manual*, Chapter 3, “Eligibility, Enrollment and Disenrollment,” Section 40.1, Rev. August 12, 2020, at <https://www.cms.gov/files/document/cy2021-pdp-enrollment-and-disenrollment-guidance.pdf>.

⁴¹ Drug plan participation in Medicare’s online enrollment center is voluntary, so not all Part D plans offer this option.

Prior to the effective date of enrollment, a plan sponsor must provide necessary information about being a member of the plan. In addition, the sponsor must provide: a copy of the completed enrollment form, if needed; a notice acknowledging receipt of the enrollment request providing the expected effective date of enrollment; and proof of health insurance coverage so that a beneficiary may begin using plan services as of the effective date. For all enrollment requests, the plan sponsor must submit the information necessary for CMS to add a beneficiary to its records as an enrollee within seven calendar days of receipt of the completed enrollment request.

LIS Enrollment

Special enrollment rules apply to LIS individuals. Generally, there is a two-step process for low-income persons to gain Part D coverage. First, a determination must be made that they qualify for the LIS; second, they must enroll, or be enrolled, in a specific Part D plan.⁴²

LIS enrollees were once allowed to change plans at any time during the plan year, unlike other Part D enrollees who generally may switch plans only during the annual enrollment period. Since 2019, LIS enrollees have been allowed a SEP once per calendar quarter during the first nine months of the year and also are eligible for SEPs (1) within three months after the start of coverage or notification that they have been enrolled by CMS or a state in a Part D plan and (2) within three months after a change to their LIS or Medicaid status.⁴³ Federal regulations place limits on SEPs for LIS enrollees who are identified by CMS as at risk of opioid abuse. (See “Part D Opioid Overutilization Monitoring.”)

Auto-Enrollment

Full-benefit, dual-eligible individuals who have not elected a Part D plan are automatically enrolled into a PDP by CMS.⁴⁴ CMS first uses data provided by state Medicaid agencies to identify full-benefit, dual-eligible individuals. CMS then identifies plan sponsors that offer at least one Part D plan in the region offering basic prescription drug coverage with a premium at or below the low-income premium subsidy amount. If more than one sponsor in a region meets the criteria, CMS auto-enrolls beneficiaries on a random basis among available PDP sponsors. CMS next identifies individual plans offered by the sponsor that include basic drug coverage with premiums at or below the low-income premium subsidy amount. The beneficiary is then randomly assigned among the sponsor’s plans meeting the criteria.

Some dual-eligible beneficiaries may be auto-enrolled in a plan that does not meet their needs. For this reason, they are provided with opportunities to change enrollment, with the new coverage

⁴² CMS, *Medicare Part D Prescription Drug Manual*, Chapter 13, “Premium and Cost-Sharing Subsidies for Low-Income Individuals,” Section 40, Rev. October 1, 2018, at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter-13-Premium-and-Cost-Sharing-Subsidies-for-Low-Income-Individuals-v09-14-2018.pdf>.

⁴³ CMS, “Medicare Program: Contract Year 2019 Policy and Technical Changes to Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, Medicare Prescription Drug Benefit Programs, and the PACE Program,” 83 *Federal Register* 16440, April 16, 2018, p. 16514, at <https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf>.

⁴⁴ Full-benefit duals who live in another country, live in one of the five U.S. territories, are inmates in a correctional facility, have already enrolled in a Part D plan, or have opted out of auto-enrollment into a Part D plan, are excepted from this process.

effective the following month. (See “LIS Enrollment.”) If an enrollee selects a new plan with a premium above the low-income benchmark, however, he or she must pay the difference.⁴⁵

Facilitated Enrollment

CMS established a process labeled “facilitated enrollment” for enrollees in MSPs, SSI enrollees, and persons who applied for and were approved for the LIS. The basic features applicable to auto-enrollment for dual eligibles (i.e., identification of eligibility through SSA and/or Medicaid data, random assignment to plans with premiums below the low-income benchmark, and assignment of MA enrollees to the lowest-cost MA-PD plan offered by the MA organization) are the same for facilitated enrollment.

Reassignment of Certain LIS Beneficiaries

Drug plans may increase premiums at the beginning of a plan year, in some cases raising them above the benchmark for LIS beneficiaries. When that is the case, CMS is to reassign full LIS recipients to different plans so they can continue to receive benefits without paying Part D premiums (or continue paying only a minimal amount). CMS may also automatically reassign LIS recipients if their current plan terminates operations. LIS beneficiaries who have voluntarily changed plans in previous years are not automatically reassigned by CMS, even if their plans charge premiums above the benchmark. LIS beneficiaries in MA-PD plans are automatically reassigned to PDPs if their current plan ceases operations or they are affected by a reduction in the plan’s service area.

About 463,000 LIS beneficiaries were enrolled in benchmark PDPs in 2022 that did not qualify as benchmark plans in 2023. CMS randomly reassigned 457,932 beneficiaries to different PDPs, and 4,460 were assigned to the same plan despite a premium increase. Another 517,183 LIS beneficiaries were not reassigned because they had previously switched plans voluntarily.⁴⁶

Part D Benefit Structure

The 2003 MMA set out a minimum drug benefit structure, known as the standard Part D benefit. Plan sponsors may, and usually do, offer different benefit designs and cost-sharing requirements, so long as they meet or exceed the standard benefit specifications.

Under the standard benefit, with some exceptions, over the course of a year a beneficiary is responsible for paying (1) a monthly premium, (2) a capped, annual deductible, and (3) co-payments or coinsurance for drug purchases. The MMA did not set an annual cap on enrollee out-of-pocket spending in the standard benefit, except for certain LIS enrollees. Additionally, under the MMA, for a certain portion in the annual benefit called the *coverage gap* (also known as the *doughnut hole*), non-LIS beneficiaries initially faced 100% out-of-pocket costs.

The Part D benefit has been reconfigured by Congress several times since the MMA was enacted. For example, the Patient Protection and Affordable Care Act of 2010 (ACA; P.L. 111-148, as amended) “closed” the coverage gap, in the sense that enrollees in 2023 pay 25% rather than 100% of drug costs in this portion of the benefit. The ACA also required drug manufacturers that

⁴⁵ CMS, *Medicare Prescription Drug Manual*, “Chapter 3—Eligibility, Enrollment and Disenrollment,” Section 40.1.4, Rev. August 12, 2020, available at <https://www.cms.gov/medicare/eligibility-and-enrollment/medicarepresdrugeligenrol>.

⁴⁶ Data on 2023 reassignment are available at <https://www.cms.gov/Medicare/Eligibility-and-Enrollment/LowIncSubMedicarePresCov/Reassignment.html>.

participate in Part D to provide a discount on certain drugs purchased in the coverage gap. (See “The Coverage Gap.”)

The 2022 IRA makes significant changes to the Medicare Part D standard benefit, including capping annual enrollee out-of-pocket spending. The new provisions are to be implemented gradually through 2025. The following sections of the report first discuss the 2023 Part D standard benefit, including several IRA changes that took effect in 2023, followed by a detailed discussion of additional changes to the standard benefit to be implemented in 2024 and in 2025.⁴⁷ For information on the drug price negotiation provisions of the IRA, see **Appendix B**.

Qualified Drug Coverage

Part D plan designs may vary, but all PDPs and MA-PD plans must offer at least a minimum package of benefits. This minimum benefit, referred to as *qualified prescription drug coverage*, may include either a standard package of prescription drug coverage established under law (the standard benefit) or an alternative package that is actuarially equivalent.⁴⁸ Plans may also offer *enhanced* coverage that exceeds the value of standard coverage. Premiums for these enhanced plans are generally higher than for standard plans. Actual costs to Part D beneficiaries vary from plan to plan depending on the benefit structure and coverage offered, the costs and amount of drugs they use, and the level of any additional assistance, such as through the LIS.

Standard Prescription Drug Coverage

For 2023, under the standard Part D benefit, a beneficiary first pays a *deductible* (\$505). After the deductible has been met, the beneficiary 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).⁴⁹ (See **Figure 2**.)

To reach the \$4,660 initial coverage limit in a 2023 standard plan, a beneficiary would pay the \$505 deductible plus \$1,038.75 in prescription costs, for total true out-of-pocket spending (TrOOP) of \$1,543.75. The plan would pay the remaining \$3,116.

After the initial coverage threshold has been reached, a beneficiary enters the *coverage gap* or “doughnut hole” where he or she remains until accumulating \$7,400 in total TrOOP in 2023 (for those not receiving the LIS) and reaches the *catastrophic threshold*.⁵⁰ Total drug spending needed by a non-LIS beneficiary to move through the deductible, the initial coverage limit, and the coverage gap to the catastrophic threshold is about \$11,206.28,⁵¹ with a portion paid by the

⁴⁷ See CRS In Focus IF12203, *Selected Health Provisions of the Inflation Reduction Act*. The IRA also requires the HHS Secretary to negotiate the price of certain Part D drugs, and requires pharmaceutical manufacturers to pay rebates to CMS if they increase the price of Part D drugs above an allowable rate of annual inflation.

⁴⁸ Social Security Act, §1860D-2.

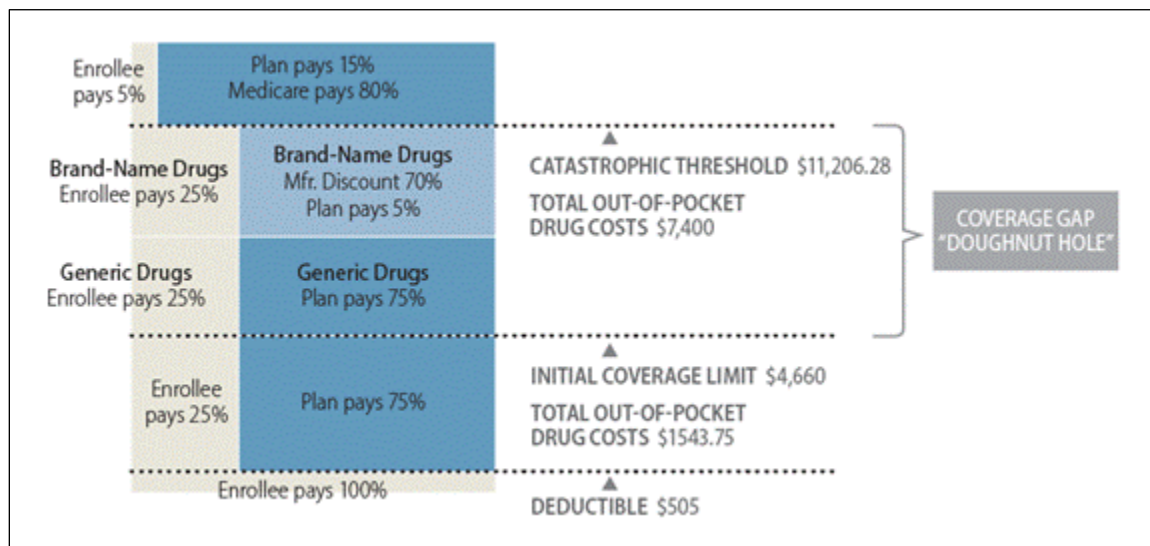
⁴⁹ The 2023 thresholds were published in the 2023 Call Letter. CMS, “Announcement of Calendar Year (CY) 2023 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment,” April 4, 2022, p. 68, at <https://www.cms.gov/files/document/2023-announcement.pdf>. The standard plan annual deductible, initial coverage limit, out-of-pocket threshold, and beneficiary cost sharing are adjusted annually under a set formula. See 42 C.F.R. §423.104(d). The standard plan deductible is the maximum deductible that can be charged for Part D plans.

⁵⁰ LIS beneficiaries do not face a coverage gap, per se, because they have set, lower cost sharing throughout the benefit. The more generous Medicare LIS drug cost-sharing subsidies count as TrOOP. For LIS enrollees, total drug spending needed to generate sufficient TrOOP to reach the catastrophic threshold in 2023 is \$10,516.25. For non-LIS beneficiaries (who may count the manufacturer discount as TrOOP) the total amount of spending needed to reach the threshold in 2023 is about \$11,206.28.

⁵¹ Total spending per beneficiary will vary depending on plan design and purchases of brand-name vs. generic drugs. CMS thresholds are based on average spending data across all plans.

beneficiary, a portion covered by the plan, and a portion offset by manufacturer discounts in the coverage gap. (See “The Coverage Gap.”)

Figure 2. 2023 Standard Medicare Prescription Drug Benefit



Source: Figure created by CRS based on data from CMS, “Announcement of Calendar Year (CY) 2023 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,” Attachments IV and V.

Notes: Beneficiaries 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. LIS beneficiaries pay less out of pocket than other beneficiaries. For example, full-benefit dual eligibles pay no deductible, minimal cost sharing in the coverage gap, and no cost sharing above the catastrophic threshold. (See **Table 5**.)

Actual spending per beneficiary will vary depending on plan design and use of brand-name vs. generic drugs. After the catastrophic threshold has been reached, under the standard benefit an enrollee pays the greater of a nominal set co-payment for drugs or 5% coinsurance.⁵² Medicare subsidizes 80% of each plan’s costs for catastrophic coverage, known as Part D reinsurance, and plan sponsors are liable for 15% of costs.

CMS uses a set formula to update annual Part D coverage parameters, including the standard deductible, initial coverage limit, and amount of beneficiary TrOOP required to reach the catastrophic threshold.⁵³ Annual percentage increases are based on average per capita spending for covered outpatient drugs for Medicare beneficiaries during the 12-month period ending in July of the previous year.

Actuarially Equivalent and Enhanced Plans

Plan sponsors have a number of options when designing pricing and benefits. Insurers may offer basic plans that provide the same level of coverage as the Part D standard plan, but may modify certain parameters such as reducing the maximum \$505 deductible, while also imposing cost-sharing requirements that are higher than 25%. For example, nearly all plans use a tiered cost-

⁵² Nominal cost sharing is defined as the greater of (1) a co-payment of \$4.15 in 2023 for a generic drug or preferred multiple source drug and \$10.35 for other drugs, or (2) 5% coinsurance.

⁵³ Social Security Act, §1860D-2.

sharing structure, where beneficiaries have a lower co-payment for generic drugs, and higher cost sharing for more expensive brand-name drugs. (See “Tiered Formularies.”)

Insurers may also offer enhanced coverage that exceeds the value of defined standard coverage. Enhanced coverage includes basic coverage and supplemental benefits such as reductions in cost sharing. A PDP sponsor may not offer an enhanced plan unless it also offers a standard or actuarially equivalent plan in the same region. The requirement is designed to ensure that Medicare beneficiaries have options for lower-cost plans. MA-PDs are more likely to offer enhanced benefits than PDPs, because MA-PD sponsors are allowed to use some of their Medicare payments to enrich Part D benefits.

In 2022, 54% of Part D enrollees in PDPs were in plans offering enhanced benefits and 46% were in plans that were actuarially equivalent to the standard benefit.⁵⁴ Some 1% of enrollees in MA-PD plans were in plans that offered basic benefits; the other 99% were in enhanced plans.

The Coverage Gap

One unique feature of the Medicare Part D drug benefit is the coverage gap (also referred to as the doughnut hole)—the period in which Part D enrollees initially were required to pay 100% of total drug costs until they reached the catastrophic threshold. Congress included the coverage gap in the benefit structure when the MMA was enacted in 2003 because the cost of continuous coverage would have exceeded budget limitations regarding total spending on the new program.

As originally enacted, Part D provided a basic level of coverage for all beneficiaries, and extra protection for those with the highest drug costs (above the catastrophic limit). Part D enrollees who did *not* receive an LIS generally paid the full cost of drugs while in the coverage gap. The ACA, as amended,⁵⁵ gradually phased out the coverage gap between 2011 and 2020, meaning that by 2020 enrollees in standard plans had a 25% cost share from the time they meet a standard plan deductible until they reached the catastrophic threshold, after which cost sharing was a maximum of 5%. (Congress included provisions in the Bipartisan Budget Act of 2018, BBA 2018; P.L. 115-123, that closed the Part D coverage gap for brand-name drugs in 2019, a year earlier than required by the ACA.⁵⁶)

The ACA closed the coverage gap two ways.

- For brand-name and biologic drugs, the ACA required manufacturers participating in Part D to pay a mandatory discount on drugs purchased in the coverage gap, while phasing in a 25% Medicare/Part D plan subsidy. (The ACA’s original manufacturer discount of 50% was increased to 70% in the BBA 2018 and expanded to cover biosimilars.) Medicare/Part D plans now provide a 5% subsidy in the coverage gap, and enrollees pay 25% coinsurance.
- For generic drugs, the ACA gradually increased the Medicare subsidy to 75% and set enrollee cost sharing at 25%. There is no generic manufacturer discount.

Even though the coverage gap has been closed (in the sense that the Part D standard benefit has 25% cost sharing from the deductible to the catastrophic threshold), for 2023 and 2024 the

⁵⁴ MedPAC, (MedPAC), *Report to the Congress: Medicare Payment Policy*, March 2023, Chapter 12, Table 12-2, p. 396, at <https://www.medpac.gov/document/march-2023-report-to-the-congress-medicare-payment-policy/>.

⁵⁵ Section 3301 of the ACA created the coverage gap manufacturer discount program. Section 1101 of the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152) added the phase-in of government subsidies to close the coverage gap by 2020.

⁵⁶ Bipartisan Budget Act of 2018 (BBA 2018; P.L. 115-123), §53116.

coverage gap is still an important part of the benefit structure for purposes of (1) calculating mandatory manufacturer discounts for certain drugs and (2) determining the required level of enrollee cost sharing and out-of-pocket spending in that portion of the benefit.⁵⁷ Some enrollees may actually pay higher cost sharing in the coverage gap than in some other phases of the benefit due to rules governing cost sharing by Part D plans. (See textbox below.)

Supplemental Cost Sharing in the Coverage Gap

Part D plan sponsors may offer plans with supplemental coverage, such as lower deductibles or cost sharing than in the standard benefit. Under Part D law and regulation, if a plan sponsor offers a supplemental benefit in the coverage gap (such as a low, set co-payment rather than 25% coinsurance) the “the applicable beneficiary shall not be provided a discounted price for an applicable drug under this section until after such supplemental benefits have been applied with respect to the applicable drug.”

For example, if a sponsor offered a plan with a \$10 co-payment on a \$100 drug in the coverage gap, the plan sponsor’s liability would be calculated as (\$100 - \$10), or \$90. The manufacturer discount would be applied to the \$10 co-payment ($\$10 \times 0.70 = \7). The enrollee would pay the remaining share ($\$100 - (\$90 + \$7) = \3).

If the plan sponsor did not offer an enhanced benefit, the manufacturer discount would be 70% of the negotiated price of \$100 ($\$100 \times 0.70 = \70). The enrollee would pay 25% coinsurance on the \$100 negotiated price ($\$100 \times 0.25 = \25), and the plan sponsor would be liable for the remaining \$5 ($\$100 - (\$70 + \$25)$). The policy can act as a disincentive for plan sponsors to offer supplemental cost sharing in the coverage gap.

Source: SSA §1860D-14(A)(c)(2) and CRS analysis.

True Out-of-Pocket Costs

Before catastrophic protection begins, Part D enrollees must incur a certain level of out-of-pocket spending. TrOOP are costs that are incurred by a beneficiary or are counted by CMS as incurred by a beneficiary, including a plan deductible, cost sharing up to the initial coverage limit, and the cost sharing for drugs while in the coverage gap.

Enrollee spending for Part D covered drugs is treated as TrOOP⁵⁸ if paid by an enrollee (including through a Medical Savings Account, Health Savings Account or Flexible Spending Account); paid by family members or friends; paid by a Qualified State Pharmacy Assistance Program; covered by the LIS; paid by most charities; covered by a drug manufacturer discount under the Medicare Coverage Gap Discount Program; covered by the Indian Health Service;⁵⁹ or paid by an AIDS Drug Assistance Program.⁶⁰

⁵⁷ Non-LIS beneficiaries are allowed count manufacturer on brand-name drugs in the coverage gap as their own out-of-pocket spending. See “Phase Out of the Coverage Gap.”

⁵⁸ CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 5, “Benefits and Beneficiary Protection,” Section 30, Rev. September 20, 2011, at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf.

⁵⁹ Added by §3314 of the ACA.

⁶⁰ Added by §3314 of the ACA.

Examples of TrOOP Spending

Consider a non-LIS enrollee in a 2023 standard plan. To reach the initial coverage limit, the enrollee would need to incur TrOOP spending consisting of the \$505 deductible plus 25% coinsurance or co-payments on total drug spending from the \$505 deductible to the \$4,660 initial coverage limit (\$505 deductible + \$1038.75 cost sharing = \$1,543.75). While beneficiaries move into the coverage gap on the basis of plan plus enrollee spending, beneficiaries move out of the coverage gap and into the catastrophic portion of the benefit based solely on enrollee out-of-pocket spending (which includes the value of manufacturer discounts.) The beneficiary would now face \$5,856.25 of additional out-of-pocket spending in the doughnut hole before he or she would reach the catastrophic threshold (a total of \$7,400 in out-of-pocket spending).

While in the coverage gap in 2023, a beneficiary would pay 25% of the cost of brand-name drugs, including any pharmacy dispensing fees. The manufacturer provides a 70% discount on the negotiated price of brand-name drugs and biologic and biosimilar products, which under law counts toward TrOOP. The federal government provides a subsidy of 5% of the cost of the brand-name drug, which would not count toward TrOOP.

A beneficiary who purchases generic drugs in the coverage gap in 2023 would pay 25% of the cost of drugs, including pharmacy dispensing fees, which would count toward TrOOP. The federal government provides a 75% coverage subsidy that does not count toward TrOOP.

In one example, the beneficiary buys a brand-name drug that has a negotiated price of \$60 and a \$2 pharmacy dispensing fee. The total cost is \$62. The beneficiary will pay 25% of the cost of the drug and dispensing fee ($\$62 \times 0.25 = \15.50). The manufacturer discount reduces the price of the drug by \$42 (70% of the \$60 negotiated price). In this case, TrOOP will be \$57.50 (the \$15.50 beneficiary price, including a portion of the dispensing fee, plus the \$42 manufacturer discount). The remaining \$4.50 (\$3.00 cost of the drug and \$1.50 of the dispensing fee) is borne by the plan and does not count toward TrOOP.

In another example, the beneficiary buys a generic drug. The price for the generic drug is \$20 and the dispensing fee is \$2. The beneficiary will pay 25% of the cost of the generic drug plus the pharmacy fee ($\$22 \times 0.25 = \5.50). The \$5.50 will count as TrOOP. The government's 75% coverage portion will not count as TrOOP.

Source: CRS analysis of CMS, "Costs in the Coverage Gap," at <https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/costs-in-the-coverage-gap>.

Incurred costs do not include Part D premiums; costs for drugs not on a plan formulary; coverage by other insurance, including group health plans, workers' compensation, Part D plans' supplemental or enhanced benefits, or other third parties; or Patient Assistance Programs operating outside of Part D. Additionally, while manufacturer discounts count toward TrOOP, federal subsidies for brand-name or generic drugs in the coverage gap do not count.⁶¹

In 2021, 4.1 million Part D enrollees exceeded the out-of-pocket threshold and reached the catastrophic phase of the benefit.⁶² Medicare picks up a larger share of spending (80% reinsurance) for enrollees who reach the catastrophic threshold, and reinsurance accounted for 55% of 2021 Part D spending. Non-LIS enrollees were 36% of those reaching the catastrophic threshold in 2021, while LIS enrollees made up 64%. Although LIS enrollees were more likely to reach the catastrophic phase of the benefit, the LIS share of enrollees reaching the catastrophic threshold has declined from more than 80% in 2010 and earlier years. The change reflects more rapid growth in Part D enrollment by non-LIS individuals, as well as an increase in the average price of drugs used by the non-LIS population.⁶³

⁶¹ For example, the Part D 70% manufacturer discount on brand-name, biologics, and biosimilar drugs in the coverage gap is counted as enrollee out-of-pocket spending, in addition to an enrollee's 25% cost share. However, the Medicare 75% contribution to the cost of generic drugs in the coverage gap does not count against enrollee out-of-pocket spending. An individual using only generic drugs is likely to accumulate TrOOP more slowly than an individual taking brand-name drugs. In addition, Part D plan sponsors have the option of providing supplemental coverage in the coverage gap, which could affect enrollee TrOOP.

⁶² MedPAC, July 2023 Data Book, *Health Care Spending and the Medicare Program*, Chart 10-19, at <http://www.medpac.gov/-documents-/data-book>. The data are the most recent available.

⁶³ MedPAC, 2023 Report to Congress, Chapter 12, p. 404.

IRA Changes to the Medicare Part D Benefit in 2023

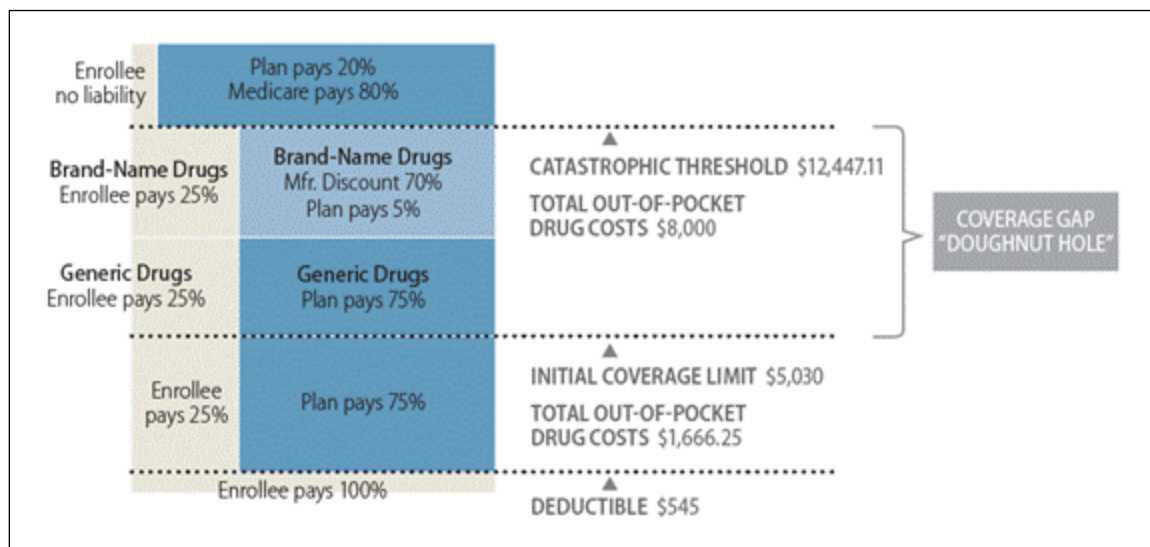
The IRA made several changes to the Part D standard benefit, effective in the 2023 plan year. Starting in 2023

- Part D plans may no longer apply a deductible, coinsurance, or other cost-sharing requirement for adult vaccinations recommended by the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) that are covered Part D drugs (e.g., shingles vaccine).
- Part D deductibles no longer apply to covered insulin products,⁶⁴ and there is a \$35 monthly cap on insulin cost sharing.⁶⁵

Part D Standard Benefit For 2024

In 2024, under the IRA, the defined standard benefit thresholds, the drug-inflation formula for updating the thresholds, and the manufacturer coverage gap discount program are unchanged. However, for 2024 and following plan years, enrollee out-of-pocket spending is capped at the catastrophic threshold, meaning enrollees have no cost sharing for prescriptions once they reach the annual threshold.⁶⁶

Figure 3. 2024 Medicare Part D Standard Benefit



Source: CRS and CMS 2024 Call Letter.

⁶⁴ Under the 2022 IRA, a "covered insulin product" means an insulin product that is a covered Part D drug covered under the PDP or MA-PD plan that is approved under §505 of the Federal Food, Drug, and Cosmetic Act or licensed under §351 of the Public Health Service Act and marketed pursuant to such approval or licensure, including any covered insulin product that has been deemed to be licensed under §351 of the Public Health Service Act pursuant to §7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 and marketed pursuant to such section.

⁶⁵ For more detailed information, see CRS Report R47396, *Health Care Provisions of the Budget Reconciliation Measure P.L. 117-169*.

⁶⁶ Under SSA §1860D-2(b)(6) the dollar amounts of thresholds are adjusted based on the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year.

In 2024 under the standard Part D benefit, a beneficiary pays a deductible (\$545). (See **Figure 2.**) After the deductible is met, the beneficiary is responsible for 25% of the cost of prescription drugs (with the plan covering the remaining 75%) up to the initial coverage limit (\$5,030).⁶⁷

To reach the \$5,030 initial coverage limit in a 2024 standard plan, a beneficiary would pay the \$545 deductible plus \$1,121.25 in prescription costs, for total out-of-pocket costs of \$1,666.25. The plan would pay the remaining \$3,363.75. After reaching the initial coverage threshold, a beneficiary enters the coverage gap, where he or she remains until accumulating \$8,000 in TrOOP and reaching the catastrophic threshold.⁶⁸ Total estimated drug spending needed by a non-LIS beneficiary to move through the deductible, initial coverage limit, and coverage gap to the catastrophic threshold in 2024 is estimated at \$12,447.11.⁶⁹ Once a beneficiary reaches the catastrophic threshold, he or she pays \$0 cost sharing.

The IRA makes a series of changes to the Part D standard benefit, effective in 2024, including the following:

- For 2024, Medicare reinsurance continues to subsidize 80% of each plan's costs for drugs dispensed to enrollees who exceed the catastrophic threshold. Part D plan sponsors are liable for 15% of costs, as in 2023, *plus* another 5% of costs that will no longer be borne by enrollees due to the new out-of-pocket spending cap.⁷⁰ In total, plan sponsors will be liable for 20% of catastrophic drug costs.
- Starting in 2024, the two separate categories of LIS (full and partial) are to be merged into one new LIS category.⁷¹ (See "Low-Income Subsidies.")
- Beginning in 2024 and running through 2029, annual increases in the Part D base beneficiary premium are to be capped at a maximum of 6%. Currently, there is no annual cap on the base premium. (See "Premiums.")

In addition to the IRA changes, a 2022 CMS regulation takes effect in 2024 that is forecasted to reduce enrollee cost sharing. Starting in 2024, Part D plans that impose fees on pharmacies as penalties for failing to meet contractual quality or other targets, or for the right to participate in certain programs, must apply the fees as a reduction to the price of a drug at the point of sale. According to the 2023 Medicare Trustees Report, the change will reduce the point-of-sale drug cost by 7% during the next decade.⁷² (For more details, see "Payments to Pharmacies.")

⁶⁷ The thresholds for 2024 were published in the 2024 Call Letter. CMS, "Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment," March 31, 2023, p. 134.

⁶⁸ For those receiving a LIS (who are not eligible for manufacturer discounts in the doughnut hole because they have set, lower cost sharing throughout the benefit), total spending needed to generate sufficient out-of-pocket spending to reach the catastrophic threshold is \$11,477.39.

⁶⁹ Total spending per beneficiary will vary depending on plan design and purchases of brand-name vs. generic drugs. CMS thresholds are based on average spending data across all plans.

⁷⁰ CMS, "Announcement of Calendar Year (CY) 2024 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies," March 31, 2023, p. 134, <https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/announcements-and-documents/371979854/2024>.

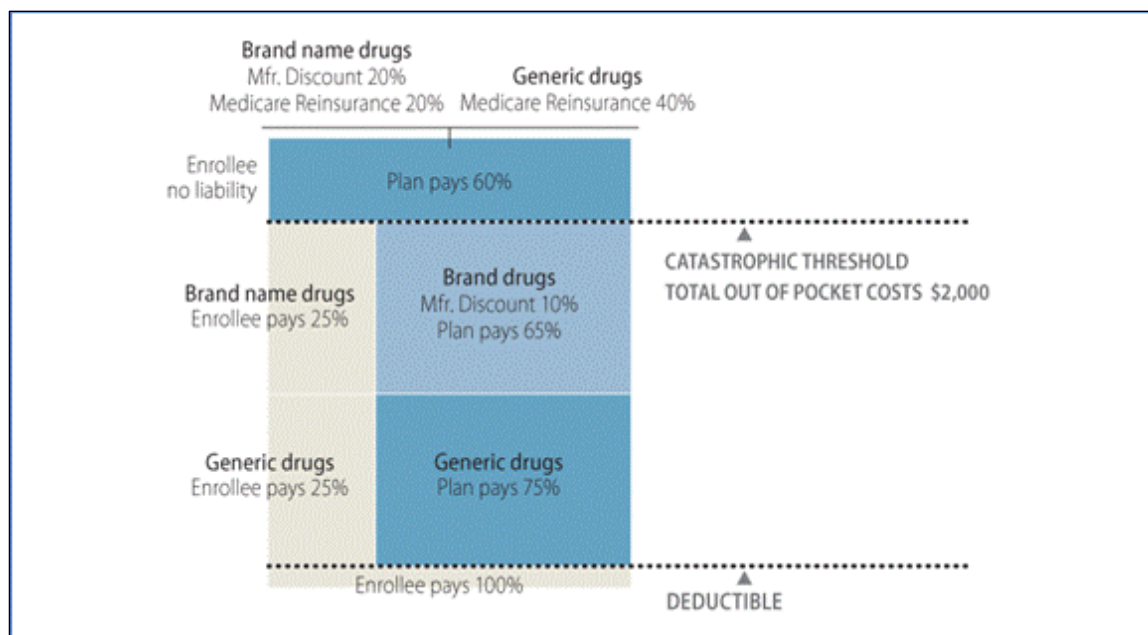
⁷¹ Under current law, certain groups of Medicare beneficiaries automatically qualify and are deemed eligible for the full LIS. Full-benefit dual eligibles who qualify for Medicaid benefits based on income and assets are automatically deemed eligible for the full LIS. Additionally, those who receive Medicare premium and/or cost-sharing assistance from Medicaid through the MSP, plus those eligible for SSI cash assistance, are automatically deemed eligible for full LIS. Others may qualify for the full LIS if they have income below 135% of the FPL and meet certain resource levels. Individuals may be eligible for the partial LIS if they have income below 150% of the FPL and meet slightly higher resource levels.

⁷² 2023 Medicare Trustees Report, p. 149. Many enrollees pay coinsurance for drugs based on the negotiated price at the point of sale.

Medicare Part D Standard Benefit in 2025

In 2025, the IRA requires a number of broad changes to the Part D standard benefit, including reducing the catastrophic threshold to \$2,000; eliminating the coverage gap and existing manufacturer discount program; and implementing a new manufacturer discount program. (See **Figure 4**.) CMS has not released the specific dollar amounts of the benefit thresholds for 2025, but **Figure 4** shows the outlines of the redesigned standard benefit.

Figure 4. 2025 Medicare Part D Standard Benefit



Source: CRS analysis of P.L. 117-169. The dollar threshold for the deductible had not been set by CMS when this report was prepared.

Notes: Phase-in for small manufacturers: For sales of drugs by specified manufacturers to LIS beneficiaries, or in cases where one Part D drug accounts for a significant share of a specified manufacturer's revenues, the 2025 manufacturer discounts would be 1% both below and above the catastrophic threshold.

Under the IRA

- Starting in 2025, there is no initial coverage limit or coverage gap. Under the redesigned standard benefit, enrollees pay average 25% cost sharing from the deductible to the catastrophic threshold and no cost sharing above the catastrophic threshold.
- For the 2025 plan year, the amount of annual TrOOP required to reach the catastrophic threshold is reduced to \$2,000 (by comparison, in 2024 an enrollee must have \$8,000 in TrOOP to reach the catastrophic threshold). The \$2,000 catastrophic threshold and plan deductible will be adjusted in subsequent years using the current law formula, which is based on Part D drug price inflation.
- Total enrollee drug spending needed to generate \$2,000 in TrOOP under the reconfigured benefit will depend on factors including (1) the dollar amount of the deductible in each plan, (2) the specific drugs used by an enrollee, and (3) whether an enrollee has other sources of coverage that, beginning in 2024, are to count as TrOOP.

- For 2025 and subsequent years, Part D enrollees may count as TrOOP reimbursement through other insurance, a group health plan, or certain other third-party payment arrangements. The IRA does not define *certain other third-party arrangements*, except to say they *do not* include Part D coverage. (Under the current law through 2024, the LIS, the manufacturer discount and other selected assistance, such as Ryan White AIDS Act, the Indian Health Service, and charitable assistance count as TrOOP. Most of those provisions continue,⁷³ but the manufacturer discount will no longer count as TrOOP [see next bullet point].)
- Starting in 2025, the current Part D manufacturer discount program ends and a new Part D manufacturer discount program takes effect. The new program provides a 10% discount on applicable drugs (brand-name drugs, biologics, and biosimilars) between the deductible and the catastrophic threshold and a 20% discount on applicable drugs above the catastrophic threshold. LIS beneficiaries, who were not covered under the previous manufacturer discount program, are eligible for the new manufacturer discount.
- Starting in 2025, Medicare reinsurance to Part D plan sponsors for drug costs above the catastrophic threshold is reduced to 20% from 80% for brand-name drugs, biologics, and biosimilars and to 40% from 80% for generics. The new manufacturer discount program is to be phased in gradually for drugs produced by specified manufacturers when (1) the drugs are dispensed to LIS beneficiaries or (2) one drug covered by a Part D manufacturer discount agreement makes up more than 80% of total spending for all of a specified manufacturer's drugs under such agreements.⁷⁴ In such cases
 - For applicable drugs dispensed to enrollees who have exceeded the deductible but have not reached the catastrophic threshold, the 10% manufacturer discount is to be phased in as follows: for 2025, 1%; for 2026, 2%; for 2027, 5%; for 2028, 8%; and for 2029 and each subsequent year, 10%.
 - For applicable drugs dispensed to enrollees who have incurred costs equal to or above the annual catastrophic threshold, the 20% manufacturer discount is to be phased in at for 2025, 1%; for 2026, 2%; for 2027, 5%; for 2028, 8%; for 2029, 10%; for 2030, 15%; and for 2031 and each subsequent year, 20%.

⁷³ Under current law and regulations, enrollees may also count as TrOOP: costs incurred by another person of behalf of the enrollee (including charities, if they are not otherwise excluded); costs paid by Medicare on behalf of a LIS enrollee; costs paid by a State Pharmaceutical Assistance Program, the Indian Health Service, or the Ryan White AIDS program. CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 5, "Benefits and Beneficiary Protection," Section 30, Rev. September 20, 2011, at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf. Single-source drugs that are subject to an HHS Secretary negotiated price under IRA will not be subject to the manufacturer discount. (The first negotiated prices take effect in 2026.) If a drug subject to a negotiated price is dispensed to a Part D enrollee who has not had sufficient spending to reach the catastrophic threshold, the HHS Secretary is to provide the Part D plan sponsor with a subsidy equal to 10% of the Part D plan's negotiated drug price.

⁷⁴ *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.

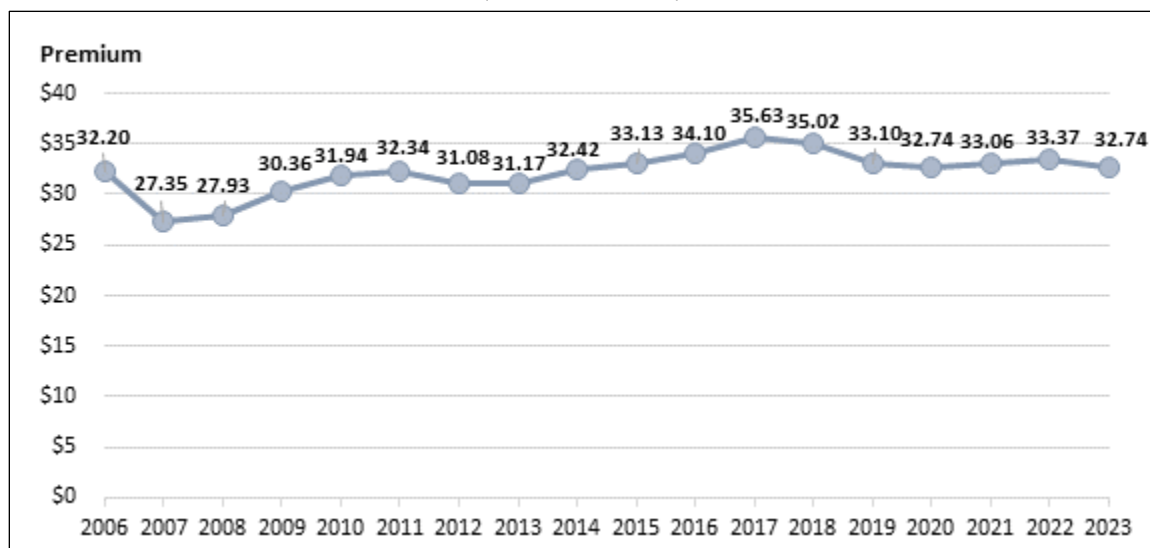
Beginning in 2025, Part D enrollees may choose to spread out their prescription cost sharing by paying required coinsurance or co-payments in capped, monthly installments.

Part D Premiums

The majority of beneficiaries enrolled in Part D pay monthly premiums for Part D coverage. On average, beneficiary premiums represent about 25.5% of the cost of a standard Part D plan, as determined through annual bids submitted by insurers. (See “Standard Prescription Drug Coverage.”)⁷⁵ The actual dollar amounts of Part D premiums vary by plan.

Figure 5. Annual Part D Base Beneficiary Monthly Premium

(in current dollars)



Source: CMS, “Annual Release of Part D National Average Bid Amount and other Part C & D Bid Information.”

Note: Amounts reflect 25.5% of the annual average of participating drug plan bids to provide basic Part D benefits.

Beneficiary premiums are based on the weighted average of annual bids submitted by participating sponsors for standard benefits (the base beneficiary premium) and are adjusted to reflect the difference between the standardized bid amount of the plan the beneficiary enrolls in and the nationwide average bid. For 2023, the base beneficiary monthly premium, 25.5% of the average adjusted bid amount, is \$32.74.⁷⁶ Historic base premiums are shown in **Figure 5**.

⁷⁵ Base Part D premiums are based on annual sponsor bids for providing standard coverage. Bids do not include expected reinsurance payments, which are direct Medicare subsidies for 80% of each plan’s costs above a set catastrophic threshold. (See “Reinsurance Subsidies.”) However, plan sponsors provide estimates of projected reinsurance subsidies, which are used by CMS to make monthly prospective payments to the plans. In 2005 rules to implement the Part D program, CMS noted that congressional intent was that average monthly premiums were to be based on total estimated standard benefits, including benefits subject to reinsurance. To ensure premiums cover a portion of the cost of reinsurance, CMS adjusts the base premium under a set formula. See CMS, “Medicare Program: Medicare Prescription Drug Benefit; Final Rule,” 70 *Federal Register* 4303, January 28, 2005, at <https://www.govinfo.gov/content/pkg/FR-2005-01-28/pdf/05-1321.pdf>.

⁷⁶ CMS, “Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information,” July 29, 2022, at <https://www.cms.gov/files/document/july-29-2022-parts-c-d-announcement-pdf.pdf>.

Beneficiaries in plans with higher costs for standard coverage face higher-than-average premiums, while enrollees in lower-cost plans pay lower-than-average premiums for such coverage. (Plans that offer supplemental benefits may set higher premiums but do not receive Medicare subsidies for the supplemental benefits.) Additionally, enrollees in MA-PD plans may have lower premiums if their sponsors choose to buy down, or reduce, the Part D premium.⁷⁷ The monthly premium is applied evenly to all persons enrolled in a specific plan, except those who are receiving the LIS or are subject to a late enrollment penalty (LIS beneficiaries have lower or zero premiums, and late enrollees pay a monthly penalty in addition to their plan premium). There are special rules for employer-sponsored Part D plans. Beneficiaries may pay plans directly or have premiums deducted from their Social Security benefits.⁷⁸

Premium Surcharge for Higher-Income Enrollees

Since 2011, as required by the ACA, Part D enrollees with higher incomes have been required to pay higher premiums. (The Part D high-income requirements are similar to the income-based premium structure under Medicare Part B.)⁷⁹ Part D beneficiaries with modified adjusted gross income (MAGI) above set thresholds are assessed a surcharge,⁸⁰ referred to as an income-related monthly adjustment amount (IRMAA), in addition to their regular plan premiums.

The higher-income surcharge is calculated as the difference between the Part D base beneficiary premium (which in 2023 represents 25.5% of the average national bid amount) and 35%, 50%, 65%, 80%, or 85% of the national average cost for providing Part D benefits,⁸¹ excluding federal reinsurance or subsidies. The surcharge is based on beneficiary income, with higher-income beneficiaries facing a larger surcharge. Because individual plan premiums vary, the law specifies that CMS calculate the Part D surcharge using the base premium, rather than each beneficiary's individual plan premium amount.⁸² (See **Table 2.**)

Table 3. 2023 Monthly Medicare Part D High-Income Surcharge

File Individual Tax Return	File Joint Tax Return	2023 Payment Is
\$97,000 or less	\$194,000 or less	Plan Premium
Above \$97,000 to \$123,000	Above \$194,000 to \$246,000	\$12.20 + Plan Premium
Above \$123,000 to \$153,000	Above \$246,000 to \$306,000	\$31.50 + Plan Premium

⁷⁷ MA plans that earn a Part C rebate (by having estimated benefit costs below the maximum possible Medicare payment) must spend the rebate on supplemental benefits, reduced cost sharing or reduced Part B or D premiums.

⁷⁸ Social Security deductions are limited to \$300 per month, the *harm limit*. SSA, HI 03001.001, "Description of the Medicare Part D Prescription Drug Program," at <https://secure.ssa.gov/poms.nsf/lnx/0603001001>.

⁷⁹ See CRS Report R40082, *Medicare Part B: Enrollment and Premiums*.

⁸⁰ The definition of *modified adjusted gross income* (MAGI) used for the calculation is the total of adjusted gross income and tax-exempt interest income. The income data is based on the most recent tax information that the Internal Revenue Service is able to provide the SSA. Generally, the tax information is from two years prior to the year for which the premium is being determined but not more than three years prior. SSA, "Medicare Premiums: Rules for Higher-Income Beneficiaries," at <https://www.ssa.gov/benefits/medicare/medicare-premiums.html>. MAGI has more than one definition in federal tax law, with the definition varying based on the program or provision utilizing the concept. See CRS Report R43861, *The Use of Modified Adjusted Gross Income (MAGI) in Federal Health Programs*. The income thresholds are the same as those used for calculating Medicare Part B premiums.

⁸¹ CMS, "2023 Medicare Parts A & B Premiums and Deductibles 2023 Medicare Part D Income-Related Monthly Adjustment Amounts," September 27, 2022, <https://www.cms.gov/newsroom/fact-sheets/2023-medicare-parts-b-premiums-and-deductibles-2023-medicare-part-d-income-related-monthly>.

⁸² Social Security Act §1860D-13(a)(7). See also SSA, "Medicare Premiums: Rules for Higher-Income Beneficiaries," at <https://www.ssa.gov/benefits/medicare/medicare-premiums.html>.

File Individual Tax Return	File Joint Tax Return	2023 Payment Is
Above \$153,000 to \$183,000	Above \$306,000 to \$366,000	\$50.70 + Plan Premium
Above \$183,000 and less than \$500,000	Above \$366,000 and less than \$750,000	\$70.00 + Plan Premium
\$500,00 and above	\$750,000 and above	\$76.40 + Plan Premium

Source: Medicare.gov, “Monthly Premium for Drug Plans.”

Note: Income figures refer to modified adjusted gross income.

There is a separate IRMAA calculation for beneficiaries who are married and lived with their spouses at any time during a year, but filed separate tax returns. In such cases for 2023

- Individuals with MAGI between \$97,000 and \$403,000 pay \$70.00 per month, plus a plan premium.
- Individuals with MAGI greater than or equal to \$403,000 pay \$76.40 per month, plus a plan premium.

Under the original ACA provisions, high-income Part D enrollees were placed into one of four IRMAA categories, depending on their income. The BBA 2018 added a fifth high-income category beginning in 2019 for individuals with annual income of \$500,000 or more or couples filing jointly with income of \$750,000 or more. Enrollees with income equal to or exceeding these thresholds pay premiums that cover 85% of the average per capita cost of the Part D benefits (instead of 80%, as they would have prior to this change). The threshold for couples filing jointly in this new income tier is calculated as 150% of the individual income level rather than 200%, as in the other income tiers. The bottom four high-income categories are adjusted annually for inflation based on the CPI-U; however, the new top high-income threshold is frozen through 2027 and then adjusted annually for inflation starting in 2028.⁸³

Beneficiaries pay the surcharge directly to the federal government, rather than to Part D plans. When applicable, IRMAA is withheld from an enrollee’s monthly Social Security check, Railroad Retirement benefit, or federal pension payment, unless the benefit is not sufficient.⁸⁴

IRA Premium Stabilization Program

The IRA created a Part D premium stabilization program, effective in 2024. Under the IRA, for 2024-2029, the annual base premium 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 the underlying Part D statutory formula of 25.5% of weighted plan bids.⁸⁵

For 2024, the base premium is required to be the lesser of (1) the 2023 base premium of \$32.74 increased by 6%, or \$34.70, or (2) the base premium derived from the underlying Part D formula. CMS announced in July 2023 that the 2024 base premium would be a 6% increase to \$34.70. According to CMS, absent the IRA premium stabilization 6% cap, the 2024 base premium (as calculated through the underlying Part D statutory formula of 25.5% of weighted plan bids)

⁸³ These threshold changes also apply to Part B income-related monthly adjustments. See CRS Report R40082, *Medicare Part B: Enrollment and Premiums*.

⁸⁴ In cases where an enrollee’s benefit payment check is not sufficient to have the IRMAA withheld, or if an enrollee is not receiving such benefits, the beneficiary must be billed directly for the IRMAA. See 42 C.F.R. §423.293.

⁸⁵ See SSA §1860D–13(a)(2). The current law formula is about 25.5% of the cost of a standard Part D plan, as determined through annual bids submitted by insurers.

would have been \$39.35.⁸⁶ That would have been a 20% increase, which would have been the largest annual rise in the base premium since Part D was implemented. (See **Figure 5**).

For 2030 and subsequent years, the base premium is to be calculated as the percentage of average plan bids necessary to ensure that 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 using the underlying Part D formula of 25.5% of the average adjusted bid amount.

However, the base premium for 2030 and subsequent years may not be set at less than 20% of the weighted average of all plan bids.

In addition, under the IRA premium stabilization program, Medicare’s direct subsidies to Part D plan sponsors increase in any year from 2024 to 2029 in which the base premium would have risen by more than 6% from the previous year, absent the cap. After 2030, the direct subsidy level to plan sponsors could be adjusted, if the IRA formula for setting the base beneficiary premium from 2030 on produced a different percentage than 25.5% of weighted bids.⁸⁷

Low-Income Subsidies

Medicare Part D provides subsidies to assist low-income beneficiaries with premiums and cost sharing.⁸⁸ For 2023, LIS cost sharing varies according to a beneficiary’s assets and income and, also, whether a beneficiary is institutionalized, or is receiving community-based care. (See “Eligibility for Low-Income Assistance.”)

Premium Assistance

Full-Subsidy-Eligible Individuals in 2023

Low-income beneficiaries who qualify for a full subsidy do not pay monthly plan premiums if they enroll in certain, lower-cost Part D plans. A PDP qualifies as a lower-cost or “benchmark” plan if it offers basic Part D coverage and charges premiums equal to, or below, a regional low-income premium subsidy amount calculated by CMS each year. (See “Availability of Low-Income Plans.”) If a LIS beneficiary selects a plan with a premium that is higher than the regional benchmark, he or she must pay the extra cost.

⁸⁶ CMS, “CMS Releases 2024 Projected Medicare Part D Premium and Bid Information,” July 31, 2023, <https://www.cms.gov/newsroom/fact-sheets/cms-releases-2024-projected-medicare-part-d-premium-and-bid-information>.

⁸⁷ 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 IRA formula. 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.”

⁸⁸ While assistance with Part B premiums and cost sharing for low-income beneficiaries is primarily paid for by state Medicaid programs (through their Medicare Savings Programs), the Part D low-income subsidy is federally funded.

Partial-Subsidy-Eligible Individuals

For plan year 2023, partial-subsidy-eligible individuals receive premium assistance based on an income sliding scale, as specified in **Table 4**.

Table 4. Sliding-Scale Premium for Partial-Subsidy-Eligible Individuals

Federal Poverty Level (FPL) and Asset Thresholds	Percentage of Premium Subsidy Amount
Income up to or at 135% FPL; assets that do not exceed the calendar year resource limits for individuals or couples.	100%
Income above 135% FPL but at or below 140% FPL; assets that do not exceed the calendar year resource limits for individuals or couples.	75%
Income above 140% FPL but at or below 145% FPL; assets that do not exceed the calendar year resource limits for individuals or couples.	50%
Income above 145% FPL but below 150% FPL; assets that do not exceed the calendar year resource limits for individuals or couples.	25%

Source: SSA Program Operations Manual, Section HI 03030.025, “Resource Limits for Subsidy Eligibility,” at <https://secure.ssa.gov/poms.nsf/lnx/0603030025>.

Cost-Sharing Subsidies

Cost-sharing subsidies for LIS enrollees are linked to the standard prescription drug benefit but represent the maximum cost sharing that can be applied to LIS enrollees in any type of Part D plan. Full-subsidy dual eligibles have no deductible, minimal cost sharing during the initial coverage period and coverage gap, and no cost sharing above the catastrophic threshold. Partial-subsidy individuals have higher cost sharing. (See **Table 5**.)

Other specific policies related to cost sharing during the initial coverage period and coverage gap for dual eligibles include the following:⁸⁹

- Full-benefit, dual eligibles who are residents of medical institutions or nursing facilities have no cost sharing, with some exceptions. Enrollees with home and community-based services in lieu of institutional care also have no cost sharing.
- Other full-benefit, dual-eligible individuals with incomes up to or at 100% of FPL pay \$1.45 for a generic drug prescription or preferred multiple-source drug prescription and \$4.30 for any other drug prescription up to the catastrophic threshold in 2023.
- Full-subsidy-eligible individuals with incomes between 100% and 135% of FPL have cost sharing, up to the catastrophic limit, of \$4.15 for a generic drug or preferred multiple-source drug and \$10.35 for any other drug in 2023.

Partial-subsidy-eligible individuals have a \$104 deductible in 2023, 15% coinsurance for all costs up to the catastrophic limit, and cost sharing above that level of \$4.15 for a generic prescription or preferred multiple source drug prescription and \$10.35 for any other prescription.

⁸⁹ CMS, *Medicare Part D Prescription Drug Manual*, Chapter 13, “Premium and Cost-Sharing Subsidies for Low-Income Individuals,” Section 60, Rev. October 1, 2018, at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter-13-Premium-and-Cost-Sharing-Subsidies-for-Low-Income-Individuals-v09-14-2018.pdf>.

Each year, cost-sharing amounts for full-benefit, dual eligibles up to or at 100% of FPL are updated by the annual percentage increase in the CPI-U. Cost sharing for all other beneficiaries, and the deductible for other full- and partial-subsidy-eligible individuals, are increased by the annual percentage increase in per capita beneficiary expenditures for Part D-covered drugs.

Table 5. Part D Standard Benefit Cost Sharing, 2023

(by per capita drug spending category)

Total drug Spending (Dollar Ranges)	Low-Income Subsidy (LIS)-Eligible Individuals					
	Non-LIS Beneficiaries		Full-Subsidy-Eligible		Other Subsidy Eligible	
	Paid by Part D	Paid by Enrollee	Paid by Part D	Paid by Enrollee	Paid by Part D	Paid by Enrollee
\$0 up to \$505 Deductible	0%	\$505	\$445	0	\$401	\$104
Between Deductible and Initial Coverage Limit (\$505.01-\$4,660)	75%	25%	100% less enrollee cost sharing	Institutionalized duals: \$0 Duals up to or at 100% of FPL: \$1.45/\$4.30 Others: \$4.15/\$10.35	85%	15%
Coverage Gap Between Initial Coverage Limit (\$4,660) and Catastrophic Threshold (about \$7,400)	5% (plus 70% manufacturer discount) for brand-name drugs and 75% for generic drugs	25% for brand-name drugs and 25% for generic drugs	100% less enrollee cost sharing	Institutionalized duals: \$0 Duals under 100% of FPL: \$1.45/\$4.30 ^a Others: \$4.15/\$10.35 ^b	85%	15%
Over Catastrophic Threshold	95%	5%	100%	\$0	100% less enrollee cost sharing	\$4.15/\$10.35 ^c

Source: CMS, “Announcement of Calendar Year (CY) 2023 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter.”

Notes: FPL is federal poverty level. Duals refers to dual eligibles.

- Maximum of \$1.45 per prescription for generic or preferred drugs that are multiple source drugs; \$4.30 per prescription for other drugs.
- Maximum of \$4.15 per prescription for generic or preferred drugs that are multiple source drugs; \$10.35 per prescription for other drugs.
- Cost sharing is the lower of 5% coinsurance or Minimum of \$4.15 per prescription for generic or preferred drugs that are multiple source drugs; \$10.35 per prescription for other drugs.

LIS Changes Starting in 2024

Starting in 2024, the IRA merges the two categories of LIS (full and partial) into one new LIS category that provides the more generous benefits of the full LIS. Also, starting in 2024, out-of-pocket spending for all Part D enrollees is capped at the catastrophic threshold. See **Table 5** for the 2024 cost-sharing subsidies for LIS and non-LIS enrollees.

Table 6. Part D Standard Benefit Cost Sharing, 2024
(by per capita drug spending category)

Total drug Spending (Dollar Ranges)	Non-LIS Beneficiaries		LIS Beneficiaries	
	Paid by Part D	Paid by Enrollee	Paid by Part D	Paid by Enrollee
\$0 up to \$545 Deductible	0%	\$545	\$545	0
Between Deductible and Initial Coverage Limit (\$545.01-\$5,030)	75%	25%	100% less enrollee cost sharing	Institutionalized duals: \$0 Duals up to or at 100% of FPL: \$0 Others: \$1.55/\$4.60
Coverage Gap Between Initial Coverage Limit (\$5,030.01) and Catastrophic Threshold (\$8,000)	5% (plus 70% manufacturer discount) for brand-name drugs and 75% for generic drugs	25% for brand-name drugs and 25% for generic drugs	100% less enrollee cost sharing	Institutionalized duals: \$0 Duals under 100% of FPL: \$1.55/\$4.60 ^a Others up to 150% FPL: \$4.50/\$11.20 ^b
Over Catastrophic Threshold	100%	0%	100%	\$0

Source: CMS, “Announcement of Calendar Year (CY) 2024 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter.” FPL is federal poverty level. Duals refers to dual eligibles.

Notes:

- Maximum of \$1.55 per prescription for generic or preferred drugs that are multiple source drugs; \$4.60 per prescription for other drugs.
- Maximum of \$4.50 per prescription for generic or preferred drugs that are multiple source drugs; \$11.20 per prescription for other drugs.

Employer Subsidies for Retiree Drug Coverage

The MMA included provisions to encourage employers to continue to offer prescription drug benefits to their Medicare-eligible retirees. Employers have several options for such coverage.

Retiree Drug Subsidy

Employers and union groups that provide prescription drug insurance to Medicare-eligible, retired workers may apply for federal retiree drug subsidies (RDS).⁹⁰ To qualify, an employer or union must offer drug benefits that are actuarially equivalent to, or more generous than, standard Part D coverage. Sponsors must submit applications for CMS approval at least 90 days prior to the beginning of a plan year.

Medicare provides payments for eligible retirees, defined as individuals entitled to Medicare Part A and/or are enrolled in Part B, and who live in the service area of a Part D plan. An individual must be a retired participant in an employer- or union-qualified group health plan or the Medicare-enrolled spouse or dependent of a retired participant. (An employer or union may sponsor its own Part D plan [see “Employer Group Waiver Plans” section, below].)

⁹⁰ CMS, “Retiree Drug Subsidy,” at <https://www.rds.cms.hhs.gov/>.

For each retiree enrolled in a qualified plan in 2023, sponsors receive a federal subsidy equal to 28% of gross prescription drug costs between a threshold of \$505 and a cost limit of \$10,350.⁹¹ The retiree subsidies have generally been less expensive for Medicare than enrolling these beneficiaries in a Part D plan. In 2023, the average annual RDS was forecast to be about \$619 per beneficiary compared to average Medicare per beneficiary costs of \$2,352 for Part D enrollees.⁹²

Prior to enactment of the ACA, group health plans offering qualified drug coverage were eligible to receive the Medicare RDS and, in addition, claim a federal tax deduction for the subsidy, along with the rest of the plan's spending on retiree health benefits. The ACA prohibited companies, beginning in 2013, from claiming a tax deduction for the Medicare RDS.⁹³ In addition, retiree health plans are not eligible for the Part D manufacturer discount program. Partly as a result, many employers have moved away from the RDS program, and toward EGWPs. The Medicare Trustees predict that the share of beneficiaries covered through the RDS will decline from about 20% of Part D enrollment in 2010 to about 1.5% by 2032.⁹⁴

Employer Group Waiver Plans

EGWPs are Part D group plans sponsored by large employers, state and local governments, and other entities.⁹⁵ EGWPs qualify for waivers of Medicare regulations in areas including enrollment, marketing, premiums, and benefit design. The waivers allow plan sponsors (employers or unions) to tailor Medicare EGWPs to their distinct retiree populations.⁹⁶

In general, CMS may waive or modify Medicare requirements that “hinder the design of, the offering of, or the enrollment in” employer-sponsored group Medicare plans.⁹⁷ More specifically, CMS may provide waivers of Medicare regulations to allow employers and unions to⁹⁸

- restrict enrollment in an EGWP to the employer's own retirees and eligible spouses and dependents of the retirees;
- subsidize EGWP premiums and set different premiums in different geographic areas of the country;
- offer national plans rather than plans in specific geographic regions;
- provide smaller networks of contracted pharmacies than are required for other Part D plans, so long as the networks are adequate to meet enrollee needs;

⁹¹ CMS, “Announcement of Calendar Year (CY) 2023 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,” p. 69.

⁹² 2023 Medicare Trustees Report, Table IV.B9, p. 152, and Table V.D1, p. 207.

⁹³ Internal Revenue Service, “Frequently Asked Questions: Retiree Drug Subsidy,” at <https://www.irs.gov/newsroom/frequently-asked-questions-retiree-drug-subsidy>.

⁹⁴ 2023 Medicare Trustees Report, Table IV.B7, p. 147.

⁹⁵ CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 12, “Employer/Union Sponsored Group Health Plans,” Rev. November 7, 2008, at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals>. Employers and unions may offer EGWP PDPs only to retirees, while MA EGWPs, including MA-PD plans, may be offered to retirees or current workers.

⁹⁶ Employers may also offer Medicare Part C (Medicare Advantage) EGWPs, including Part C plans with a Part D component. See CMS, “Employer Group Waiver Plans,” <https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/employer-group-waiver-plans-egwps>.

⁹⁷ Specific authority for EGWPs can be found at SSA §§1857(i) and 1860D-22(b).

⁹⁸ CMS, “Approved Part D Waivers,” <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/EGWP-Waivers.pdf>.

- offer a different benefit structure than Part D plans, so long as the EGWP meets requirements for the gross value of the overall benefit; and
- hold annual open enrollment periods at different times than the national Medicare open enrollment period for MA and Part D (October 15 through December 15).

Employers and unions may offer EGWPs under direct contract with CMS or through third parties that design and administer the benefit. EGWPs must comply with Part D requirements to offer an adequate formulary, provide lower cost sharing for LIS enrollees, and other enrollee protections. EGWP sponsors are not required to submit annual bids to CMS on the grounds that the process of putting together a bid could “hinder the design, offering, or enrollment in employer-sponsors coverage given the additional complexity and level of effort that would be required.”⁹⁹ EGWPs instead are paid by CMS based on the average national average bid of other Part D plans.

In addition, the coverage gap manufacturer discount is calculated differently for EGWPs than for regular Part D plans. In 2012, CMS issued rules that changed the definition of Part D supplemental benefits to exclude supplemental benefits offered through EGWPs.¹⁰⁰ Under the rule, supplemental benefits offered by an EGWP sponsor are considered non-Medicare benefits and treated instead as other health insurance that pays in a secondary position to Medicare. That means, in part, that manufacturer discounts in the coverage gap for EGWP plans are calculated based on the standard Part D benefit without taking into account any supplemental benefits.¹⁰¹ This allows EGWP sponsors to reduce cost sharing for enrollees in the coverage gap but still collect the maximum manufacturer discount. A Medicare Payment Advisory Commission (MedPAC) analysis found EGWPs made up about 16% of Part D enrollment in 2018 but accounted for 45% of manufacturer discounts.¹⁰² Starting in 2025, under the IRA, there will no longer be a coverage gap for all plans, including EGWPs, and the manufacturer discount program will be reconfigured.

Formulary Requirements

For a drug to be paid by Medicare’s prescription drug benefit, it must be a drug that is covered under Part D and included in the formulary of an individual’s Part D plan. (See “Formularies.”)

The MMA defines covered Part D drugs as (1) outpatient prescription drugs approved by the Food and Drug Administration (FDA), and used for a medically accepted indication; (2)

⁹⁹ CMS, “Insurance Standards Bulletin Series: Employer Prescription Drug Coverage that Supplemental Medicare Part D Coverage provided through an Employer Group Waiver Plan,” January 23, 2013. CMS, “Part C and D User Call,” November 6, 2013, at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartD-EGWP>.

¹⁰⁰ CMS, “Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes; Final Rule,” 77 *Federal Register* 22072, April 12, 2012, p. 22081, at <https://www.govinfo.gov/content/pkg/FR-2012-04-12/html/2012-8071.htm>. In its rulemaking, CMS amended 42 C.F.R. §423.100 to include in the definition of “other health or prescription drug coverage” any coverage offered by EGWPs other than basic prescription drug coverage. CMS also made a conforming change to the definition of supplemental benefits in §423.100 to exclude benefits offered by EGWPs. “With respect to EGWPs, this would mean that a manufacturer discount always would be applied before any additional coverage beyond Part D, whether offered by the EGWP itself or by another party,” according to CMS.

¹⁰¹ In 2014, CMS published a rule requiring EGWPs to ensure that any supplemental benefits comply with any applicable requirements for issuance under state insurance laws and/or ERISA rules (see January 25, 2013 Insurance Bulletin from the Center for Consumer Information and Insurance Oversight: [http://www.cms.gov/ccio/resources/Regulations-and-Guidance/index.html#Health Market Reforms](http://www.cms.gov/ccio/resources/Regulations-and-Guidance/index.html#Health%20Market%20Reforms)).

¹⁰² MedPAC, *Report to the Congress: Medicare Payment Policy*, March 13, 2020, p. 416, at https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-mar20_entirereport_sec-pdf/.

biological products that may be dispensed only upon a prescription and that are licensed under the Public Health Service (PHS) Act and produced at a licensed establishment; (3) insulin (including medical supplies associated with the injection of insulin); and (4) vaccines licensed under the PHS Act. Drugs can also be treated as part of a plan's formulary as the result of a beneficiary coverage determination or appeal.

Certain drugs are excluded from Part D coverage by law, including drugs specifically excluded from coverage under Medicaid. The exclusion applies to (1) drugs used for anorexia, weight loss, or weight gain; (2) fertility drugs; (3) drugs used for cosmetic purposes or hair growth; (4) drugs for symptomatic relief for coughs and colds; (5) prescription vitamins and minerals; and (6) covered drugs when the manufacturer requires, as a condition of sale, that associated tests be purchased exclusively from the manufacturer. Drugs used for the treatment of sexual or erectile dysfunction are excluded from coverage unless they are used to treat another condition for which the drug has been approved by the FDA.¹⁰³

If a state covers excluded drugs for Medicaid beneficiaries, it must also cover them for dual eligibles in cases where the drugs are determined to be medically necessary. Dual eligibles may therefore receive coverage from Medicaid for some drugs that are excluded from Medicare. Additionally, a Part D sponsor may elect to include one or more of these drugs in an enhanced Part D plan; however, no federal subsidy is available for the associated costs.

Drugs Covered by Other Parts of Medicare

Part D drug plans are prohibited from covering drugs covered by other parts of Medicare. This includes prescriptions provided during a stay in a hospital or skilled nursing facility that are paid for by the Part A program, and the limited circumstances when Part B covers outpatient prescription drugs. Part B-covered drugs include drugs that are not usually self-administered and are provided incident to a physician's professional services or drugs necessary for the proper functioning of Part B durable medical equipment. These include such things as immunosuppressive drugs for persons who have had a Medicare-covered transplant; erythropoietin (an anti-anemia drug) for persons with end-stage renal disease; oral anticancer drugs; drugs requiring administration via a nebulizer or infusion pump in the home; and certain vaccines (influenza, pneumococcal, and hepatitis B for intermediate- or high-risk persons).¹⁰⁴

Formularies

Part D plans operate formularies, which are lists of drugs that a plan covers and the terms under which they are covered. A Part D sponsor's formulary must be developed and reviewed by a CMS-approved Pharmacy and Therapeutics (P&T) Committee.¹⁰⁵ A majority of the committee members must be practicing physicians or practicing pharmacists, and the committees must each

¹⁰³ CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 6, "Part D Drugs and Formulary Requirements," Section 20.1, Rev. January 15, 2016, at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

¹⁰⁴ For an examination of Part D vs. Part B coverage issues see CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 6, "Part D Drugs and Formulary Requirements," Appendix C, Rev. January 15, 2016, at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

¹⁰⁵ CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 6, "Part D Drugs and Formulary Requirements" Section 30.1, Rev. January 15, 2016, at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>. The committee may be set up by a sponsor or a pharmacy benefit manager acting on behalf of the plan sponsor. Committee members must sign conflict of interest statements detailing economic or other relationships with entities affected by drug coverage decisions that could influence committee decisions.

include one physician and one pharmacist who are experts in caring for elderly or disabled individuals. CMS requires that P&T committees “must review for clinical appropriateness the practices and policies for formulary management activities, such as prior authorizations, step therapies, quantity limitations, generic substitutions, and other drug utilization activities that affect enrollee access.” However, P&T committee recommendations regarding these activities are advisory only and not binding on the Part D sponsors.¹⁰⁶ (See “Drug Utilization.”)

Formulary Categories and Classes

Formulary drugs are grouped into categories and classes of products that work in a similar way or are used to treat the same condition. The MMA required CMS to ask the United States Pharmacopeial Convention (USP)¹⁰⁷ to develop a list of categories and classes for plans and to periodically revise such classifications. A plan formulary must include at least two drugs in each category or class used to treat the same medical condition (unless only one drug is available in the category or class, or two drugs are available but one drug is clinically superior). The two-drug requirement must be met by providing two chemically distinct drugs. (Plans cannot meet the requirement by including two dosage forms or strengths of the same drug or a brand-name drug and its generic equivalent.)

Six Classes of Clinical Concern

In general, Part D drug plans are required to operate formularies that cover at least two drugs in each drug class and category. However, Part D plans are required to cover substantially all available drugs in the following six categories or classes: immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic.¹⁰⁸ Plan sponsors are not allowed to steer beneficiaries who are already using these drugs toward alternative therapies via policies such as requiring prior authorization or step-therapy mandates (see “Drug Utilization”). The protected classes requirement, which started as CMS guidance, is designed to mitigate the risk that drug therapy could be interrupted for vulnerable populations.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA; P.L. 110-275) and the ACA codified the six protected classes requirement, while directing the HHS Secretary to spell out more specific criteria for identifying drug categories or classes of clinical concern.¹⁰⁹ As part of this process, the statutes allow HHS to revamp the current protected classes and categories, including permitting Part D sponsors to exclude certain drugs from their formularies (or limit access to such drugs through utilization management or prior authorization

¹⁰⁶ CMS, *Medicare Prescription Drug Benefits Manual*, Chapter 6, “Part D Drugs and Formulary Requirements,” §30.1.5, Rev. January 15, 2016, at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>; and SSA 1860D-4(b)(3).

¹⁰⁷ The United States Pharmacopeial Convention (USP) is a nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients and dietary supplements.

¹⁰⁸ CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 6, “Part D Drugs and Formulary Requirements,” Section 30.2.5, Rev. January 15, 2016, at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

¹⁰⁹ The MIPPA required that, beginning with plan year 2010, the HHS Secretary identify categories and classes of drugs for which both of the following criteria are met: (1) restricted access to drugs in the category or class would have major or life threatening clinical consequences for individuals who have a disease or disorder treated by the drugs in such category or class and (2) there is significant clinical need for such individuals to have access to multiple drugs within a category or class due to unique chemical actions and pharmacological effects of the drugs within the category or class. The ACA specified that the six drug categories or classes of clinical concern would remain in place until the HHS Secretary established new criteria to identify drug categories or classes of clinical concern under §1860D-4(b)(3)(G) of the Social Security Act through notice and rulemaking.

restrictions).¹¹⁰ In November 2018, CMS published a proposed rule that would have given Part D plan sponsors more authority to use step therapy and prior authorization to control enrollee utilization in the protected classes.¹¹¹ In May 2019, CMS announced it would not implement most of the proposed changes but instead would put into regulatory form existing guidance regarding protected class drugs. Under the final rules, plans may use step therapy and prior authorization for enrollees beginning a course of therapy with drugs in the six protected classes to confirm a drug's intended use is for a protected class indication; to ensure clinically appropriate use; and to promote utilization of preferred formulary alternatives, or a combination thereof. Step therapy and prior authorization are not allowed for antiretroviral (HIV/AIDs) medications.¹¹² CMS decided against a broader expansion of step therapy because the risks of inappropriately interrupting therapy outweighed the potential clinical benefits and cost savings.¹¹³

Vaccines

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

The Tax Relief and Health Care Act of 2006 (P.L. 109-432) required that Part D plans, beginning in 2008, include all commercially available vaccines in their drug formularies, with the exception of vaccines covered under Medicare Part B. Medicare Part B generally covers vaccinations for influenza, pneumonia, and the Hepatitis B vaccine for intermediate to high-risk cases. Part B will cover immunizations for patients exposed to an injury or disease, such as tetanus shots.¹¹⁴ Part B also covers COVID-19 vaccines.¹¹⁵

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

¹¹⁰ In January 2014, CMS issued proposed rules that would have narrowed the protected classes to anticonvulsants, antiretrovirals, and antineoplastics, beginning in plan year 2015. Antipsychotic drugs would have continued to be treated as a class of clinical concern in 2015 and until CMS determined that it was appropriate to change the criteria for these products. In May 2014, CMS announced it would not finalize the proposed regulations relating to the six protected classes. See CMS, "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs; Proposed Rule," 79 *Federal Register* 29844, pp. 1936 and 2063, January 10, 2014, at <http://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2013-31497.pdf>.

¹¹¹ CMS, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses," Proposed Rule, 83 *Federal Register* 62152, November 30, 2018, p. 62152, <https://www.federalregister.gov/documents/2018/11/30/2018-25945/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses>.

¹¹² *Ibid.*, §30.2.5. Part D sponsors may not implement prior authorization or step therapy requirements designed to steer enrollees already taking a drug to a preferred alternatives within the six classes. This includes beneficiaries already enrolled in a Part D plan as well as new enrollees who were actively taking drugs in any of the six classes of clinical concern prior to enrollment into the plan. If a sponsor cannot determine at the point of sale whether an enrollee is currently taking a drug (e.g., new enrollee filling a prescription for the first time), the sponsor is to treat such enrollee as though he or she is currently taking the drug.

¹¹³ CMS, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses," Final Rule, 84 *Federal Register* 23832, May 23, 2019, p. 23840, at <https://www.federalregister.gov/documents/2019/05/23/2019-10521/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses>.

¹¹⁴ CMS, Medicare Learning Network, "Medicare Part D Vaccines," June 2023, at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Vaccines-Part-D-Factsheet-1CN908764.pdf>.

¹¹⁵ CRS Report R46334, *Selected Health Provisions in Title III of the CARES Act (P.L. 116-136)*.

Starting in 2023, under the IRA, Part D plans may no longer apply a deductible, coinsurance, or other cost-sharing requirement for adult vaccines covered by Part D that are recommended by ACIP.¹¹⁶ An enrollee may have to pay a vaccine administration fee for an ACIP-recommended vaccine at the point of service, but can receive full reimbursement from their Part D plan. Part D plans may apply cost sharing to other, non-ACIP recommended vaccines.

Plan-Year Formulary Changes

Part D plans may alter their formularies from year to year and are allowed to make limited changes to their formularies within a plan year.¹¹⁷ Plans generally may not change therapeutic categories and classes of drugs within a plan year, except to account for new therapeutic uses or add newly approved Part D drugs. If Part D plans remove drugs from their formularies during a plan year (or change cost-sharing or access requirements), they must provide timely notice to CMS, affected enrollees, physicians, pharmacies, and pharmacists.

Part D sponsors may immediately remove brand-name drugs from a formulary (or change the cost-sharing tier) during a plan year if they replace the brand-name product with a therapeutically equivalent generic that is placed on the same or lower cost-sharing tier and is subject to the same or less restrictive utilization criteria than the brand-name drug. To qualify for substitution, the new generic must have been released to the market after the initial formulary was submitted.¹¹⁸

Other formulary changes may be made in the following circumstances:

- Plans may immediately remove drugs that are deemed unsafe by the FDA or are pulled from the market by their manufacturers. Plans do not have to provide prior notice of such actions, but must provide retrospective notice to CMS and other affected parties.
- After March 1 each year, Part D sponsors may make maintenance changes to their formularies, such as replacing brand-name with new generic drugs or modifying formularies due to new information on drug safety or effectiveness.
- Plans, with CMS approval, may remove drugs from a formulary, move covered drugs to a less-preferred tier status, or add utilization management requirements in accordance with approved procedures after 30 days' advance notice.¹¹⁹

¹¹⁶ CMS, "Contract Year 2023 Program Guidance Related to Inflation Reduction Act Changes to Part D Coverage of Vaccines and Insulin," September 26, 2022, <https://www.cms.gov/files/document/irainsulinvaccinesmemo09262022.pdf>. According to CMS, the ACIP Vaccine Recommendations and Guidelines also provide recommendations for use in limited populations and circumstances for certain other vaccines that are not on the CDC/ACIP Adult Immunization Schedule for routine immunization. CMS interprets the requirements of P.L. 117-169 as also applying to vaccines provided in such limited populations and circumstances, when used for adults in accordance with ACIP recommendations.

¹¹⁷ CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 6, "Part D Drugs and Formulary Requirements," Section 30.3, Rev. January 15, 2016, at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

¹¹⁸ CMS, "Medicare Program: Contract Year 2019 Policy and Technical Changes to Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, Medicare Prescription Drug Benefit Programs, and the PACE Program," 83 *Federal Register* 16440, April 16, 2018, p. 16604, at <https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf>.

¹¹⁹ *Ibid.* In most cases, plans may not remove covered Part D drugs from their formularies, or make any change in preferred or tiered cost-sharing status of a covered Part D drug, between the beginning of the annual coordinated election period October 15, and 60 days after the beginning of the contract year.

Transition Policies

CMS established Part D formulary transition policies to ensure that enrollees who move to a new plan do not abruptly lose coverage for drugs used in ongoing therapy—for example, in a case where a new plan does not cover a drug a beneficiary has been using. Transition policies also cover cases where enrollees are affected by formulary changes in their current plan from one year to the next.¹²⁰ In such cases, a beneficiary may request that their physician check to see if a prescription can be switched to a similar drug on the new formulary. If the physician determines that a specific drug is medically necessary, the doctor may request a plan exception.

Plans must continue a beneficiary's previous prescription during the first 90 days of a calendar year. Any refill must be for an approved month's supply (unless the prescription is written for a shorter period) for any drug not on the plan's formulary.¹²¹ The requirement also applies to drugs that are on a plan's formulary, but which require prior authorization or step therapy. Transition policies also cover situations where enrollees undergo changes in the level of care, such as moving from a hospital to home care.

Drug Utilization Management Programs

CMS regulations require that each Part D plan have an appropriate drug utilization management program that (1) includes incentives to reduce costs when medically appropriate, and (2) maintains policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications.¹²² In general, over the years plans have imposed more stringent cost-sharing and utilization management. Congress and CMS have also imposed utilization requirements on plans in an effort to identify possible program fraud and abuse involving certain prescription drugs, particularly opioids. (See “Part D Opioid Overutilization Monitoring.”)

Tiered Formularies

Plan D plan sponsors may assign formulary drugs to tiers that correspond to different levels of cost sharing. In general, this structured pricing encourages use of generic medications by placing these medicines on the plan tier with the lowest out-of-pocket costs, and discourages the use of more expensive or less effective drugs by putting them on tiers that require higher out-of-pocket spending. Plans have some flexibility in structuring the tiers, so long as the overall plan is at least actuarially equivalent to a standard Part D plan. In 2023, a Part D formulary design could include a mix of the following tiers: preferred generics, generics, preferred brands, non-preferred brands, non-preferred drugs, and two specialty drug tiers.¹²³ Specialty drug tier designation in Part D is

¹²⁰ For example, if a plan sponsor alters an announced formulary to account for a new drug or therapeutic use. According to CMS, a minimum of a 108-day look-back (consistent with other reviews) is typically needed to document ongoing drug therapy.

¹²¹ CMS, “Medicare Program: Contract Year 2019 Policy and Technical Changes to Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, Medicare Prescription Drug Benefit Programs, and the PACE Program,” 83 *Federal Register* 16440, April 16, 2018, p. 16604, at <https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf>. See also 42 C.F.R. §423.120. The rule changed the transition requirement to an approved month's supply (from a 30-day supply) so that it will be equivalent to the approved month's supply measurement in the applicable plan's annual bid to provide Part D services. The rule also shortened the length of transition prescriptions that are provided to residents of long-term care facilities to an approved month's supply.

¹²² 42 C.F.R. §423.153.

¹²³ CMS, “Contract Year (CY) 2023 Final Part D Bidding Instructions,” February 3, 2022, <https://www.cms.gov/files/document/2023partdbiddinginstructions.pdf>.

based on cost (\$830 per month in 2023), not on special handling requirements.¹²⁴ (For 2024, a drug will qualify for specialty tier placement if it is at least \$950 for a month.¹²⁵)

Part D plans may institute two specialty tiers for expensive products (e.g., unique drugs or biologics). Beneficiaries cannot appeal cost-sharing amounts for drugs placed on a specialty tier, except to request that a specialty drug on a higher cost-sharing tier be placed on a lower cost-sharing specialty tier.¹²⁶ Plans typically charge a percentage of the cost of a drug on the specialty tier (coinsurance), rather than a flat co-payment. To ensure beneficiaries dependent on specialty drugs are not unduly discouraged from enrolling in tiered plans, CMS sets the maximum allowable cost sharing for a single specialty tier—or, in the case of a plan with two specialty tiers, the higher cost-sharing specialty tier—at 25% coinsurance if the plan requires a standard deductible and up to 33% cost sharing if no deductible is required, or some percentage in between if a plan offers a reduced (but not zero) deductible. Therefore, according to CMS, for plans that offer two specialty tiers, the cost sharing for the lower cost-sharing, preferred specialty tier must be anything less than that of the higher cost-sharing specialty tier.¹²⁷

The specialty tier is not necessarily the tier with the highest coinsurance. Part D plans may charge coinsurance of up to 50% for drugs on a non-preferred brand-name formulary tier. According to CMS, best practices for developing formularies dictate that drugs are placed in a non-preferred tier only when drugs that are therapeutically similar (i.e., drugs that provide similar treatment outcomes) are in more preferable positions on the formulary.¹²⁸ CMS reviews plan sponsors' drug tier placement to ensure their formulary does not substantially discourage enrollment of certain beneficiaries, such as those with potentially high drug costs.

Other Drug Utilization Controls

Other utilization restrictions include (1) prior authorization, in which a beneficiary, with assistance of a prescribing physician, must obtain a plan's approval before it will cover a particular drug; (2) step therapy, where a beneficiary must first try a generic or less expensive drug, or a drug that a plan has deemed to be therapeutically equivalent to a prescribed drug, rather than the drug that was originally prescribed; and (3) quantity limits, where the supply of drugs is initially limited to reduce the likelihood of waste (e.g., if a drug was not effective for a beneficiary or had intolerable side effects). A beneficiary who wants his or her plan to waive a utilization control must provide a physician statement indicating that a prescribed drug and dosage is medically necessary and providing a rationale as to why restrictions are not appropriate.

¹²⁴ Ibid. Under 42 C.F.R. §423.104(d)(2)(iv)(D), CMS sets the maximum allowable cost sharing for a single specialty tier, or, in the case of a plan with two specialty tiers, the higher cost-sharing specialty tier, at 25% if the plan requires the standard deductible, 33% cost sharing if no deductible is required, or some percentage in between dependent on a decreased deductible. For plans that offer two specialty tiers, the cost sharing for the lower cost-sharing, preferred specialty tier must be anything less than that of the higher cost-sharing specialty tier.

¹²⁵ CMS, "Final Contract Year (CY) 2024 Part D Bidding Instructions," April 4, 2023, <https://www.cms.gov/files/document/final-cy-2024-part-d-bidding-instructions.pdf>.

¹²⁶ CMS, "Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly," 86 *Federal Register* 5864, January 19, 2021, p. 5931, <https://www.federalregister.gov/documents/2021/01/19/2021-00538/medicare-and-medicare-programs-contract-year-2022-policy-and-technical-changes-to-the-medicare>.

¹²⁷ CMS, "Contract Year (CY) 2023 Final Part D Bidding Instructions," February 3, 2022.

¹²⁸ CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 6, "Part D Drugs and Formulary Requirements," Section 30.2.7, Rev. January 15, 2016, at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

Part D Opioid Overutilization Monitoring

Since 2013, CMS has operated a system to combat inappropriate utilization of opioids in Part D. First, CMS has encouraged Part D plans to enhance their formulary and drug utilization review programs to provide opioid safety controls at the point of sale, retrospectively review drug claims to identify beneficiaries at risk of overutilization, and perform case management for beneficiaries deemed at risk of opioid abuse.¹²⁹ Second, CMS developed a program-wide Overutilization Monitoring System (OMS) to verify that Part D sponsors have established effective and appropriate opioid management programs. Under the OMS, CMS performs retrospective reviews of Part D prescription data to identify enrollees at risk of opioid overutilization. CMS defines at-risk beneficiaries as those using high dosages of opioids (over a specified period of time) provided by multiple prescribers or pharmacies.¹³⁰

The Comprehensive Addiction and Recovery Act of 2016 (CARA; P.L. 114-198) provided Part D sponsors with authority to limit the number of pharmacies and prescribers that can be used by enrollees identified as at risk of overutilization of frequently abused drugs, beginning in 2019. This “lock-in” provision is designed to reduce fraud and abuse by making it easier to control enrollee opioid use.¹³¹ Starting in 2022, the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act; P.L. 115-271) required Part D plan sponsors to implement lock-in programs.¹³²

OMS and lock-in policies do not apply to Part D beneficiaries who are being treated for active cancer-related pain, receiving palliative or end-of-life care, or are residents of certain long-term care facilities, including those that dispense frequently abused drugs through a contract with a single pharmacy.¹³³

Medication Therapy Management

Part D plans (with some exceptions) must include a Medication Therapy Management (MTM) program, which is a system of coordinated pharmacy care for patients with multiple medical conditions who may be seeing a series of practitioners. A MTM program includes medication reviews, patient consultation and education and other services. Each plan’s program must be reviewed and approved annually by CMS, and is one of several, required elements considered when CMS evaluates a sponsor’s bid to participate in the Part D program.

Part D sponsors must automatically enroll beneficiaries in a MTM program if they meet the following criteria: (1) they have multiple chronic diseases, with three being the maximum that

¹²⁹ CMS, “Announcement of Calendar Year (CY) 2013 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,” April 2, 2012, p. 131, at <https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/2013-Call-Letter.pdf>.

¹³⁰ For a description of the OMS, see “Announcement of Calendar Year (CY) 2018 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, and see p. 234 of the CMS 2019 Final Call Letter, at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvSpecRateStats/Downloads/Announcement2019.pdf>.

¹³¹ CMS, “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program,” 83 *Federal Register* 16440, April 16, 2018, pp. 16442-16480. <https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf>.

¹³² For the latest information, see CMS, “Part D Drug Management Programs,” Rev. 5, April 20, 2023, <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/rxutilization>.

¹³³ CMS, “Part D Drug Management Program Policy Guidance,” November 20, 2018, <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization>.

can be required; (2) they are taking at least two to eight Part D drugs; and (3) they are likely to have annual covered drug costs that exceed \$4,935 in 2023.¹³⁴ (The 2024 MTM program annual cost threshold is \$5,330.¹³⁵)

In addition, the SUPPORT Act added Part D enrollees identified as at risk for prescription drug abuse to the list of targeted MTM program enrollees. The provision took effect in 2022.¹³⁶

Part D Plans: Payment and Participation

Medicare Part D enrollees must obtain coverage through a private insurer, or other entity, that contracts with Medicare (a plan sponsor). As previously described, beneficiaries may select either a stand-alone PDP or a MA plan that includes prescription drug coverage.¹³⁷

PDPs are required to be available region-wide within each of the 34 designated PDP regions. MA-PD plans are generally local, operating on a countywide basis; however, region-wide MA-PD plans are available in many of the 26 MA regions in the United States. A PDP sponsor may offer a PDP in more than one region, including all PDP regions; however, the sponsor must submit separate coverage bids for each region it serves.¹³⁸ Medicare payments to plans are determined through a competitive bidding process, and enrollee premiums are tied to plan bids. (See “Approval of PDPs.”)

Approval of PDPs

Each year, CMS issues guidance through an annual call letter, and publishes updated program regulations and bidding instructions to sponsors planning to offer PDP and/or MA plans in the following year. Potential PDP and MA sponsors must submit bids by the first Monday in June of the year prior to the plan benefit year. The following information must be included in the bid: (1) coverage to be provided; (2) actuarial value of qualified prescription drug coverage in the region of a beneficiary with a national average risk profile; (3) information on the bid, including the basis for the actuarial value, the portion of the bid attributable to basic coverage and, if applicable, the portion attributable to enhanced coverage, and assumptions regarding the reinsurance subsidy; and (4) service area. The bid also includes costs (including administrative costs and return on investment/profit) for which the plan is responsible. The bid must exclude costs paid by enrollees, payments expected to be made by CMS for reinsurance (although plans provide a separate estimate of reinsurance costs), and any other costs for which the sponsor is not responsible.¹³⁹

¹³⁴ CMS, “2023 Medication Therapy Management Program Information and Submission Instructions,” April 15, 2022, <https://www.cms.gov/files/document/memo-contract-year-2021-medication-therapy-management-mtm-program-submission-v-052220.pdf>.

¹³⁵ 42 C.F.R. §423.153(d)(2) and CMS, “2024 Medication Therapy Management Program Information and Submission Instructions,” April 23, 2023, <https://www.cms.gov/files/document/memo-contract-year-2021-medication-therapy-management-mtm-program-submission-v-052220.pdf>.

¹³⁶ §6064 of the SUPPORT Act. CRS Report R45449, *The SUPPORT for Patients and Communities Act (P.L.115-271): Medicare Provisions*.

¹³⁷ The Part D sponsors are private entities licensed to offer health insurance under state law. Alternatively, they could meet solvency standards established by CMS for entities not licensed by the state.

¹³⁸ If two or more plans are not available in a region (one of which is a PDP), Medicare is required to contract with a “fallback” plan to serve beneficiaries in that area. Because of the large number of Part D plans participating in the program, CMS has not needed to solicit bids from fallback contractors.

¹³⁹ See CMS, “Instructions For Completing the Prescription Drug Plan Bid Pricing Tool for Contract Year 2023,” April 8, 2022.

CMS may approve a drug plan only if certain requirements are met. For example, the plan must meet requirements relating to actuarial determinations and beneficiary protections. The plan cannot be designed in a way (including any formulary or tiered formulary structure) that would likely discourage enrollment by certain beneficiaries. If their bids are approved, plan sponsors enter into 12-month contracts with CMS. CMS imposes a two-year Part D application ban on sponsors that were approved to offer PDPs for a coming plan year, but withdrew their bids after CMS announced the annual LIS premium benchmark amounts.¹⁴⁰

Noninterference Provision

To bolster market competition and limit the federal role, the MMA included a *noninterference provision* (SSA §1860D-11(i)), stating that in carrying out the requirements of the Part D program, “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.”¹⁴¹

In the nearly two decades since the MMA was enacted, Congress has debated proposals to repeal or modify the noninterference provision in order to give the HHS Secretary authority to negotiate drug prices. Supporters of secretarial negotiation maintain that by leveraging the combined purchasing power of tens of millions of Part D enrollees, the Secretary could secure larger price reductions from manufacturers than can be obtained by plan sponsors. The Congressional Budget Office (CBO) in analyses of such legislation generally held that the Secretary was not likely to have sufficient negotiating leverage unless given authority to create a central formulary, set prices administratively, and/or take other actions if manufacturers failed to cut prices.

In 2022, as part of the IRA, Congress amended the noninterference provision to give the HHS Secretary authority to negotiate prices for a set number of high spending Part D drugs each year, with the first negotiated prices taking effect in 2026.¹⁴² The CBO scored the drug price negotiation provision as having a cost savings, because the IRA imposes a steep excise tax on manufacturers of Part D drugs that refuse to negotiate.¹⁴³

Plan Availability

According to MedPAC, for 2023, Part D plan sponsors offered 3,539 MA-PDs and 1,254 MA-PDs that are special needs plans aimed at specific populations, an increase of 5% and 11%, respectively, from the previous year. In 2023, plan sponsors offered 804 PDPs, 5% above 2022.¹⁴⁴

Availability of Low-Income Plans

A Part D plan qualifies as a LIS benchmark plan if it offers basic Part D coverage and charges premiums that are equal to, or lower than, the average, regional low-income benchmark premium. Regional LIS benchmark premiums are recalculated annually, based on the weighted average of

¹⁴⁰ CMS, “CMS Finalizes Program Changes for Medicare Advantage and Prescription Drug Benefit Programs for Contract Year 2016,” February 6, 2015, at <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-02-06.html>.

¹⁴¹ Social Security Act, §1860D-11(i).

¹⁴² CRS In Focus IF11318, *Negotiation of Drug Prices in Medicare Part D*.

¹⁴³ CRS Report R47396, *Health Care Provisions of the Budget Reconciliation Measure P.L. 117-169*.

¹⁴⁴ MedPAC, *Report to the Congress: Medicare Payment Policy*, March 15, 2023, p. 385 at <https://www.medpac.gov/document/march-2023-report-to-the-congress-medicare-payment-policy/>.

all premiums in each of the 34 PDP regions. LIS beneficiaries are eligible for a full or reduced premium, up to the benchmark amount.¹⁴⁵

The formula for determining the benchmark is based on premiums for basic prescription drug coverage, or the actuarial value of basic prescription drug coverage for plans that offer enhanced coverage. For MA-PD plans, the formula uses the portion of the premium attributable to basic prescription drug benefits.

In 2023, there are 191 benchmark plans available, down 4% from 2022. All regions have at least three benchmark Part D plans available.¹⁴⁶ LIS beneficiaries enrolled in a plan that loses its benchmark status for a coming plan year either are enrolled automatically in a new plan by CMS or must select a new plan to avoid paying premiums and other cost-sharing requirements. (See “LIS Enrollment.”)

Plan Payments

Medicare provides a subsidy for each non-LIS Medicare enrollee in a Part D plan that is equal to 74.5% of average, standard coverage. The average subsidy takes two forms: *direct subsidy payments* and *reinsurance payments*. Medicare also establishes *risk corridors* to limit a plan’s overall losses or profits. In addition, Medicare pays most of the cost sharing and premiums for LIS beneficiaries enrolled in PDP or MA-PD plans.

Direct Subsidies

Medicare makes monthly prospective payments (direct subsidies) to plans for each Part D enrollee. The per-enrollee subsidy is based on the nationwide average of plan bids for providing basic drug coverage,¹⁴⁷ weighted by the plans’ shares of total enrollment. (The national average monthly bid is \$34.71 for plan year 2023.)¹⁴⁸ A plan’s total subsidy amount across all plan enrollees is risk-adjusted to account for the health status of the beneficiaries expected to enroll; plans with sicker enrollees receive a higher subsidy based on Medicare data on the health history of those enrollees. The subsidy is further adjusted to cover expected, additional costs associated with LIS enrollees in that plan. Lastly, the payment is reduced by the base beneficiary premium for the plan times the number of enrollees.

Reinsurance Subsidies

Medicare subsidizes 80% of each plan’s costs for catastrophic coverage—the reinsurance subsidy. For 2023, plan sponsors are liable for 15% of costs and enrollees have maximum 5% coinsurance. (See “Part D Benefit Structure.”) Prospective reinsurance payments to plans are made on a

¹⁴⁵ CMS, Medicare Part D Prescription Drug Manual, Chapter 13, “Premium and Cost-Sharing Subsidies for Low-Income Individuals,” Section 50.2.1, Rev. October 1, 2018, at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter-13-Premium-and-Cost-Sharing-Subsidies-for-Low-Income-Individuals-v09-14-2018.pdf>. The premium subsidy is equal to the lesser of the plan’s premium for basic prescription drug coverage or the regional low-income premium subsidy amount as calculated. The regional low-income premium subsidy amount is the greater of the PDP region’s low-income benchmark premium amount or the lowest monthly beneficiary premium for a PDP that offers basic prescription drug coverage in the PDP region.

¹⁴⁶ Ibid.

¹⁴⁷ The calculation of the national average monthly bid amount does not include bids submitted by Medical Savings Account (MSA) plans, MA private fee-for-service plans, specialized MA plans for special needs populations (SNP), Program of All-Inclusive Care for the Elderly (PACE) plans, or plans established through reasonable cost contracts.

¹⁴⁸ CMS, “Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information,” July 29, 2022, at <https://www.cms.gov/files/document/july-29-2022-parts-c-d-announcement-pdf.pdf>.

monthly basis during the year, with final reconciliation made after the close of the year when plans have data on their actual costs. Medicare subsidies for reinsurance are now the largest component of Part D and also are the fastest-growing portion of the program.

As explained in “Standard Prescription Drug Coverage,” beginning in 2025, the IRA reduces to 20% from 80% the federal reinsurance subsidy to Part D sponsors for catastrophic coverage for applicable drugs (brand-name, biologic, and biosimilar drugs) and to 40% from 80% for non-applicable drugs (generics).¹⁴⁹

Beneficiary Cost Sharing/Direct and Indirect Remuneration

Beneficiary cost sharing for Part D drugs dispensed by network pharmacies is based on each sponsor’s negotiated price for a drug.¹⁵⁰ Negotiated prices, as defined by CMS for 2023, are the total amount network pharmacies receive from Part D plans for dispensing a covered drug, inclusive of all pharmacy price concessions except those that cannot reasonably be determined at the point of sale.¹⁵¹ Starting in 2024, CMS will define negotiated prices as the lowest possible price paid by a plan to a pharmacy at the point of sale. Negotiated prices must not be rebated back to a plan sponsor in full or in part.¹⁵²

When a beneficiary fills a prescription at a network pharmacy, the plan sponsor compiles a summary record called a Prescription Drug Event (PDE). The PDE includes a range of information, such as the amount paid to the pharmacy for the drug, quantity dispensed, out-of-pocket spending by the beneficiary, and coverage by qualified third parties, such as other insurers. CMS and plan sponsors use PDE data to track out-of-pocket and total drug spending (plan plus beneficiary spending) as enrollees move through stages of the Part D benefit.¹⁵³

Prescription drug price concessions that are not passed on to enrollees at the point of sale are not included in PDE records but instead are reported to CMS as direct and indirect remuneration (DIR). DIR includes such things as discounts, manufacturer rebates, free or reduced-price services, grants, or other benefits from manufacturers, pharmacies, or similar entities.¹⁵⁴ Plans must submit detailed DIR reports to CMS within six months after the close of a plan year.

During each plan year, CMS makes monthly prospective payments to Part D sponsors based on estimated costs in their annual plan bids. After the close of each plan year, CMS uses PDE and DIR data along with other information during the reconciliation process, to determine whether sponsors have been overpaid or whether Medicare owes them money. (See “Reconciliation.”)

¹⁴⁹ CRS Report R47396, *Health Care Provisions of the Budget Reconciliation Measure P.L. 117-169*.

¹⁵⁰ As defined at 42 C.F.R. §423.100. Enrollees can be charged the usual and customary price (list price) for a drug, rather than the negotiated price, when filling a prescription at an out-of-network pharmacy.

¹⁵¹ 42 C.F.R. §423.100.

¹⁵² 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.

¹⁵³ For more CMS information on PDE data see <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PartDData.html>.

¹⁵⁴ DIR is defined at 42 C.F.R. §423.308, under “Actually Paid.”

Risk Corridor Payments

The MMA established risk corridors for Part D plans. Under the risk corridors, Medicare limits plan sponsors' potential losses, or gains, by financing some higher-than-expected costs, or recouping some excessive profits, relative to the amount the plan originally bid to offer Part D. Risk corridors are based on a plan's allowable costs (spending) relative to a percentage of its target amount (revenues), as defined below:

- Allowable costs are defined as costs (excluding administrative costs, but including costs directly related to drug dispensing) incurred by a plan sponsor or organization that are actually paid (net of discounts, chargebacks, and average percentage rebates from drug manufacturers) by the sponsor or organization. Plans may not include costs for benefits beyond the Part D basic benefit amount. The costs are reduced by the sum of reinsurance payments and LIS payments.¹⁵⁵
- The target amount is defined as total payments to a plan (including amounts paid by both Medicare and enrollees) based on a plan's standardized bid for offering the Part D drug benefit,¹⁵⁶ as risk adjusted. The target amount does not include administrative expenses assumed in the plan's standardized bid.¹⁵⁷

At the end of each year, CMS compares a Part D plan's allowable costs to its target amount and shares in any gains or losses within a predetermined range, or corridor. For 2023, a plan that has higher-than-expected costs must cover all benefit spending up to 105% of its standardized bid. A plan with costs above 105% and up to 110% of its bid must cover 50% of the costs within this range and CMS will pay the other 50%. A plan with costs above 110% of the bid must pay 20% of this additional amount, with CMS covering the other 80%.

Likewise, a plan that spends less than its standardized bid may keep all savings between 100% and 95% of the bid. A plan that has spending below 95% to 90% of its bid may keep 50% of the savings within this range, while rebating 50% to CMS. A plan with savings below 90% of the bid may keep 20% of the savings within this range and must rebate 80% to CMS. CMS has the authority to leave the risk corridors unchanged or to widen them. CMS has elected to keep the corridors at 2011 levels through the 2024 program year.¹⁵⁸ CMS does not have authority to narrow the risk corridors.

Table 7. Plan Liability Under Part D Risk Corridor Provisions

Risk Corridor	Plan Liability for Costs Above and Below Target
2006-2007	
Costs below 95% of target	80% refund
Costs between 95% and 97.5% of target	75% refund
Costs between 97.5% and 102.5% of target	Full risk
Costs between 102.5% and 105% of target	Risk for 25% of amount

¹⁵⁵ Social Security Act §1860D-15(e)(1)(B).

¹⁵⁶ The plans' standardized bid is their estimated cost of providing the standard Part D drug benefit. This bid is used in the calculation to determine plan payments.

¹⁵⁷ Social Security Act §1860D-15(e)(3)(B).

¹⁵⁸ CMS, "Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies," February 1, 2023, p. 91, <https://www.cms.gov/medicare/health-plans/medicareadvtspecratestats/announcements-and-documents/2024-advance-notice>.

Risk Corridor	Plan Liability for Costs Above and Below Target
Costs over 105% of target	Risk for 20% of amount
2008-2021	
Costs below 90% of target	80% refund
Costs between 90% and 95% of target	50% refund
Costs between 95% and 105% of target	Full risk
Costs between 105% and 110% of target	Risk for 50% of amount
Costs over 110% of target	Risk for 20% of amount

Source: CMS, “2023 Initial Call Letter.”

Reconciliation

Following the close of a calendar year, CMS makes retroactive adjustments to sponsors’ direct subsidy payments. The direct subsidy payments are adjusted based on updated data about actual beneficiary health status and enrollment. Additionally, prospective payments for reinsurance and LIS payments are compared to actual incurred costs, net of any DIR (including discounts, chargebacks, or rebates from drug manufacturers), and other related data, and adjustments are made to the plan payments. Finally, any necessary adjustments are made to reflect risk sharing under the risk corridor provisions. (See **Table 8**.)

Table 8. Medicare Part D Risk Corridor Payments

(in billions of dollars)

Year	Net Risk-Sharing Payments
2013	- 0.7
2014	- 0.1
2015	- 1.1
2016	- 1.1
2017	-0.5
2018	0.0
2019	0.5
2020	1.5
2021	1.2
2022	1.1
2023	2.7

Source: 2023 Medicare Trustees Report, Table IV.B10.

Notes: Positive amounts represent net payments from CMS to Part D insurers, and negative amounts represent net payments from the plans to CMS. The amounts may include the delayed settlement of risk sharing from prior years. Figure for 2023 is an estimate.

Reduction of Part D Plan Payments Under Sequestration

Under the Budget Control Act of 2011 (BCA; P.L. 112-25), most Medicare benefit-related payments have a 2% sequestration reduction.¹⁵⁹ The BCA mandatory spending sequester is scheduled to continue each year through FY2031. Under Part D, Medicare payments to plans for direct subsidies and retiree drug subsidies are reduced by this amount. Payments for reinsurance, risk-sharing, and the LIS are exempt from these reductions. Part D plans are not permitted to increase premiums or cost sharing or to reduce benefits to make up for their lower payments.¹⁶⁰

Expected Shifts in Part D Sponsor Reimbursement Due to the IRA

The 2022 IRA requires changes to the Part D standard benefit that are projected to result in large shifts in subsidy payments to Part D sponsors. For example, effective in 2025, the IRA reduces reinsurance payments to Part D plans; caps enrollee out-of-pocket spending at \$2,000; and reconfigures the manufacturer discount program to, among other things, apply to drugs purchased by LIS enrollees. The IRA also imposes mandatory price negotiation for certain Part D drugs, as well as mandatory rebates for drugs with price increases above consumer inflation. The 2023 Medicare Trustees Report projects that, in part due to the IRA, Part D reinsurance spending will decline from \$1,153 per enrollee in 2024 to \$628 per enrollee by 2032. At the same time, the direct subsidy will rise from a forecast \$383 per enrollee in 2024 to \$1,618 in 2032. Medicare per capita LIS will decline from \$2,588 in 2024 to \$1,434 in 2032. The Medicare Trustees also project that Medicare will make larger risk-sharing payments to plans under the Part D risk corridors through 2032.¹⁶¹

Pharmacy Access and Payment

Part D sponsors are required to establish pharmacy networks sufficient to ensure access to covered Part D drugs for all enrollees. Sponsors must provide (1) convenient access to retail pharmacies, (2) adequate access to home infusion pharmacies, (3) convenient access to long-term care (LTC) pharmacies for residents of LTC facilities, and (4) access to Indian Health Service, Tribes, or Urban Indian Programs pharmacies operating in a sponsor's service area.

Any Willing Pharmacy

Part D sponsors must permit any pharmacy that is willing to accept the sponsor's standard contracting terms and conditions to participate in the plan's network, including mail-order pharmacies.¹⁶² A sponsor's standard terms and conditions, particularly reimbursement terms, may vary to accommodate geographic areas or types of pharmacies, so long as all similarly situated pharmacies are offered the same standard terms and conditions. Part D plans are required to (1) make standard pharmacy contract terms and conditions available by September 15 of each year

¹⁵⁹ For additional information on sequestration and Medicare, see CRS Report R45106, *Medicare and Budget Sequestration*.

¹⁶⁰ CMS Memorandum, "Additional Information Regarding the Mandatory Payment Reductions in the Medicare Advantage, Part D, and Other Programs," May 1, 2013, at <https://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/Downloads/PaymentReductions.pdf>.

¹⁶¹ 2023 Medicare Trustees Report, pp. 148-152.

¹⁶² CMS, *Medicare Prescription Drug Manual*, Chapter 5, "Benefits and Beneficiary Protections," Section 50.8.1, Rev. September 30, 2011, at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf.

for contracts effective on January 1 of the following year, and (2) provide a copy of a standard contract to a requesting pharmacy within seven business days after receiving such a request.¹⁶³

Preferred Pharmacy

While any qualified pharmacy can participate in a plan network, Part D plans, with the exception of plans offering defined, standard coverage,¹⁶⁴ may contract with a smaller subset of pharmacies, or pharmacy chains, to serve as preferred pharmacies.¹⁶⁵ Preferred pharmacies generally are marketed as having lower beneficiary cost sharing than other pharmacies in the plan network. Enrollees who sign up for a preferred pharmacy plan may still use other network pharmacies in their plan region, but may pay more to fill a prescription at a non-preferred pharmacy.

The creation of a preferred pharmacy network must not increase overall CMS payments to a Part D plan.¹⁶⁶ In addition, the cost differential between preferred and non-preferred pharmacies cannot be set at a level that discourages enrollees in certain locations, such as inner cities or rural areas, from enrolling in a Part D plan.

Retail Pharmacy Access

To ensure that enrollees have convenient access to covered drugs, Part D networks must include a sufficient number of pharmacies that dispense drugs directly to patients (other than mail order).

CMS defines *convenient access* as follows:

- In urban areas, at least 90% of Medicare beneficiaries in a Part D sponsor's service area, on average, live within 2 miles of a retail pharmacy participating in the sponsor's network.
- In suburban areas, at least 90% of Medicare beneficiaries in the sponsor's service area, on average, live within 5 miles of a retail pharmacy participating in the sponsor's network.
- In rural areas, at least 70% of Medicare beneficiaries in the sponsor's service area, on average, live within 15 miles of a retail pharmacy participating in the sponsor's network.¹⁶⁷

¹⁶³ CMS, "Medicare Program: Contract Year 2019 Policy and Technical Changes to Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, Medicare Prescription Drug Benefit Programs, and the PACE Program," 83 *Federal Register* 16440, April 16, 2018, p. 16589, at <https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf>. Final rule is 42 C.F.R. §423.38.

¹⁶⁴ Because cost sharing cannot be changed under defined standard coverage, such plans cannot have price differences based on the pharmacy used.

¹⁶⁵ The rules are waived in certain instances, such as MA-PD plans that offer access to drugs through retail pharmacies owned and operated by the MA organization that offers the plan. See CMS, *Medicare Prescription Drug Manual*, Chapter 5, "Benefits and Beneficiary Protections," Section 50.9, Rev. September 30, 2011, at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf.

¹⁶⁶ *Ibid.*

¹⁶⁷ CMS recognizes that the rural standard can be impracticable or impossible to meet in such areas, and will consider modifications in certain cases. CMS, *Medicare Prescription Drug Manual*, Chapter 5, "Benefits and Beneficiary Protections," Section 50.10, Rev. September 30, 2011, at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf.

Mail-Order Pharmacy Access

Part D plans have the option of including mail-order pharmacies in their networks, although they may not count such pharmacies in meeting retail pharmacy access requirements.¹⁶⁸ Plan sponsors may offer a subset of formulary drugs (such as a particular tier of drugs or maintenance drugs) through mail-order pharmacies. If a Part D plan offers a mail-order pharmacy benefit (such as a 90-day supply of a maintenance drug) it must ensure that enrollees have reasonable access to the same benefit at retail network pharmacies. Part D sponsors may charge enrollees more for filling certain prescriptions at a retail pharmacy, rather than a mail-order pharmacy, within set limits.¹⁶⁹

Specialty Pharmacy Access

Part D plans may designate certain pharmacies as *specialty pharmacies* for the distribution of drugs where the FDA has restricted distribution of the drug to certain facilities or physicians or appropriate dispensing requires extraordinary special handling, provider coordination, or patient education that cannot be met by a network pharmacy. Part D plans may not require enrollees to use a specialty pharmacy to fill a prescription solely because a drug has been placed on a Part D plan specialty drug tier. Plans may set their own definition and fee structure for specialty pharmacies and specialty networks, including preferred specialty networks. However, such contracting conditions must be reasonable and relevant and must be applied consistently.

Long-Term Care Pharmacy Access

Part D sponsors must offer convenient LTC pharmacy access to beneficiaries in LTC facilities.¹⁷⁰ In meeting this access requirement, plan sponsors must offer standard LTC pharmacy network contracts to all LTC pharmacies operating in their service area that request such contracts. The pharmacies must be able to meet performance and service criteria specified by CMS, as well as any standard terms and conditions established by the Part D sponsor. Part D sponsors may not rely on out-of-network pharmacies to meet the LTC convenient access standards.

Home Infusion Pharmacy Access

Part D covers certain home-infusion drugs, which are prescription drugs given intravenously in a home setting. Administration of such drugs may require supplies and equipment such as tubing and catheters or special pumps. Part D plan sponsors must be able to deliver home-infusion drugs to enrollees within 24 hours after the enrollees are released from an acute care setting, unless the next dose of the medication is not due to be taken for more than 24 hours. (An acute care setting

¹⁶⁸ CMS, *Medicare Prescription Drug Manual*, Chapter 5, “Benefits and Beneficiary Protections,” Section 50.10 and 50.2, Rev. September 30, 2011, at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf.

¹⁶⁹ *Ibid.*, §50.10. Sponsors may require an enrollee to pay higher cost sharing up to an amount equal to the mail-order cost sharing plus any differential in contracted rates between retail and mail-order, but plans may charge beneficiaries a lower cost sharing at retail if they so choose. Some pharmacies may ship drugs to patients in long-term care facilities or in rural areas. A pharmacy that makes some but not the predominance of its deliveries through the mail is not a mail-order pharmacy.

¹⁷⁰ *Ibid.*, §50.5.1. “Part D sponsors must demonstrate that they have a network of contracted LTC pharmacies that provide convenient access to LTC pharmacies for enrollees who reside in LTC facilities. In order to demonstrate convenient access to LTC pharmacies, Part D sponsors must include, as part of their initial pharmacy access submissions, a list of all contracted LTC pharmacies. In addition, Part D sponsors are required to submit an updated list of all contracted LTC pharmacies as part of the annual Part D reporting requirements.”

is a hospital, ambulatory care unit, or similar facility where a patient receives treatment for a serious but brief illness.)

Out-of-Network Access

In general, a beneficiary must go to a pharmacy in his or her Part D network. However, in cases where enrollees cannot reasonably be expected to obtain covered drugs at a network pharmacy, and when such cases are not routine, a Part D plan must ensure that enrollees have adequate access to out-of-network pharmacies.¹⁷¹ One example would be if a Part D enrollee were traveling in the United States, came down with an illness, and needed to have a prescription filled. Another possible scenario would be a federal disaster declaration in the case of major storm or other event, where a beneficiary was not able to use an in-network provider. In 2020, CMS and Congress made special provision for Part D early refills and out-of-network pharmacy access during the COVID-19 public health emergency (PHE).¹⁷²

Part D plans must craft reasonable guidelines for out-of-network usage, including limits on out-of-network access such as limiting the quantity of drugs dispensed or the purchase of maintenance medications via mail order for extended out-of-area travel. In general, plans may not routinely allow more than a month's worth of medication to be dispensed at an out-of-network pharmacy. Enrollees likely will be required to pay more for a covered Part D drug purchased out of the plan network than one purchased at a network pharmacy.

Payments to Pharmacies

Part D sponsors often own or hire pharmacy benefit managers (PBMs) that design and/or administer many aspects of their Part D plans. PBMs are the middlemen in the prescription drug pricing system. Among other things, PBMs contract with pharmacies to participate in Part D networks, design plan formularies, and operate electronic systems for processing Part D claims. (See **Appendix A** for more information.) PBMs, acting on behalf of plan sponsors, generally reimburse pharmacies at a contractually set rate for the cost of a drug (ingredient cost) plus a dispensing fee.¹⁷³ Sponsors separately reimburse the PBMs for the drugs. PBM pharmacy reimbursement for generic drugs generally is based on a maximum allowable cost (MAC) list, where a PBM sets a ceiling price based on a survey of market prices for the product. Part D MAC lists must be updated on a regular basis.¹⁷⁴ For brand-name drugs, PBMs often reimburse pharmacies based on a list price (such as the Average Wholesale Price, or AWP, which is the estimated price paid by a retailer to a wholesaler), minus a set percentage.

Pharmacies negotiate separately with wholesalers or manufacturers for the drugs they dispense. PBM pharmacy contracts and accompanying guidance may impose various conditions, including

¹⁷¹ CMS, *Medicare Prescription Drug Manual*, Chapter 5, “Benefits and Beneficiary Protections,” Section 60, Rev. September 30, 2011, at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf.

¹⁷² CRS Report R46334, *Selected Health Provisions in Title III of the CARES Act (P.L. 116-136)*. See Section 3714.

¹⁷³ 42 C.F.R. §423.100 Dispensing fees are costs incurred at the point of sale in excess of the ingredient cost of a covered Part D drug. Dispensing fees include pharmacy costs such as checking insurance status, performing quality assurance, physical delivery, special packaging, and salaries of pharmacists and other pharmacy workers as well as the costs associated with maintaining the pharmacy facility and acquiring and maintaining technology and equipment.

¹⁷⁴ 42 C.F.R. §423.505(b)(21). Under CMS regulations for plan contracting, plan sponsors must update MAC lists at least every seven days and indicate the source for pricing data for the updates. Sponsors must disclose MAC prices in advance of their use for reimbursement.

pricing; audit terms; and quality requirements, such as set targets for accuracy in dispensing drugs. Contracts are confidential.

Part D sponsors are required to make payment for “clean claims,” within 14 calendar days of the date an electronic claim is received, and within 30 calendar days of the date that non-electronically submitted claims are received.¹⁷⁵ A clean claim is a claim that does not require further development or investigation (e.g., has all required documentation) or other special treatment that would prevent the claim from being paid in a timely manner. If payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days, the PDP sponsor or MA-PD plan must pay interest to the pharmacy that submitted the claim.

In recent years, Part D sponsors have imposed fees on pharmacies for not meeting contractually specified quality metrics (such as accuracy in filling prescriptions or goals for generic dispensing) or as a condition of participating in a preferred pharmacy network. PBM contracts also may provide incentive payments to pharmacies that exceed set standards. Because plan sponsors and their PBMs often calculate pharmacy fees based on performance over a period of time, the fees are reported to CMS as DIR. According to CMS, DIR pharmacy price concessions, net of all plan incentive payments to pharmacies, grew more than 45,000% from 2010 to 2017.¹⁷⁶

CMS considers pharmacy fees to be price concessions in the sense that they lower a Part D plan’s cost for dispensing a drug. In May 2022 CMS issued a final rule, effective in 2024, that changes the definition of a Part D negotiated price to the lowest possible reimbursement a network pharmacy is to receive for a particular drug, taking into account pharmacy price concessions such as fees.¹⁷⁷ The change is expected to reduce average prices at the pharmacy, benefiting enrollees.

Coverage Determinations, Appeals, and Grievances

Part D enrollees have the right to request or appeal coverage determinations, file grievances against plan sponsors, and file complaints regarding quality of care.¹⁷⁸ Part D plans must provide enrollees with written information about their rights, and institute both standard and expedited procedures for addressing coverage issues.¹⁷⁹ If a Part D sponsor operates a drug management program, the sponsor must comply with special appeal procedures for issues involving beneficiaries deemed at risk of prescription drug abuse. (See “Part D Opioid Overutilization Monitoring.”)¹⁸⁰

¹⁷⁵ This provision was added by MIPPA and may be found at SSA §1860D-12(b)(4)(A)(ii).

¹⁷⁶ CMS, “Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenditures,” 83 *Federal Register* 62152, November 30, 2018, at <https://www.federalregister.gov/documents/2018/11/30/2018-25945/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses>.

¹⁷⁷ CMS, “Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs,” 87 *Federal Register* 27704, May 2022, at <https://www.federalregister.gov/documents/2022/05/09/2022-09375/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and>.

¹⁷⁸ CMS, *Medicare Appeals*, at <https://www.medicare.gov/Pubs/pdf/11525-Medicare-Appeals.pdf>.

¹⁷⁹ CMS, “Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance,” Effective August 2023, at <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev>.

¹⁸⁰ CMS, “Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance,” Section 40.3, Effective August 2023, <https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG> and <https://www.cms.gov/medicare/appeals-and-grievances/mmcag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf>.

An enrollee may appoint a representative to act on his or her behalf during the Part D grievance and appeals process such as a friend, relative, attorney, physician, or an employee of a pharmacy or a charity. To appoint a representative, an enrollee must submit a written statement to the drug plan sponsor.¹⁸¹ Alternatively, a surrogate or representative may be appointed by a court or authorized under a state or other applicable law to act on behalf of an enrollee. A prescribing physician or other prescriber may request a standard or expedited coverage determination, redetermination, or independent review entity (IRE) reconsideration on behalf of an enrollee without being named a representative.¹⁸² (Physicians or prescribers do not have all the rights of a designated representative unless they have gone through the formal appointment process.)

Coverage Determination

A coverage determination is any decision (whether an approval or denial) made by a plan sponsor with regard to covered benefits. Examples of coverage determinations include (1) a decision about whether to provide or pay for a Part D drug that an enrollee believes may be covered;¹⁸³ (2) a decision concerning a request about a specific drug payment tier;¹⁸⁴ (3) a decision concerning a request to cover a drug that is not included on a plan formulary; (4) a decision regarding cost-sharing levels; or (5) a decision regarding whether an enrollee has satisfied a prior authorization or other utilization management requirement. An enrollee, an enrollee's appointed representative, or his or her physician may file a request for a coverage determination.¹⁸⁵

An enrollee may also request an expedited decision regarding a drug that has not already been furnished. The plan is to make a decision within 24 hours in cases where using the standard timeframe may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function. A Part D sponsor that approves a request for expedited determination must make its determination and notification, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than within 24 hours.¹⁸⁶ If a Part D plan sponsor denies a request for an expedited determination, it must

- make the determination within the 72-hour timeframe established for a standard determination and
- give the enrollee and prescribing physician or other prescriber prompt oral notice of the denial.

¹⁸¹ An enrollee may request a representative by using a government form (Form CMS-1696) or by submitting an equivalent written notice that includes information about enrollee and is signed and dated by both the enrollee and the representative. There are exceptions in the case of institutionalized or incapacitated enrollees.

¹⁸² CMS, "Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance," Section 60.1, Effective August 2023.

¹⁸³ This includes a decision not to pay because the drug is not on the plan's formulary, the drug is determined not medically necessary, or the drug is furnished by an out-of-network pharmacy.

¹⁸⁴ The MMA provided that if a Part D plan includes a tiered cost-sharing structure, a plan enrollee can request an exception to the structure. Under an exception, a nonpreferred drug could be covered as a preferred drug if the prescribing physician determined that the preferred drug for treatment of the same condition would not be as effective for the individual, would have adverse effects for the individual, or both.

¹⁸⁵ CMS, "Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance," Section 40.2.

¹⁸⁶ CMS, "Coverage Determinations," <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/CoverageDeterminations->.

If a sponsor fails to notify the beneficiary of its decision within the established time frames, the decision is deemed an automatic denial, at which point the sponsor must forward the case to the independent review entity, the second level of appeal.¹⁸⁷

Appeals

If a plan sponsor's coverage determination is unfavorable, it must provide the affected enrollee with a written denial notice that includes information on appeals rights. An appeal is a request for a further review of a coverage determination.¹⁸⁸ There are five levels of appeals.

Redetermination

The first level of appeal is a *redetermination* by the plan. An enrollee, enrollee's representative, or enrollee's prescribing physician or other prescriber may request a standard or expedited redetermination by filing a written request with the plan sponsor. The request generally must be filed within 60 calendar days from the date printed or written on the written coverage determination denial notice. If a physician asks for, or supports, an expedited appeal on the grounds that waiting seven days could seriously harm an enrollee's health, the appeal is to automatically be expedited.¹⁸⁹

Plan sponsors must provide immediate access to the redetermination process through their websites. CMS strongly encourages plans to establish interactive, web-based systems to meet this requirement.

A plan sponsor must also provide an enrollee or prescribing physician with a reasonable opportunity to present evidence, and the redetermination must be made by a person not involved in the original coverage decision.¹⁹⁰ Enrollees are to be notified of the results within 7 days in the case of standard redetermination or within 72 hours for an expedited request. Part D sponsors must authorize payment for a benefit within 14 calendar days and must mail the payment no later than 30 calendar days after receiving the request.¹⁹¹

Reconsideration by an Independent Review Entity

At the second level of appeal, an enrollee dissatisfied with a redetermination has a right to *reconsideration* by an independent review entity (IRE) working under contract with CMS. An enrollee or an enrollee's appointed representative may request a standard or expedited reconsideration. The request must be made within 60 days of a redetermination. The IRE is required to make a decision within 7 days for a standard reconsideration and 72 hours for an expedited reconsideration. Plans must make payment in 14 days for a standard reconsideration.¹⁹²

¹⁸⁷ 42 C.F.R. §423.570.

¹⁸⁸ Individuals can appeal coverage determinations related to formulary drugs and nonformulary drugs. They cannot appeal denial of coverage for excluded drugs.

¹⁸⁹ CMS, "Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance," Section 50.7.1, Effective August 2023.

¹⁹⁰ If the issue is the denial of coverage based on medical necessity, the redetermination must be made by a physician.

¹⁹¹ CMS, "Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance," Section 60.3, Effective August 2023.

¹⁹² Ibid.

Additional Levels of Appeal

If the above appeals result in decisions unfavorable to the enrollee, several additional levels of review may be pursued.

At the third level of appeal, an enrollee or the appointed representative may request a hearing with an *administrative law judge* (ALJ). A request must be made within 60 days of the IRE decision letter. To qualify for an ALJ hearing, the projected value of denied coverage must meet a minimum dollar amount (\$180 for 2023).¹⁹³ An enrollee cannot request an expedited hearing if the only issue at question involves a request for payment of Part D drugs that have already been furnished.¹⁹⁴ There is a 90-day limit for a regular decision and a 10-day limit for an expedited decision.

The fourth level of appeal is the *Medicare Appeals Council* (MAC). A beneficiary or the appointed representative may request a review by the MAC within 60 days of the ALJ decision. The MAC may grant or deny the request for review. If it grants the request, it may issue a final decision or dismissal, or remand the case to the ALJ with instructions on how to proceed with the case. The review is to be completed within 90 days for a regular review and 10 days for an expedited review.

Standard Hearing

The final appeal level is a *federal district court*. A beneficiary or the appointed representative may request a review by a federal court within 60 days of the MAC decision notice. To receive a review by the court, the projected value of denied coverage must be greater than or equal to a minimum dollar amount (\$1,850 for 2023).

Grievances

Grievances are complaints or disputes other than those involving coverage determinations. Grievances may include such things as complaints about a plan's customer service hours of operation, the time it takes to get a prescription filled, or a plan's benefit design. A grievance may also include a complaint that a Part D plan refused to expedite a coverage determination or redetermination. A beneficiary with a grievance may file a complaint within 60 days of the event. Although CMS regulations do not require a Part D plan sponsor to consider a grievance that is filed after the 60-day deadline, the regulations do not prevent a plan sponsor from doing so on a case-by-case basis.¹⁹⁵

Plan sponsors are to respond in a timely manner. A Part D plan sponsor must respond to an enrollee grievance within 24 hours if it involves a refusal by the Part D plan to grant an enrollee's request for an expedited coverage determination or an expedited redetermination and the enrollee has not yet purchased or received the drug in dispute.¹⁹⁶ (Sometimes a complaint may involve both a grievance and a coverage determination.)

¹⁹³ "Medicare Part D Flowchart 2023," at <https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/Flowchart-Medicare-Part-D.pdf>.

¹⁹⁴ CMS, "Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance," Section 30, Effective August 2023.

¹⁹⁵ 42 C.F.R. §423.564.

¹⁹⁶ 42 C.F.R. §423.564.

Quality of Care Complaints

Complaints regarding quality of care received by Part D enrollees may be resolved by the plan sponsor, but also may be handled through a separate process: the Quality Improvement Organization (QIO) process.¹⁹⁷ The QIO program is implemented by a network of contractors throughout the United States that work with providers and beneficiaries to improve the quality of health care delivered to Medicare beneficiaries. When a Part D plan responds to an enrollee's grievance in writing, it must include a description of the enrollee's right to file a QIO grievance.¹⁹⁸ Quality of care grievances filed with a QIO may be filed and investigated beyond the 60-day time frame.

Program Spending and Financing

Medicare's financial operations are accounted for through two trust funds maintained by the Department of the Treasury—the Hospital Insurance (HI) trust fund for Part A and the Supplementary Medical Insurance (SMI) trust fund, which contains separate accounts for Parts B and Part D.¹⁹⁹ Unlike the HI program, SMI was not intended to be fully supported through dedicated sources of income. Instead, it relies primarily on general tax revenues and beneficiary premiums as revenue sources.

Expenditures

According to the 2023 *Medicare Trustees Report*, during 2022, total Part D expenditures were approximately \$125.7 billion.²⁰⁰ (See **Table 9**.) This amount included the combined costs of prescription drugs provided by Part D plans to enrollees, Medicare payments to employer-sponsored retiree health plans, and federal administrative expenses including expenses incurred by HHS, SSA, and the Department of the Treasury in administering Part D. Such duties include making payments to Part D plans and implementing fraud and abuse control activities.

Revenues

The major sources of revenue for the Part D account include general revenues, beneficiary premiums, and state contributions. In 2022, of the \$124.3 billion in total Part D income, general revenues accounted for \$92.4 billion, premiums accounted for \$17.6 billion, and transfers from states for \$13.7 billion.

The appropriation language adopted for the Part D account provides resources for benefit payments without the need for congressional approval. This allows substantial flexibility in the amount of general revenues available to the account, and eliminates the need for a contingency reserve. As a result, assets in the Part D account are generally low and only need to be held for a short time until they are used to meet immediate expenditures. As premium and general revenue

¹⁹⁷ Social Security Act, §1154(a)(14).

¹⁹⁸ For more information, see CMS, "Quality Improvement Organizations," at <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/index.html?redirect=/qualityimprovementorgs>.

¹⁹⁹ The MMA established within the Supplementary Medical Insurance (SMI) trust fund the Medicare Prescription Drug Account to be used in conjunction with the Part D prescription drug program. For additional information on Medicare program financing, see CRS Report R43122, *Medicare Financial Status: In Brief*.

²⁰⁰ 2023 Medicare Trustees Report, Table III.D3, p. 110, at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html>.

income for Part D is reset each year to match expected costs, the Medicare Trustees consider the Part D account to be in satisfactory financial condition under current law.

Beneficiary Premiums

Premiums made up 14.2% of total Part D program revenues in 2022. See “Part D Premiums.” The base premium is set at 25.5% of the expected per capita plan costs for basic coverage, although beneficiaries pay different premiums depending on the plan they select.²⁰¹ (The IRA premium stabilization formula caps base premium increases at 6% a year through 2029 and resets the formula for determining the base premium as a percentage of expected per capita plan costs in 2030.) LIS beneficiaries may have minimal or no premiums, depending on the plan in which they are enrolled. Beneficiaries with higher incomes pay income-related monthly premium adjustments in addition to the premiums charged by the plans in which they have enrolled. (See “Premium Surcharge for Higher-Income Enrollees.”) These extra amounts are credited to the Part D trust fund account and reduce the amount of general revenue funding needed.

General Revenues

General revenues are transferred from the Treasury to the Part D Account on an as-needed basis to cover the portion of program expenditures funded by federal subsidies. These transfers are based on expected costs of the direct subsidy, reinsurance payments, employer subsidies, LISs, net risk-sharing payments, administrative expenses, and advanced discount payments.²⁰² In 2022, contributions received from the general fund of the Treasury amounted to \$92.4 billion, or about 74.3% of total Part D revenue.

Table 9. Statement of Operations of Part D Account, CY2022
(in millions of dollars)

Assets at Beginning of Year	\$19,692.7
Revenues	\$124,344.0
Premiums from Enrollees	17,611.1
<i>Premiums deducted from Social Security checks</i>	5,236.4
<i>Premiums paid directly to plans</i>	12,374.7
Government Contributions	92,372.0
<i>Prescription drug benefits</i>	91,644.6
<i>Administrative expenses</i>	727.4
Payments from States	13,676.7
Interest	144.5
Expenditures	\$125,700.9
Benefit Payments	125,184.0
Federal Administrative Expenses	517.0

²⁰¹ CMS, “Annual Release of Part D National Average Bid Amount and Other Part C & D Bid Information,” July 29, 2022, at <https://www.cms.gov/files/document/july-29-2022-parts-c-d-announcement-pdf.pdf>.

²⁰² Beginning in 2011, prescription drug manufacturers of brand-name drugs provide a discount for their drugs when used during the coverage gap. Medicare makes payments prospectively to non-employer Part D plan sponsors and is reimbursed for these amounts once the sponsors receive the discounts from the manufacturers. This discount reduces beneficiary out-of-pocket costs, but has little net effect on federal Part D spending.

Assets at End of Year**\$18,335.8****Source:** 2023 Medicare Trustees Report, Table III.D1.**Note:** Totals may not add due to rounding.**State Contributions**

Subsequent to the availability of Part D drug coverage and LISs beginning in 2006, Medicaid is no longer the primary payer of drug costs for full-benefit dual-eligible beneficiaries. However, MMA contained a provision (labeled by some as the “clawback provision”) that requires states to pay the Part D account in the SMI trust fund a portion of the costs that they would have incurred for this population if they were still the primary payer. These amounts are based on the product of the estimated annual per capita full dual-eligible drug payment amount and the monthly State enrollment of full dual eligibles.

Starting in 2006, states paid 90% of these estimated costs. This percentage phased down over a 10-year period to 75% starting in 2015. In 2022, state payments amounted to \$13.7 billion, or about 11.3% of Part D revenues.

Estimated Future Part D Expenditures

Over the 10-year period from 2022 to 2032, the Medicare Trustees project that aggregate benefits are to increase 5.1% annually, on average, and the average per capita rate of growth is projected to be 2.6%. That is a slower rate of growth than the Medicare Trustees projected in 2022. The projections reflect the impact of the IRA provisions governing Part D redesign, as well as regulatory changes. See **Table 10** for information on historical and projected growth in Part D benefits.

Table 10. Historical and Projected Growth in Part D Benefits

Calendar Year	Aggregate Benefits^a (Billions)	Percentage Change	Per Capita Benefits	Percentage Change	Part D Benefits as a Percentage of GDP
<i>Historical data</i>					
2004	\$0.4	—	\$362	—	0.00%
2005	1.1	—	596	—	0.01
2006	47.1	—	1,708	—	0.34
2007	48.8	3.7%	1,556	–8.9%	0.34
2008	49.0	0.4	1,504	–3.3	0.33
2009	60.5	23.4	1,798	19.6	0.42
2010	61.7	2.0	1,775	–1.3	0.41
2011	66.7	8.1	1,868	5.3	0.43
2012	66.5	–0.4	1,776	–5.0	0.41
2013	69.3	4.2	1,772	–0.2	0.41
2014	77.7	12.1	1,919	8.3	0.44
2015	89.4	15.1	2,140	11.5	0.49
2016	99.5	11.2	2,302	7.6	0.53

Calendar Year	Aggregate Benefits ^a (Billions)	Percentage Change	Per Capita Benefits	Percentage Change	Part D Benefits as a Percentage of GDP
2017	100.1	0.7	2,251	-2.2	0.51
2018	94.7	-5.4	2,068	-8.1	0.46
2019	97.0	2.5	2,058	-0.5	0.45
2020	104.6	7.7	2,148	4.4	0.50
2021	104.5	-0.1	2,092	-2.6	0.45
2022	125.2	19.8	2,437	16.5	0.49
<i>Intermediate Estimates</i>					
2023	129.5	3.4	2,447	0.4	0.49
2024	138.7	7.2	2,545	4.0	0.50
2025	151.8	9.4	2,677	5.2	0.53
2026	161.5	6.3	2,767	3.3	0.54
2027	168.9	4.6	2,823	2.0	0.54
2028	173.3	2.6	2,831	0.3	0.53
2029	182.5	5.3	2,921	3.2	0.53
2030	190.2	4.2	2,992	2.4	0.54
2031	195.7	2.9	3,034	1.4	0.53
2032	205.7	5.1	3,151	3.9	0.53

Source: 2023 Medicare Trustees Report, Table III.D4

Notes: Amounts shown are on a cash basis. The Trustees Report uses three sets of assumptions: low cost, intermediate, and high cost. The intermediate assumptions represent the Trustees' best estimates of likely future economic and demographic conditions.

a. This amount does not include administrative expenses.

Appendix A. Drug Rebates and PBMs in Medicare Part D

Part D plan sponsors typically contract with or own pharmacy benefit managers (PBMs), which are intermediaries that perform services for health insurers such as developing plan formularies and negotiating price concessions from drug manufacturers. PBMs also develop networks of contracted retail pharmacies that dispense prescriptions for Part D plans for set reimbursement. PBMs generally do not take delivery of drugs, with the exception of in-house mail-order or specialty pharmacies.²⁰³

Part D price concessions primarily take the form of rebates—price reductions provided after the point of sale—from a list price for a brand-name drug.²⁰⁴ Plan sponsors and PBMs can secure rebates for including a brand-name drug on a plan formulary or for placing the drug on a favorable cost-sharing tier. The final value of a rebate can be tied to sales volume of a drug and may be aggregated and paid to the PBM in installments.

PBMs have the most leverage to negotiate rebates when there are competing drugs on the market for treating a condition. They have less ability to negotiate rebates for sole-source drugs or drugs in the six protected classes, where all drugs must be covered.

When Part D plan sponsors contract with PBMs under a pass-through pricing arrangement, the sponsor reimburses the PBM the same amount that the PBM paid the pharmacy for a given drug. If the sponsor uses a PBM lock-in contract, the PBM may negotiate to compensate pharmacies at a lower price for a drug than the price the PBM has guaranteed to the plan—a practice that is known as *spread pricing*.²⁰⁵ However, under Part D regulations, any difference between the PBM and pharmacy reimbursement must be reported to CMS as an administrative cost and enrollee cost sharing must be based on the lower pharmacy price. The Part D rules act as a disincentive to use spread pricing in the Part D program.

A 2019 Government Accountability Office (GAO) study found that PBMs performed 74% of drug benefit management services for Part D plans. PBM compensation primarily consisted of fees from plan sponsors, with PBMs retaining less than 1% of rebates they negotiated for Part D plans as compensation.²⁰⁶ According to the GAO, PBMs earned Part D revenue from a volume-based fee on PBM-processed claims; a per member, per month fee on plan sponsors; or a combination of the two.

Part D plans also may impose fees on network pharmacies for not meeting quality and other plan requirements. Over time, the volume of such pharmacy fees has increased dramatically.

²⁰³ Some large Part D sponsors own their own PBMs, including CVS Caremark, UnitedHealth Group, and a coalition of Blue Cross/Blue Shield plans. Other sponsors may contract with outside PBMs for services.

²⁰⁴ CMS, “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 Fees,” 84 *Federal Register* 2340, February 6, 2019, p. 2340, at <https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>.

²⁰⁵ HHS Office of the Inspector General, “Memorandum Report: Medicare Part D Pharmacy Discounts for 2008, OEI-02-10-100120, November 17, 2010, at <https://oig.hhs.gov/oei/reports/oei-02-10-00120.pdf>.

²⁰⁶ GAO, “Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization,” <https://www.gao.gov/assets/710/700260.pdf>.

According to CMS, Part D pharmacy price concessions, net of all pharmacy incentive payments, grew more than 107,400% between 2010 and 2020.²⁰⁷

Under the CMS interpretation of Part D negotiated price, plan sponsors have some latitude to include price concessions at the point of sale or to report them to CMS later as DIR.

In a 2005 *Federal Register* notice of final rules to implement the Part D program, CMS said it expected plan sponsors would pass through a high percentage of any drug price concessions in negotiated prices at the point of sale.²⁰⁸ However, in a 2018 *Federal Register* notice, CMS said that less than 1% of sponsors had passed through price concessions at retail pharmacies.²⁰⁹ The vast majority of price concessions, including manufacturer rebates and pharmacy fees are collected after the point of sale and reported to CMS as DIR.²¹⁰ In addition, plan sponsors generally have not included the value of pharmacy fees, which reduces plans' costs for dispensing drugs, in the Part D negotiated price.

Overall, DIR, which consists mainly of rebates, has risen from the equivalent of 12.9% of total Part D drug costs in 2013 to an estimated 33.6% of drug costs in 2023.²¹¹

The way in which plan sponsors apply and report price concessions—in negotiated prices or as DIR—has an impact on beneficiary out-of-pocket spending, plan premiums, and Medicare spending. Specifically,

- When plan sponsors do not apply rebates and other price concessions to negotiated prices at the point of sale, enrollees prescribed more expensive brand-name drugs may pay cost sharing, such as coinsurance, based on a plan's higher pharmacy price, rather than the lower net price that includes rebates and other price concessions that plan sponsors receive after the point of sale. Higher cost sharing means a greater burden on beneficiaries, and it also means more beneficiaries accumulate out-of-pocket spending sufficient to reach the catastrophic portion of the Part D benefit, where Medicare subsidizes a higher share of drug costs and sponsors' financial risk is reduced.
- When plan sponsors submit bids to CMS each June to provide Part D benefits for the following plan year, they must provide CMS with an estimate of expected DIR. The DIR reduces sponsors' projected costs for offering the Part D benefit. That, in turn, reduces plan premiums, which are based on the average of plan bids. Sponsors have a financial incentive to keep premiums low, because they are a key factor considered by beneficiaries when selecting Part D plans. Because

²⁰⁷ CMS, "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* 27704, May 9, 2022, p.1411, <https://www.federalregister.gov/d/2022-09375/p-1411>.

²⁰⁸ CMS, "42 C.F.R. Parts 400, 403, 411, 417, and 423 Medicare Program; Medicare Prescription Drug Benefit; Final Rules," 70 *Federal Register* 4194, January 28, 2005, p. 4244, at <https://www.federalregister.gov/documents/2005/01/28/05-1321/medicare-program-medicare-prescription-drug-benefit>.

²⁰⁹ According to CMS, in recent years less than 1% of plans have passed through any price concessions to beneficiaries at the point of sale, and the amount that is passed through is less than 1% of the total price concessions those plans receive. CMS, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenditures," 83 *Federal Register* 62152, November 30, 2018, p. 62174, at <https://www.federalregister.gov/documents/2018/11/30/2018-25945/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses>.

²¹⁰ Ibid.

²¹¹ 2023 Medicare Trustees Report, Table IV.B8, p. 150.

Medicare subsidizes about 75% of premiums, lower premiums also reduce Medicare spending in this area of the benefit.

During the past several years, CMS has put forth proposals to alter the Part D bidding and payment system to address concerns about rising drug prices, greater use of DIR, rising reinsurance costs, and enrollee out-of-pocket costs. For example, in a 2018 *Federal Register* notice, CMS asked for comment on whether to alter the definition of negotiated prices to (1) include all pharmacy price concessions received by a plan sponsor for a covered Part D drug and (2) reflect the lowest possible reimbursement a network pharmacy would receive, in total, for a particular drug.²¹² No rule was published at that time.²¹³ In May 2022, CMS issued a final rule, effective in plan year 2024, that changes the definition of a Part D negotiated price to the lowest possible reimbursement a network pharmacy is to receive for a particular drug, taking into account pharmacy price concessions such as fees.²¹⁴

On November 20, 2020, HHS issued a final rule to bar most drug rebates in Medicare Part D, effective in plan year 2022.²¹⁵ Implementation of the rule was delayed until 2026 as part of the Infrastructure Investment and Jobs Act (P.L. 117-158), subsequently was delayed until 2027 as part of the Bipartisan Safer Communities Act (P.L. 117-159), and was further delayed until 2032 as part of the 2022 IRA.

The IRA includes provisions that will affect drug prices and plan payment, including negotiation of certain Part D-covered drugs, mandatory rebates from manufacturers that raise prices above the rate of consumer inflation, and changes in Part D cost sharing. These changes are expected to have a large effect on drug pricing, including possible rebates and discounts. The 2023 Medicare Trustees Report projects that DIR will fall substantially as a share of Part D spending in coming years, largely due to the CMS regulations on negotiated prices and pharmacy payment, and the IRA provisions. The Medicare Trustees expect DIR to decline from the equivalent of 35% of Part D drug costs in 2023 to 14% by 2032.²¹⁶

²¹² CMS, “Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,” 83 *Federal Register* 62152, November 30, 2018, p. 62174, at <https://www.federalregister.gov/documents/2018/11/30/2018-25945/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses>.

²¹³ *Ibid.*, 62174.

²¹⁴ CMS, “Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; etc.,” May 9, 2022, <https://www.regulations.gov/document/CMS-2022-0012-4335>.

²¹⁵ CMS, “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 Fees,” November 20, 2020, at <https://www.hhs.gov/sites/default/files/rebate-rule-discount-and-pbm-service-fee-final-rule.pdf>. (Rule has not yet been published in the *Federal Register*.) According to the rule, “Several of the positive and negative transfers are imperfect offsets of one another. For example, the analyses commissioned for this rule estimated that the amount saved by reducing cost sharing exceeds the cost of any increase in premiums for beneficiaries overall. However, more beneficiaries would pay more for premiums, if premiums rise, than they would save in cost sharing, suggesting that out-of-pocket impacts are likely to vary by individual and the greatest benefit of these transfers accrues to sicker beneficiaries (e.g., those with more drug spending and/or those using high cost drugs).”

²¹⁶ 2023 Medicare Trustees Report, p. 150.

Appendix B. IRA Drug Price Negotiation in Part D

The 2022 law known as the Inflation Reduction Act (IRA; P.L. 117-169) requires the Secretary of the Department of Health and Human Services (HHS) to negotiate prices for certain single-source chemical drugs and biologics covered under Medicare Parts D and B.²¹⁷ To be selected for negotiation, a chemical drug cannot have a marketed generic substitute and must have been approved by the Food and Drug Administration (FDA) for at least seven years, while a biologic cannot have a marketed biosimilar substitute and must have been licensed by FDA for at least 11 years. In addition, the product must be among the 50 qualifying single-source drugs with the highest gross spending in Part B or Part D.

The Secretary must negotiate maximum fair prices (MFPs) for 10 drugs that come into effect in 2026, 15 additional drugs for each of 2027 and 2028, and 20 additional drugs for 2029 and each following year. For the first two years (2026 and 2027), the program applies only to Part D drugs.

The IRA excludes the following drugs from negotiation:

- low-spend drugs (i.e., drugs with Medicare spending of less than \$200 million; indexed for inflation in subsequent years);
- plasma-derived products;
- orphan drugs designated for only one rare disease and for which the only FDA-approved indication is for such disease;²¹⁸ and
- certain products made by small biotech firms (through 2028).²¹⁹

The Secretary may delay negotiation of qualifying biologic products for up to two years when the Secretary determines there is a high likelihood that a biosimilar will soon enter the market.²²⁰

In August 2023, HHS announced the first 10 drugs selected for negotiation under the Program, with negotiated prices to become effective in 2026.²²¹ In October 2023, the Secretary announced that all nine manufacturers of the selected drugs had agreed to participate in negotiations.²²²

²¹⁷ Biologics are pharmaceuticals derived from a living organism that can be many times the size of a conventional (small-molecule or chemical) drug and have a more complex structure. A biosimilar is a follow-on to a biologic that is “highly similar,” notwithstanding minor differences in clinically inactive components. There are no clinically meaningful differences between a biosimilar and the reference biologic product in terms of safety, purity, and potency of the product. The Patient Protection and Affordable Care Act (ACA; P.L. 111-148, as amended) provided a period of exclusivity for manufacturers of certain biologic brand-name drugs and biosimilar products.

²¹⁸ The Orphan Drug Act covers drugs intended to treat rare conditions, generally defined as those affecting fewer than 200,000 people in the United States, or those affecting more than 200,000 people but for which there is no reasonable expectation that the costs of developing the drug will be recouped in the United States. (21 U.S.C. §360bb). Under the provisions of the Orphan Drug Act, an orphan drug may be indicated for use in multiple diseases or conditions. The IRA’s orphan drug exception is thus not inclusive of all orphan drugs.

²¹⁹ See IRA §11001.

²²⁰ IRA §11002

²²¹ HHS, “Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026,” August 29, 2023, <https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html>. HHS Assistant Secretary for Evaluation and Planning, “—Inflation Reduction Act Research Series—Medicare Enrollees’ Use and Out-of-Pocket Expenditures for Drugs Selected for Negotiation under the Medicare Drug Price Negotiation Program,” Revised September 13, 2023. CMS was required to choose the 10 drugs from the negotiation-eligible pool of 50 based on their total spending rank.

²²² HHS, “Biden-Harris Administration Moves Forward with Medicare Drug Price Negotiations to Lower Prescription Drug Costs for People with Medicare,” October 3, 2023, <https://www.hhs.gov/about/news/2023/10/03/biden-harris-administration-moves-medicare-drug-price-negotiations-lower-prescription-drug-costs-people-medicare.html>.

The Secretary and manufacturers are to engage in negotiations on MFPs for the selected drugs from October 1, 2023 to August 1, 2024. During the negotiation period, the Secretary is to consider factors including each manufacturer’s research and development costs for the drug, production cost, any federal financial support for development of the drug, data on patents and on existing and pending exclusivities. The Secretary is to publish the negotiated MFPs for 2026 no later than September 1, 2024. Each subsequent year under the program, MFPs are to take effect two years after new drugs are selected for negotiation.

The IRA sets a ceiling on the MFP, based on the lesser of

- the weighted average net price of the drug or biologic under Part D (and starting in 2028, average Part B prices)²²³ or
- a percentage of the non-federal average manufacturer price (non-FAMP). The non-FAMP is a wholesaler price, minus certain discounts, that is used in calculating a maximum price for drugs by the “big four” federal purchasers: the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the Coast Guard. The MFP ceiling is 75% of the non-FAMP for a drug that has been approved for less than 16 years or 40% of the non-FAMP for a drug that has been approved for at least 16 years.²²⁴

An MFP is calculated across all dosage forms and strengths of a drug and is in effect until the first year beginning at least nine months after a generic or biologic substitute for a drug is marketed. Part D plans must carry all drugs with an MFP in their formularies.

Author Information

Suzanne M. Kirchhoff
Analyst in Health Care Financing

Disclaimer

This document was prepared by the Congressional Research Service (CRS). CRS serves as nonpartisan shared staff to congressional committees and Members of Congress. It operates solely at the behest of and under the direction of Congress. Information in a CRS Report should not be relied upon for purposes other than public understanding of information that has been provided by CRS to Members of Congress in connection with CRS’s institutional role. CRS Reports, as a work of the United States Government, are not subject to copyright protection in the United States. Any CRS Report may be reproduced and distributed in its entirety without permission from CRS. However, as a CRS Report may include copyrighted images or material from a third party, you may need to obtain the permission of the copyright holder if you wish to copy or otherwise use copyrighted material.

²²³ For Part B drugs, the average price is the ASP from the previous year. For Part D, the average price is based on data from the most recent year available.

²²⁴ Starting in 2030, the IRA includes a third MFP ceiling, which is to be 65% of the non-FAMP for a selected drug that has been approved or licensed for at least 12 years but fewer than 16 years.