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Medicare Part D Prescription Drug Benefit

Updated December 18, 2020

Congressional Research Service
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R40611

CRS REPORT
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SUMMARY

R40611

December 18, 2020

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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 61.3 million Medicare beneficiaries in 2019 (the most recent data available) who were eligible for Part D, 45.4 million (74% of beneficiaries) were enrolled in a Part D plan and another 1.4 million (about 2% of beneficiaries) had prescription drug coverage through a former employer that received a Part D subsidy for a portion of the coverage. Of the remaining roughly 24% of Medicare beneficiaries, about half (12% of beneficiaries) had drug coverage as generous as Part D through another source, such as the Federal Employees Health Benefits program, TRICARE, or private coverage; the other half (about 12% of beneficiaries) had either less generous coverage than Part D or no drug coverage at all.

Total Part D expenditures were approximately $97.6 billion in calendar year 2019. Medicare Part D has cost less than originally forecasted, due in part to lower-than-predicted enrollment and increased use of less expensive generic drugs. However, the Medicare Trustees project spending on Part D benefits will accelerate over the next 10 years due to the expectation of further increases in the number of enrollees, costs associated with the elimination of the out-of-pocket cost coverage gap in 2020, changes in the distribution of enrollees among coverage categories, a slowing of the trend toward greater generic drug utilization, and an increase in the usage and prices of specialty drugs.

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Overview

On January 1, 2021, the Medicare outpatient prescription drug benefit (Medicare Part D) begins its 16th year of operation. Congress created Part D 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 (so-called *dual eligibles*). Since the program's enactment, Part D has been modified by a series of statutes, including by the Patient Protection and Affordable Care Act of 2010, as amended (ACA; P.L. 111-148; P.L. 111-152).[1]

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. 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.

Medicare provides plan sponsors a monthly subsidy for each non-low income subsidy (LIS) 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*, which are adjusted for health conditions, and *reinsurance payments* for enrollees with the highest drug spending. In addition, Medicare pays most of the cost sharing and premiums for LIS beneficiaries enrolled in PDP or MA-PD plans. Monthly payments are based on forecasted costs in sponsors' annual bids and are reconciled with actual costs at the end of each plan year. Medicare also establishes *risk corridors* to limit a plan's overall losses or profits. (See "Plan Payments.")

A growing number of employers and unions are offering retirees (and their eligible spouses and dependents) Part D benefits through employer-group waiver plans (EGWPs). (See "Employer Group Waiver Plans.") In addition, rather than enrolling in a Part D plan, beneficiaries may be enrolled in commercial retiree prescription drug plans offered by their former employers. The MMA provides employer subsidies for retiree drug plans as an incentive to continue such plans. (See "Retiree Drug Subsidy.")

As of October 2020, 47.7 million Medicare beneficiaries were enrolled in Part D plans. Of that total, about 25.1 million were in PDPs, about 22.1 million were in MA-PD plans, and about 500,000 were in other types of plans.[2]

A major focus of the Part D program is providing subsidized coverage to qualified, low-income beneficiaries. Individuals with incomes up to 150% of the federal poverty level (FPL) and limited assets are eligible for a low-income subsidy (LIS).[3] The LIS reduces beneficiaries' out-of-pocket

[1] The regulations governing the Part D program are set forth in 42 C.F.R. Part 423—Voluntary Medicare Prescription Drug Benefit. The Part D program has been amended in a series of laws including the ACA, the QI, TMA, and Abstinence Programs Extension and Hurricane Katrina Unemployment Relief Act of 2005 (P.L. 109-91); the Tax Relief and Health Care Act of 2006 (TRHCA; P.L. 109-432), the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA; P.L. 110-275), the Comprehensive Addiction and Recovery Act of 2016 (CARA; P.L. 114-198), the Medicare Access and CHIP Reauthorization Act (MACRA; P.L. 114-10), the Balanced Budget Act of 2018 (BBA 2018; P.L. 115-123) and the SUPPORT for Patients and Communities Act, (SUPPORT Act; P.L. 115-271).

[2] CMS, "Monthly Contract Summary Report," October 2020, at https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldatamonthly/contract-summary-2020-10. Figures are based on enrollment data for the Part D component of Medicare plans including MA-PDs, 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.

[3] The federal poverty guidelines, referred to as the *federal poverty level*, are issued annually by the Department of

spending by paying for all, or some, of the Part D monthly premium and annual deductible, and limiting co-payments or coinsurance. The LIS is progressive, meaning the lowest-income beneficiaries receive the greatest assistance. An estimated 13.3 million beneficiaries received the LIS in 2020.[4]

The ACA made major changes to Part D in an effort to improve coverage and to make the premium structure more progressive, including requiring higher-income beneficiaries to pay more for coverage. Starting in 2011, the ACA required Part D enrollees with incomes above a certain threshold to pay a monthly surcharge in addition to their regular plan premiums. (See "Premium Surcharge for Higher-Income Enrollees.")

In addition, the ACA phased out the Part D coverage gap (commonly referred to as the *doughnut hole*) by requiring drug manufacturers to provide discounts for brand-name drugs purchased by beneficiaries in the Part D coverage gap and gradually phasing in Medicare subsidies to plans to cover 75% of the cost of generic drugs and 25% of the cost of brand name drugs in the coverage gap.[5] (See "The Coverage Gap.") The ACA provisions were further modified by subsequent laws, including the Balanced Budget Act of 2018 (BBA 2018; P.L. 115-123), which, among other things, accelerated the closing of the coverage gap, increased the required manufacturer discount, and reduced the Medicare subsidy for brand-name drugs in the coverage gap. Although the coverage gap was fully "closed" in 2020, it is still referred to in this report for several reasons. including (1) differences in the calculation of enrollee out-of-pocket spending in the coverage gap as opposed to other portions of the benefit and (2) the application of manufacturer discounts for coverage gap drugs.

Medicare Part D relies on participating private insurance plans to provide coverage and bear part of the financial risk of the program. All Part D plans must meet certain minimum requirements, though 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. In 2021, a total of 996 PDPs are to be offered nationwide, a 5% increase from 2020. On average, Medicare beneficiaries are to have 30 PDPs and 27 MA-PD plans to choose from in their geographic area.[6]

Eligibility

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

Health and Human Services for administrative purposes such as determining eligibility for certain federal programs. See "Poverty Guidelines," at https://aspe.hhs.gov/poverty-guidelines.

[4] CMS, "The 2020 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds," April 22, 2020, Table IV.B7, p. 140, at https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf. (Hereinafter, 2020 Medicare Trustees Report.)

[5] The *coverage gap* refers to the period when a Medicare beneficiary has exceeded a drug plan's standard payment threshold and faces higher out-of-pocket expenses until he or she reaches an annual catastrophic threshold. Once the catastrophic threshold is reached, federal subsidies cover most prescription costs and enrollees pay a maximum of 5% coinsurance.

[6] Juliette Cubanski and Anthony Damico, "Medicare Part D: A First Look at Prescription Drug Plans in 2021," Kaiser Family Foundation, October 29, 2020, at https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-medicare-prescription-drug-plans-in-2021/.

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.[7]

For most people, joining Part D is voluntary, although dual-eligible beneficiaries (see "Full-Subsidy-Eligible Individuals") 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 61.3 million Medicare beneficiaries in 2019 who were eligible for Part D, 45.4 million about 74% were enrolled in a Part D plan and another 1.4 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 24% of Medicare beneficiaries, about half (12% of beneficiaries) had drug coverage as generous as Part D through another source, such as the Federal Employees Health Benefits program, TRICARE, or private coverage; the other half (about 12% of beneficiaries) had either less generous coverage than Part D or no drug coverage at all.[8] (See **Table 1**.)

Table 1. Total Medicare Beneficiaries with Prescription Drug Coverage, 2019

Description	Number of Medicare Beneficiaries (in millions)	Percentage of Eligible Beneficiaries
Medicare Beneficiaries Eligible for Part D	**61.3**	**100.0%**
Medicare Part D	45.4	74.1%
Stand-Alone PDP	*25.5*	*56.0%*
MA with Drug Coverage	*20.0*	*44.0%*
Medicare Retiree Drug Subsidy (RDS)	1.4	2.3%
Other Creditable Drug Coverage	7.3	11.8%
Total Beneficiaries with Drug Coverage	**55.5**	**88.2%**
Beneficiaries Without Equivalent Coverage	**7.3**	**11.8%**

Source: Medicare Payment Advisory Commission (MedPAC), "Report to Congress, Medicare Payment Policy," March 2020, Tables 14-2 and 14-3. Based on monthly Part D enrollment data.

Notes: Totals may not add due to rounding.

Eligibility for Low-Income Assistance

Beneficiaries with limited incomes and resources may qualify for assistance with their Part D premiums, cost sharing, and other out-of-pocket expenses. In 2020, a forecast 13.3 million Medicare beneficiaries received low-income subsidies (LISs). (See **Table 2** below.)

There are two categories of LIS beneficiaries, based on income and assets: (1) those with the lowest income and assets who are eligible for the full LIS subsidy and (2) those with slightly higher income and assets who qualify for a partial LIS subsidy. Individuals may be automatically

[7] 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 must 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.

[8] Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Medicare Payment Policy*, March 13, 2020, Chapter 14, Table 14-2, p. 414, at http://medpac.gov/docs/default-source/reports/mar20_medpac_ch14_sec.pdf?sfvrsn=0.

deemed eligible for the full LIS if they are dually eligible for Medicaid. 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.

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
2010	6.6	3.5	0.3	10.4
2011	6.6	3.7	0.3	10.6
2012	6.9	3.7	0.3	11.0
2013	7.2	4.0	0.3	11.5
2014	7.4	4.1	0.3	11.8
2015	7.5	4.2	0.3	12.1
2016	7.8	4.3	0.3	12.4
2017	8.0	4.5	0.3	12.7
2018	8.1	4.6	0.3	12.9
2019	8.2	4.6	0.3	13.1
2020	8.3	4.6	0.3	13.3

Source: 2016 and 2020 Medicare Trustees Reports, Table IV.B7.

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. So-called *full-benefit dual eligibles* who qualify for Medicaid benefits based on income and assets are automatically deemed eligible for the full Medicare prescription drug LIS. Additionally, those who receive Medicare premium and/or cost-sharing assistance from Medicaid through the Medicare Savings Program (MSP),[9] plus those eligible for Supplemental Security Income (SSI) cash assistance,[10] are automatically deemed eligible for full LIS. These three

[9] 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 must meet certain income limits which change annually.

[10] 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.

categories include all eligible persons who (1) have incomes below 135% of the FPL, or $17,266 for an individual and $23,274 for a couple in 2020;[11] and (2) have resources below $7,860 for an individual and $11,800 for a couple in 2020.[12] 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.[13] (See **Figure 1**.)

The Centers for Medicare & Medicaid Services (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 a reduced co-payment obligation.

Eligibility for the LIS is not always continuous from year to year. For example, LIS beneficiaries who lose eligibility for Medicaid or SSI during the 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, as they may qualify for the LIS through the application process. (See "LIS Enrollment.")

At the end of each plan year, CMS reassigns LIS beneficiaries who are enrolled in Part D plans if their plan is terminated. CMS also reassigns full LIS beneficiaries enrolled in PDPs if their plan raises its monthly premium to a level above the LIS benchmark premium for the plan region.[14] (See "Reassignment of Certain LIS Beneficiaries")

[11] Social Security benefits, veterans' benefits, public and private pensions, annuities, and in-kind support are counted as income. The 2020 income limits apply for LIS beneficiaries who seek benefits on or after January 1, 2020. HHS sets separate poverty levels for Alaska and Hawaii. See 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.

[12] 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.

[13] 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.

[14] The low-income benchmark premium is the weighted average of monthly premiums for basic PDP plans, enhanced PDP plans, 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 will randomly reassign affected beneficiaries to other PDP sponsors that have at least one qualifying PDP in that region.

Figure 1. Overview of How Medicare Beneficiaries Qualify for Low-Income Subsidy

	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. **Individuals who meet these criteria may also qualify for Medicaid and SSI benefits, which would change their status to "automatically deemed."*	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.

Partial-Subsidy-Eligible Individuals

Other individuals with limited incomes and resources who do not automatically qualify may apply for the LIS and have their eligibility determined by either the Social Security Administration (SSA) or their state Medicaid agency. This group includes all other persons who (1) are enrolled in a PDP plan or MA-PD plan; (2) have incomes below 150% of the FPL ($19,140 for an individual and $25,860 for a couple in 2020); and (3) have assets below $13,110 for an individual and $26,160 for a couple in 2020[15] (increased in future years by the percentage increase in the CPI-U). An individual who applies, and is determined eligible for the LIS, is allowed to 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, generally the insurer that is offering the Part D benefit, must ensure that the 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 subsidy takes effect on the first day of the month when his or her Medicare eligibility begins.[16]

[15] 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," hat ttps://www.ssa.gov/pubs/EN-05-10508.pdf.

[16] CMS, *Medicare Part D Prescription Drug Manual*, Chapter 13, "Premium and Cost-Sharing Subsidies for Low-

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

LIS determinations are also reviewed in the case of certain developments that could affect the amount of the subsidy. Throughout each plan year, CMS uses SSA data and state Medicare Modernization Act files of individuals dually eligible for Medicare and Medicaid to initiate the LIS eligibility process for new recipients, and look for any changes in LIS eligibility status for current, low-income beneficiaries.[17]

The ACA created new rules for LIS redeterminations subsequent to the death of a spouse. Beginning in 2011, the surviving spouse of an LIS-eligible couple receives a grace period for the determination or redetermination of benefits.[18] For example, after the death of her spouse, a widow would fill out and send a Part D redetermination form to CMS. After CMS reviews the document,

- if the information indicates that the widow qualifies for a more generous subsidy or has a more favorable resources level for purposes of LIS calculations, the change would take effect in the month following the month when the redetermination report was received;
- if the information indicates no change in status, the widow would not be sent a redetermination form the following year (with some exceptions); and
- if the information indicates a need to reduce the LIS, or provides a less favorable resources level, the redetermination would be postponed.

Enrollment in 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 different enrollment periods,[19] depending on the individual's circumstances:

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.

[17] CMS Informational Bulletin, "Annual Redetermination of Medicare Part D Low-Income Subsidy Deemed Status (Re-deeming)," July 25, 2017, at https://www.medicaid.gov/federal-policy-guidance/downloads/cib072517.pdf.

[18] 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.

[19] CMS, "Understanding Medicare Part C & D Enrollment Periods," at https://www.medicare.gov/Pubs/pdf/11219-Understanding-Medicare-Part-C-D.pdf.

- 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 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.[20] 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.[21] Coverage for new enrollees begins on 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 Medicare's standard prescription drug package, may choose not to sign up for Part D during the initial enrollment period. Sources of possible creditable coverage include some employer-based prescription drug coverage, including the Federal Employees Health Benefits Program; qualified State Pharmaceutical Assistance programs (SPAPs); and military-related coverage (e.g., VA, TRICARE). However, these individuals could face a 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 a Part D plan may change their plans during the annual open enrollment period.

Beneficiaries may wish to change plans for a variety of reasons, including changes in their health status and prescription drug needs or in response to modifications by their plans. Generally, sponsors make changes to plan benefits effective at the beginning 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 besides 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. These special enrollment periods (SEPs) are open to individuals who (1) move to a new geographic area,[22] (2) involuntarily lose creditable coverage, (3) receive inadequate information about their

[20] CMS, *Medicare & You 2021*, Section 7, at https://www.medicare.gov/pub/medicare-you-handbook.

[21] CRS Report R40082, *Medicare Part B: Enrollment and Premiums*.

[22] This includes being released from jail or out of an institution.

creditable coverage status, (4) are subject to a federal error, or (5) are enrolled in a PDP that has failed or has been terminated.[23]

Late Enrollment Penalty

A 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.

The Part D late 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.[24] The penalty is calculated by multiplying 1% of the national base premium ($33.06 for 2021)[25] 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 2018 but did not sign up until the 2021 open enrollment period, (with coverage effective January 2021), and did not have creditable coverage during the 30-month interim period, the individual would pay an additional $9.90 per month.[26]

The late 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 will increase in subsequent years if the base premium rises. Dual-eligible and other LIS beneficiaries are not subject to the late enrollment penalty.

Plan Selection

Sponsors can 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 each year, 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.

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[23] CMS, "Understanding Medicare Part C & D Enrollment Periods," 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.

[24] 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 applicable enrollees even if the plan's Part D basic premium is $0.

[25] CMS, "Annual Release of Part D National Average Bid Amount and other Part C & D Bid Information," July 20, 2020, at https://www.cms.gov/files/document/2021-announcement.pdf.

[26] CMS, "Part D Late Enrollment Penalty?," at http://www.medicare.gov/part-d/costs/penalty/part-d-late-enrollment-penalty.html. (To calculate, 1% × 30 months equals 0.30, and $33.06 × 0.30 equals $9.918. The amount is then rounded to $9.90.)

Sponsors are required to send plan enrollees other enrollment-related materials and information such as the Summary of Benefits and Evidence of Coverage documents.[27] 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 face the need 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 the price of the drugs they use, whether the plans offer preferred pharmacy options, and what, if any, utilization management requirements the plans impose for drugs, such as prior authorization or step therapy. (See "Drug Utilization Management Programs.")

CMS posts information on its open enrollment web page to help beneficiaries compare Part D plan information.[28] Beneficiaries, and persons assisting them, can also use the Medicare drug plan finder to search for information on individual drugs.[29] After a beneficiary enters information into the plan finder regarding medications being used, the dosages, and the pharmacy he or she plans to use, the plan finder displays Part D plans in the area that cover those particular drugs.[30] 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 will send 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 47 quality and performance measures, while PDP sponsors are assessed on up to 14

[27] 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 are 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 PACE Program," 83 *Federal Register*, April 16, 2018, p. 16621; at https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf.

[28] CMS, "Medicare Open Enrollment," at http://www.cms.gov/Center/Special-Topic/Open-Enrollment-Center.html.

[29] Medicare Plan Finder, at http://www.medicare.gov/find-a-plan/questions/home.aspx.

[30] For example, a plan with the lowest premium and/or no deductible may end up not being the lowest-cost plan for the beneficiary if the total cost sharing (including any deductible, co-payments, or coinsurance) for the beneficiary's specific drugs is more than under a different plan.

[31] The plans are rated on how well they perform in different categories, including (1) drug plan customer service, (e.g., how long members wait on hold and how frequently they meet deadlines for timely appeals); (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 and receive federal funding for their activities. See http://www.medicare.gov/contacts.

measures.[33] For each measure, plans are ranked on a scale of one to five stars, with five stars considered excellent. By CMS practice, Part D sponsors must provide star rating information to beneficiaries through a standard document that must be 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.[34] 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 will be directed to contact the plan directly to enroll in the low-performing plan.[35] Plans that receive five-star ratings may display a special icon recognizing them as high-performing plans. Part D enrollees are provided with a special enrollment period during which they can switch to a five-star plan, provided they meet other enrollment requirements.[36]

Plan Marketing

Plan sponsors are required to provide timely and accurate information in their marketing materials.[37] With the implementation of Part D in 2006, plans were required to submit all marketing materials to CMS for review. Starting in 2019, a smaller share of annual plan materials provided to enrollees and prospective enrollees have been subject to CMS prior review. Under revised rules, CMS classifies activities and materials used to provide information to enrollees and prospective enrollees as communications. Marketing is a subset of plan communications and is defined, in part, as activities and the use of materials that are likely to lead a beneficiary to make an enrollment decision.[38] For example, communications materials issued by a plan sponsor that simply describe a Part D sponsor organization but do not include information about a plan's benefit structure, costs, or star ratings are not marketing information and are not subject to prior review. A brochure issued by a plan sponsor that touted the benefits of joining a specific Part D

[33] CMS, "Medicare 2021 Part C & D Star Ratings Technical Notes," p. 12. Available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PerformanceData. Only a portion of the 47 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] A contract receives a low performing icon as a result of its performance on Part C or Part D ratings. The low performing icon is calculated by evaluating the Part C and Part D summary ratings for the current year and the past two years. If the contract had any combination of Part C or Part D summary ratings of 2.5 or lower in all three years of data, it is marked with a low performing icon.

[35] Beginning with plan year 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.

[36] *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.

[37] CMS, "FY 2019 Medicare Communication and Marketing Guidelines," Rev. September 5, 2018, at https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/CY2019-Medicare-Communications-and-Marketing-Guidelines_Updated-090518.pdf.

[38] 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 PACE Program," 83 *Federal Register*, April 16, 2018, p. 16624, at https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf. For definitions see 42 C.F.R. §423.2260.

plan and spelled out benefits and cost sharing would be considered marketing material and subject to review.

In general, Medicare rules are designed to ensure that beneficiaries have complete and accurate information when making decisions about drug plans. 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. Plans must use standardized names and materials across their service region and must receive prior agreement from plan enrollees to provide certain information in a format other than a mailing.[39] Plans are not allowed to market via unsolicited contacts, such as door-to-door sales. There are also limits on marketing and sales events. All plan sponsors must have interpreters in their call centers to translate for people who are not proficient in English.[40]

Plans are required to 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) to potential enrollees, though they may not take the form of cash or rebates.[41]

Enrollment Process

Beneficiaries can join a Part D plan in a variety of ways,[42] 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;[43] (4) calling the company offering the drug plan; or (5) calling 1-800-MEDICARE. In general, a PDP 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 the information required to process the enrollment. Upon receiving an enrollment request, a PDP 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 of the reasons why.

Prior to the effective date of enrollment, under CMS rules, a plan sponsor must provide necessary information about being a member of the PDP, including the PDP rules and the member's rights and responsibilities. In addition, the PDP sponsor must provide the following: 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

[39] CMS, "FY 2019 Medicare Communication and Marketing Guidelines," Rev. September 5, 2018, at https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/CY2019-Medicare-Communications-and-Marketing-Guidelines_Updated-090518.pdf. See Section 100. 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 formulary.

[40] Ibid, Section 80.1. The interpreters should be available within eight minutes of reaching a call center.

[41] Ibid, Section 40.4.

[42] CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 3, "Eligibility, Enrollment and Disenrollment," Section 40.1 and 40.4.1., Rev. August 12, 2020, at https://www.cms.gov/files/document/cy2021-pdp-enrollment-and-disenrollment-guidance.pdf.

[43] Medicare drug plan participation in Medicare's online enrollment center is voluntary, so not all Medicare drug plans will offer this option.

that a beneficiary may begin using the plan services as of the effective date. For all enrollment requests, the PDP sponsor must submit the information necessary for CMS to add the beneficiary to its records as an enrollee of the PDP sponsor within seven calendar days of receipt of the completed enrollment request.

LIS Enrollment

Special enrollment rules apply to low-income 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 assistance; second, they must enroll, or be enrolled, in a specific Part D plan.[44]

LIS enrollees had once been 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 at the end of the year. Since 2019, LIS enrollees have no longer been allowed an open-ended, monthly SEP. Instead, LIS enrollees are 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.[45] The rules also 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 one by CMS.[46] 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.

If an individual is not eligible to enroll in a PDP because he or she is enrolled in a Medicare Advantage plan (other than a MA private-fee-for-service plan [MA-PFFS] that does not offer Part D, or a medical savings account [MSA] plan), CMS is to direct the MA organizations to facilitate the enrollment of these individuals into an MA-PD plan offered by the same MA organization.

Some dual-eligible beneficiaries may find that they have been auto-enrolled in a plan that may not best meet their needs. For this reason, they are provided with more opportunities to change enrollment, with the new coverage effective the following month. (See "LIS Enrollment.") If an

[44] 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.

[45] 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 PACE Program," 83 *Federal Register*, April 16, 2018, p. 16514, at https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf.

[46] 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.

enrollee selects a plan with a premium above the low-income benchmark, however, he or she is required to pay the difference.

Facilitated Enrollment

CMS established a process labeled "facilitated enrollment" for enrollees in Medicare Savings programs (MSPs), SSI enrollees, and persons who applied for and were approved for low-income subsidy assistance. 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 433,473 LIS beneficiaries were enrolled in benchmark PDPs in 2019 that did not qualify as benchmark plans in 2020. CMS randomly reassigned 100,334 beneficiaries to different PDPs, and 333,139 were assigned to the same plan despite a premium increase. Another 700,499 million LIS beneficiaries were not reassigned because they had previously switched plans voluntarily.[47] The ACA made changes to Part D in an effort to reduce the need for automatic reassignment of LIS beneficiaries. For instance, the law changed the methodology for calculating the benchmark premium for some plans. In addition, PDPs with premiums above LIS-eligible levels no longer have LIS beneficiaries reassigned if they voluntarily agree to waive a de minimis portion of the premium above the benchmark. However, such plans would not qualify to receive other LIS beneficiaries who are automatically reassigned from their current plans.[48]

Part D Benefit Structure

The MMA set out a standard prescription drug benefit structure. Plan sponsors may, and often do, offer different benefit designs and cost-sharing requirements, so long as they meet certain specifications. Under the standard benefit structure, with some exceptions, over the course of a year a beneficiary is responsible for paying (1) a monthly premium, (2) an annual deductible, and (3) co-payments or coinsurance for drug purchases. Additionally, for a certain portion in the annual benefit called the *coverage gap* (also known as the *doughnut hole*), beneficiaries initially faced 100% out-of-pocket costs. However, provisions in subsequent legislation resulted in closure of the coverage gap as of 2020. (See "The Coverage Gap.")

[47] Data on 2019 Reassignment for 2020 PDPs are available at https://www.cms.gov/Medicare/Eligibility-and-Enrollment/LowIncSubMedicarePresCov/Reassignment.html.

[48] CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 3, "Eligibility, Enrollment and Disenrollment," Section 40.1.5, Rev. August 12, 2020, at https://www.cms.gov/files/document/cy2021-pdp-enrollment-and-disenrollment-guidance.pdf. The de minimis amount is announced annually along with plan benchmarks.

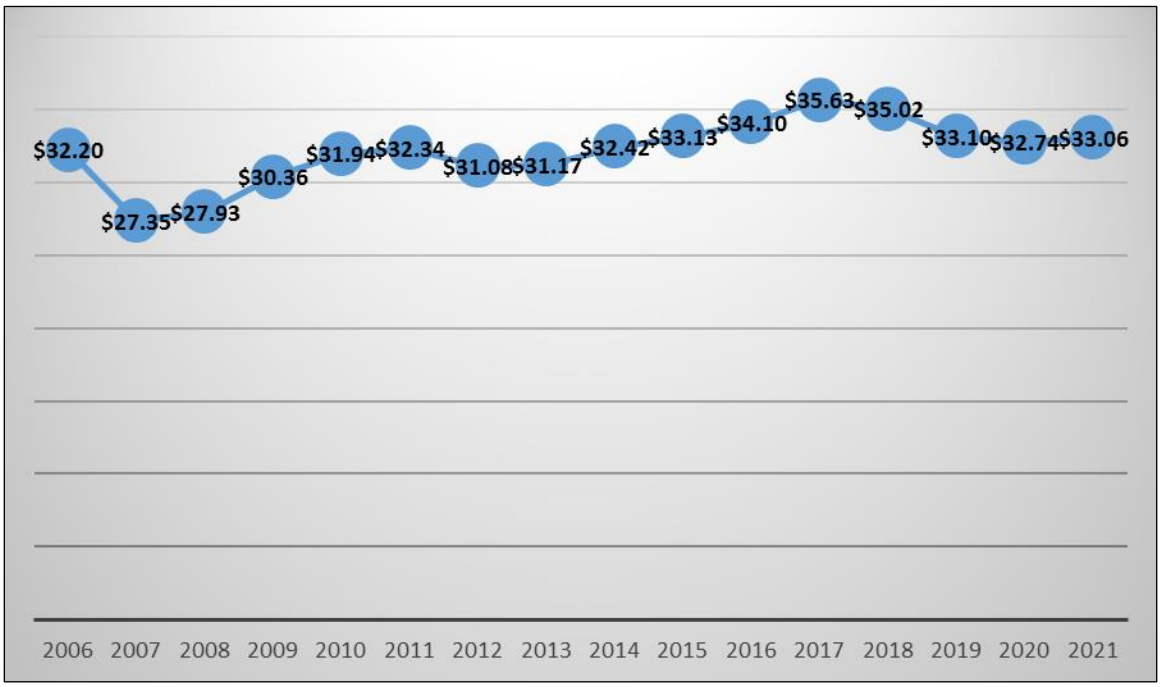
Actual costs to Part D beneficiaries vary from plan to plan depending on the benefit structure and coverage offered, the costs and amount of drugs they use, and the level of any additional assistance such as through a low-income subsidy.

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.")[49] The actual dollar amount of Part D premiums will vary by plan.

Figure 2. Annual Part D Base Beneficiary Monthly Premium

In dollars



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

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

[49] 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 accordingly. The base premium is a fraction, with a numerator of 25.5% and a denominator equal to 100% of the average bid minus a percentage equal to (i) the total reinsurance payments estimated to be paid to plans in the coverage year, divided by (ii) that amount plus the total payments that CMS estimates will be paid to Part D plans based on the standardized bid amount during the year, taking into account amounts paid by both CMS and plan enrollees. 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.

As noted, beneficiary premiums are based on the average of bids submitted by participating sponsors for standard benefits (the base beneficiary premium) each year 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 2021, the base beneficiary monthly premium, 25.5% of the average adjusted bid amount, is $33.06.[50] Base premiums from 2006 through 2021 are shown in **Figure 2**.

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.[51] The monthly premium is applied evenly to all persons enrolled in a specific plan, except those who are receiving low-income subsidies 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.[52] Higher-income beneficiaries pay a monthly premium surcharge.

Premium Surcharge for Higher-Income Enrollees

When Part D began in 2006, all beneficiaries enrolled in the same plan (except those receiving the low-income subsidy) were subject to the same premium. Beginning in 2011, as required by the ACA, Part D enrollees with higher incomes pay higher premiums. (The Part D high-income requirements are similar to the income-based premium structure under Medicare Part B.)[53] Part D beneficiaries who have a modified adjusted gross income (MAGI)[54] above set thresholds[55] are assessed a special surcharge, referred to as an income-related monthly adjustment amount (IRMMA), in addition to their regular PDP or MA-PD plan premiums. According to the SSA, fewer than 5% of Medicare enrollees are subject to the IRMMA.[56]

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[50] CMS, "Annual Release of Part D National Average Bid Amount and other Part C & D Bid Information," July 20, 2020, at https://www.cms.gov/files/document/2021-announcement.pdf. Includes an adjustment for projected reinsurance.

[51] Medicare Advantage plans that earn a Part C rebate (by having estimated costs for providing benefits that are less than the maximum possible Medicare payment) must spend that rebate on supplemental benefits, reduced cost sharing or reduced Part B or D premiums.

[52] 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.

[53] See CRS Report R40082, *Medicare Part B: Enrollment and Premiums*.

[54] 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 Social Security Administration. 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. Social Security Administration, "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*.

[55] The income thresholds are the same as those used for calculating Medicare Part B premiums.

[56] SSA, "Medicare Premiums: Rules for Higher-Income Beneficiaries," at https://www.ssa.gov/benefits/medicare/medicare-premiums.html.

The higher-income surcharge is calculated as the difference between the Medicare Part D base beneficiary premium (which 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,[57] 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 premium amount.[58] (See **Table 3.**)

Table 3. 2021 Monthly Medicare Part D High-Income Surcharge

If Annual Income in 2019 Was			
File Individual Tax Return	**File Joint Tax Return**	**Married and File Separate Tax Returns**	**2021 Payment Is**
$88,000 or less	$176,000 or less	$88,000 or less	Plan Premium
Above $88,000 to $111,000	Above $176,000 to $222,000	Not applicable	$12.30 + Plan Premium
Above $111,000 to $138,000	Above $222,000 to $276,000	Not applicable	$31.80 + Plan Premium
Above $138,000 to $165,000	Above $276,000 to $330,000	Not applicable	$51.20 + Plan Premium
Above $165,000 and less than $500,000	Above $330,000 and less than $750,000	Above $88,000 and less than $412,000	$70.70 + Plan Premium
$500,00 and above	$750,000 and above	$412,000 and above	$77.10 + Plan Premium

Source: Medicare.gov, "Monthly Premium for Drug Plans."

Notes: Income figures refer to modified adjusted gross income.

At the time the ACA was enacted, high-income Part D enrollees could be placed into one of four high-income adjustment categories, depending on their level of income. Section 53114 of 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 will be frozen through 2027 and then adjusted annually for inflation starting in 2028.[59]

The surcharge is calculated using a statutory formula that multiplies the base Part D premium by a set ratio.[60] For 2021, the ratios are (35% − 25.5%)/25.5%; (50% − 25.5%)/25.5%; (65% − 25.5%)/25.5%, (80% − 25.5%)/25.5%, or (85%-25.5%)/25.5%. For example, for 2021 (with a

[57] CMS, "2021 Part D Income-Related Monthly Premium Adjustment," November 6, 2020, at https://www.cms.gov/files/document/2021-part-d-income-related-monthly-premium-adjustment.pdf.

[58] 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.

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

[60] Social Security Act §1860D-13(a)(7).

base premium of $33.06) the surcharge for an individual with a 2019 adjusted gross income between $138,000 and $165,000 would be calculated as

IRMMA = $33.06 x ((65% − 25.5%)/25.5%)

IRMMA = $33.06 x 1.549

IRMMA = $51.21, rounded down to the nearest dime = $51.20.

Beneficiaries pay the surcharge directly to the federal government, rather than to Part D plans. When applicable, IRMMA will be withheld from an enrollee's monthly Social Security check, Railroad Retirement benefit, or federal pension payment, unless the benefit check is not sufficient for the purpose.[61] If a beneficiary is directly billed for IRMAA, he or she has the option of paying through an electronic funds transfer or by other means.[62]

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 by Medicare or an alternative package that is actuarially equivalent.[63] 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. MA organizations offering MA-coordinated care plans are required to offer at least one plan for the service area that includes drug coverage. The drug coverage can be either basic or enhanced.[64]

Standard Prescription Drug Coverage

Under the standard Part D benefit, a beneficiary first pays a *deductible* ($445 in 2021). 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* ($4,130 in 2021).[65] (See **Figure 3**.)

To reach the initial coverage limit in a 2021 standard plan, a beneficiary would pay the $445 deductible plus $921.25 in prescription costs, for total out-of-pocket costs of $1,366.25. The plan would pay the remaining $ 2,763.75

After the initial coverage threshold has been reached, a beneficiary enters the *coverage gap* or "doughnut hole" where he or she remains until accumulating $6,550 in total out-of-pocket

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

[62] See CRS Report R43962, *The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA; P.L. 114-10)*.

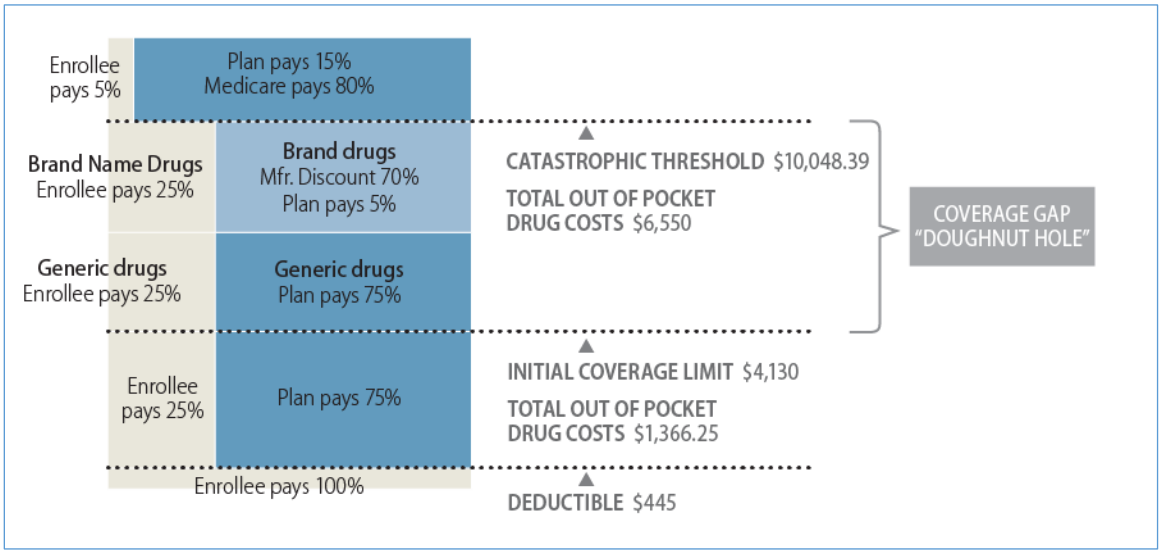
[63] Social Security Act, §1860D-2.

[64] CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 5, "Benefits and Beneficiary Protection," Section 20.4.4, Rev. September 20, 2011, at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf.

[65] The thresholds for 2021 were published in the 2021 Call Letter. CMS, "Announcement of Calendar Year (CY) 2021 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," April 6, 2020, p.71, at https://www.cms.gov/files/document/2021-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.

spending in 2021 (for those not receiving the LIS) and reaches the *catastrophic threshold*.[66] Total drug spending needed to move through the deductible, the initial coverage limit, and the coverage gap to the catastrophic threshold is estimated at about $10,048.39,[67] with a portion paid by the beneficiary, a portion covered by the plan, and a portion offset by manufacturer discounts for brand-name drugs. (See "The Coverage Gap.")

Figure 3. 2021 Standard Medicare Prescription Drug Benefit



Source: Figure created by CRS based on data from CMS, "Announcement of Calendar Year (CY) 2021Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," Attachments IV and V.

Note: Beneficiaries above the catastrophic threshold pay the greater of a $3.70 co-payment for generic drugs and a $9.20 co-payment for brand-name drugs or 5% cost sharing in 2021. 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 6**.)

Actual spending per beneficiary will vary depending on plan design and purchases of brand-name vs. generic drugs. After the catastrophic threshold has been reached, plans charge a beneficiary the greater of a nominal set co-payment for drugs or 5% coinsurance.[68] Medicare subsidizes 80% of each plan's costs for this catastrophic coverage, which is called Part D reinsurance.

CMS uses a set formula to update annual Part D coverage parameters, including the standard deductible, initial coverage limit, and amount of beneficiary true out-of-pocket spending (TrOOP) required to reach the catastrophic threshold.[69] There is no annual cap on out-of-pocket spending in Part D, except for full subsidy LIS beneficiaries. Annual percentage increases are based on

[66] For those receiving a low-income subsidy (who are not eligible for manufacturer discounts in the doughnut hole because they have set, lower cost sharing throughout the benefit), the catastrophic threshold is $9,313.75. For beneficiaries eligible for the manufacturer discount, the threshold depends on the mix of brand name and generic drugs used; the average non-LIS threshold is about $10,048.39

[67] Total reflects catastrophic limit of about $10,048.39 minus initial coverage limit of $4,130. 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.

[68] Nominal cost sharing is defined as the greater of (1) a co-payment of $3.70 in 2021 for a generic drug or preferred multiple source drug and $9.20 in 2021 for other drugs, or (2) 5% coinsurance.

[69] Social Security Act, §1860D-2.

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 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 and cost sharing such as reducing the maximum $445 deductible, while also imposing cost-sharing requirements that are higher than 25%. For example, nearly all plans use a tiered cost-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.")

In 2020, 42% of Part D enrollees in PDPs were in plans offering enhanced benefits, and 58% were in plans that were actuarially equivalent to the standard benefit. No PDP enrollees were in defined standard benefit plans.[70]

Enhanced Plans

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, including reductions in cost sharing in the coverage gap. 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.

The structure of the Part D program, including the large number of plans available in each region, can make it complicated for beneficiaries to compare plans. The ACA required CMS to streamline the number of Part D plans in each region and simplify the enrollment process. Starting in the 2011 plan year, CMS required Part D sponsors that offer more than one plan per region to demonstrate meaningful differences between their plans, in terms of premiums, cost sharing, formulary design, or other benefits.[71] Plan sponsors were allowed to offer only one basic plan benefit design in a service area and no more than two enhanced alternative plans in each service area. Beginning in 2019, CMS no longer required Part D sponsors offering two enhanced plans in a region to demonstrate meaningful differences between the enhanced plans. The sponsor still must demonstrate that the enhanced plans have meaningful differences from the basic plan, however. The change is designed to give Part D sponsors more flexibility in plan design. CMS continues to limit Part D sponsors to offering no more than two enhanced plans in each region.[72]

Enrollee cost sharing for prescriptions can vary widely during the course of a plan year for enrollees that accumulate sufficient spending to move through the various phases of the Part D benefit. For example, in 2021, an enrollee could be in a plan where he or she pays 100% of the plan's negotiated price for a drug until meeting the $445 deductible; a flat co-payment in the

[70] MedPAC, (MedPAC), *Report to the Congress: Medicare Payment Policy*, March 13, 2020, Chapter 14, Table 14-5, p. 418 at http://medpac.gov/docs/default-source/reports/mar20_medpac_ch14_sec.pdf?sfvrsn=0.

[71] CMS, *Medicare Prescription Drug Benefit Manual*, Chapter 5, "Benefits and Beneficiary Protection," Rev. September 20, 2011, at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf.

[72] 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 PACE Program," 83 *Federal Register*, April 16, 2018, p. 16613, at https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf.

initial coverage period; 25% coinsurance in the coverage gap; and 5% coinsurance in the catastrophic portion of the benefit.

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 coverage level. 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 goals for total spending.

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 a low-income subsidy generally paid the full cost of drugs while in the coverage gap. (See original Part D in **Figure 4**.) The ACA, as amended,[73] included provisions to gradually phase out the coverage gap by 2020, meaning that by 2020 enrollees in standard plans would have a 25% cost share from the time they meet a standard plan deductible until they reached the catastrophic threshold, after which cost sharing is reduced. (See "Phaseout of the Coverage Gap.") Congress included provisions in BBA 2018 that closed the Part D coverage gap for brand-name drugs in 2019, a year earlier than required by the ACA.[74] However, even though the coverage gap has been closed (in the sense that the Part D standard benefit now has 25% cost sharing from the deductible to the catastrophic threshold), the 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.[75]

Beneficiaries may have different levels of actual out-of-pocket spending in the coverage gap depending on how their specific plans are structured and the percentage of brand-name and generic drugs that they use.[76]

In 2018, about 21% of Medicare Part D enrollees reached the coverage gap.[77] CMS offers enrollees suggestions for avoiding or delaying the coverage gap and for saving money while in the gap.[78] Strategies for minimizing out-of-pocket spending include switching to generic,[79] over-

[73] 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.

[74] Balanced Budget Act of 2018 (BBA 2018; P.L. 115-123), Section 53116.

[75] 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."

[76] For example, the Part D required 70% manufacturer discount on brand-name, biologics, and biosmilar 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. Although few sponsors currently offer coverage gap supplemental benefits, CMS is beginning a pilot program for insulin in 2021 that limits cost sharing to $35 and is designed in part to reduce enrollee spending in the coverage gap. See textbox "Supplemental Cost Sharing in the Coverage Gap."

[77] MedPAC, July 2020 Data Book, *Health Care Spending and the Medicare Program*, Chart 10-19. Available at http://www.medpac.gov/-documents-/data-book. The data are the most recent available.

[78] For more information on the coverage gap see CMS, "Costs in the Coverage Gap," https://www.medicare.gov/drug-coverage-part-d/costs-for-medicare-drug-coverage/costs-in-the-coverage-gap.

[79] Part D sponsors are required to ensure that their network pharmacies inform enrollees of any price differential

the-counter, mail-order, or other lower-cost drugs when possible; exploring national and community-based charitable programs or State Pharmacy Assistance Programs (SPAPs) that might offer assistance;[80] and looking into Pharmaceutical Assistance Programs (also called Patient Assistance Programs, or PAPs) offered by pharmaceutical manufacturers or independent charities.[81]

Phaseout of the Coverage Gap

As noted, the ACA gradually closed the coverage gap by 2020 through a combination of manufacturer discounts and government subsidies. Under the ACA, pharmaceutical manufacturers that choose to participate in Medicare Part D must sign agreements to take part in the Medicare Coverage Gap Discount Program.[82] The ACA required companies to provide a 50% discount on brand-name and biologic drugs for non-LIS Part D participants in the coverage gap. Drug makers began providing the brand-name drug discount in 2011. The ACA also gradually phased in additional federal subsidies for brand-name drugs purchased in the coverage gap, so that by 2020 a beneficiary would have 25% cost sharing in the coverage gap, Medicare would cover 25% of the cost of the drug, and the manufacturer discount would defray 50%. For generic drugs, the ACA phased in a 75% federal subsidy by 2020. Enrollees are allowed to count the manufacturer discounts as part of their own out-of-pocket spending. The ACA did not impose a manufacturer discount on the less expensive generic drugs. (Those enrollees who reached the coverage gap in 2010 received a $250 discount, in the form of a check.) (See **Table 4**.)

BBA 2018 included provisions to close the coverage gap for brand-name drugs one year early, in 2019. Beginning in 2019 and continuing forward, BBA 2018 (1) increased the manufacturer discount for brand-name drugs in the coverage gap to 70% from 50%; (2) expanded the manufacturer discount to include biosimilar drugs,[83] (3) set the federal subsidy for brand-name drugs in the coverage gap at 5%, and (4) set beneficiary cost sharing at 25%.

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between a covered drug and the lowest-price generic version of the drug that is therapeutically equivalent, bioequivalent, on the plan's formulary, and available at that pharmacy. In addition, under the 2018 Know the Lowest Price Act, (P.L. 115-262), Part D plans may not restrict or penalize network pharmacies from informing enrollees of any difference between the price/cost sharing for a drug using the Part D benefit and a lower cash price an enrollee could pay by purchasing the drug outside the Part D benefit.

[80] Some states offer payment assistance for drug plan premiums and/or other drug costs for individuals who have trouble affording their medication but do not qualify for LIS. For example, a state may offer assistance to individuals with incomes between 150% and 300% of the FPL. To learn which states offer this assistance and for details on the state programs, see http://www.medicare.gov/pharmaceutical-assistance-program/state-programs.aspx.

[81] Many major drug manufacturers offer assistance programs for the drugs they manufacture. Manufacturer patient assistance programs may be used outside the Part D benefit, and the value of benefits received under these programs does not count toward true out-of-pocket expenses. Independent charity patient assistance programs may provide assistance with Part D cost sharing, which does count toward true out-of-pocket expenses. To learn which manufacturers offer assistance, see http://www.medicare.gov/pharmaceutical-assistance-program/index.aspx. See also CRS Report R44264, *Prescription Drug Discount Coupons and Patient Assistance Programs (PAPs)*.

[82] CMS, "Part D Information for Pharmaceutical Manufacturers," at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Pharma.html.

[83]Beginning in 2019, Section 53113 of BBA 2018 expanded the manufacturer discount to biosimilars, which are lower-cost versions of biologic drugs. Biologics and biosimilars are drugs produced from living organisms, rather than through a chemical process. The ACA originally excluded biosimilars from the manufacturer discount. In a separate 2018 rulemaking, CMS applied generic drug cost-sharing requirements to biosimilars purchased by LIS beneficiaries in all phases of the Part D benefit. The change made biosimilars more affordable for LIS beneficiaries. See 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 PACE Program," 83 *Federal Register*, April 16, 2018, p. 16610, at https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf.

BBA 2018 did not alter ACA requirements for generic drugs purchased in the coverage gap. For generic drugs, the coverage gap closed in 2020, as scheduled under the ACA. (See **Table 4**).

Table 4. Closing the Coverage Gap Between 2011 and 2020

(phase-in of subsidies and reduction in beneficiary cost sharing)

	Brand Name Drugs			Generic Drugs	
	Manufacturer Discount	Medicare Subsidy	Beneficiary Cost Share	Medicare Subsidy	Beneficiary Cost Share
2011	50%	0	50%	7%	93%
2012	50%	0	50%	14%	86%
2013	50%	2.5%	47.5%	21%	79%
2014	50%	2.5%	47.5%	28%	72%
2015	50%	5%	45%	35%	65%
2016	50%	5%	45%	42%	58%
2017	50%	10%	40%	49%	51%
2018	50%	15%	35%	56%	44%
2019	70%	5%	25%	63%	37%
2020 on	70%	5%	25%	75%	25%

Source: CRS analysis of ACA, as amended by BBA 2018.

Notes: The federal government provides the generic drug subsidy.

From 2020 onward, Medicare will subsidize 75% of Part D plan costs for generic drugs in the coverage gap and enrollees will pay 25%.[84] (See **Figure 4**.)

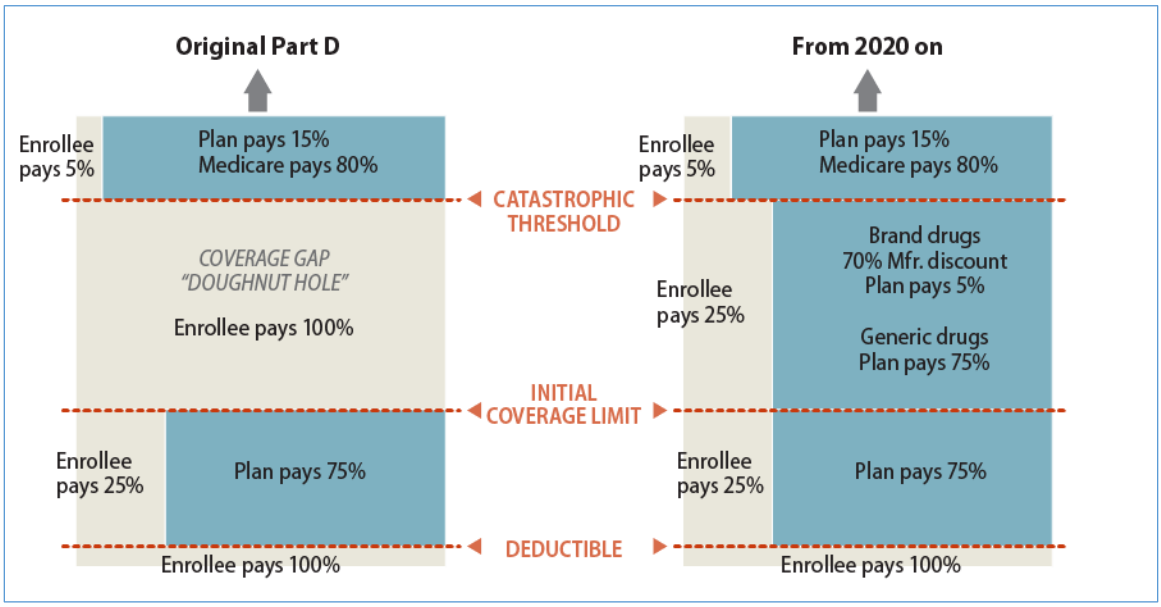
Based on the latest CMS data available, in 2016 more than 4.9 million beneficiaries who were in the coverage gap received manufacturer discounts on brand-name drugs they purchased. Overall, 2016 discounts totaled about $5.65 billion, with an average discount per beneficiary of $1,149.[85] (Note that the manufacturer discount was set at 50% in 2016, compared to the current 70% level.)

[84] 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. Medicare subsidies are based on projected costs in annual plan bids. Medicare reconciles plans' projected and actual costs at the end of each plan year.

[85] CMS, "Coverage Gap Discount Program," at http://www.cms.gov/Medicare/Medicare-Advantage/Plan-Payment/CGDP.html. The data are the most recent available on the website.

Figure 4. Closure of the Coverage Gap for Brand and Generic Drugs

(the ACA, as amended by BBA 2018, closed the doughnut hole for *all* drugs in 2020)



Source: CRS analysis of the ACA and BBA 2018.

Note: Beneficiaries above the catastrophic threshold pay the greater of a specified co-payment or 5% coinsurance. 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 6** for beneficiary cost sharing in 2021.) Non-LIS beneficiaries are allowed to count manufacturer discounts on brand-name drugs in the coverage gap drugs as out of pocket spending.

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 legislation and regulations, 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."[86]

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 x 0.70 =$7). The enrollee would pay the remaining share ($100 – ($90 + $7) = $3).

If the plan sponsor did not offer an enhanced benefit in the coverage gap, the manufacturer discount would be 70% of the negotiated price of $100 ($100 x 0.70 =$70). The enrollee would pay 25% coinsurance on the $100 negotiated price ($100 x 0.25 = $25); and the plan sponsor would be liable for the remaining $5 ($100 - ($70 + $25.)

For the 2021 plan year, CMS is offering a pilot program (for non-LIS beneficiaries) that modifies supplemental cost sharing for insulin, which is one of the most widely used drugs in Medicare Part D. Under the pilot, participating Part D plan sponsors would charge no more than a $35 co-payment for a 30-day supply of insulin from the plan deductible through the coverage gap. The 70% manufacturer discount in the coverage gap would be based on the plan's negotiated price for insulin rather than on the $35 co-payment.[87]

CMS noted that because of the current financial disincentives, Part D sponsors generally do not offer supplemental benefits in the coverage gap. According to CMS, one in every three Medicare beneficiaries has diabetes, and over 3.3 million use one or more of the common forms of insulin.

True Out-of-Pocket Costs

Before catastrophic protection begins, Part D enrollees must incur a certain level of out-of-pocket costs.[88] *True out-of-pocket costs* (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 of certain drugs while in the doughnut hole, including the manufacturer subsidy.

Enrollee spending for Part D covered drugs is treated as TrOOP[89] if paid by the 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 a low-income subsidy; paid by most charities; covered by a drug manufacturer discount under the Medicare Coverage Gap Discount Program; covered by the Indian Health Service;[90] or paid by an AIDS Drug Assistance Program.[91]

Incurred costs do not include Part D premiums; costs for drugs that are not on the enrollee's 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 the manufacturer drug discounts count

[86] SSA Section 1860D-14(A)(c)(2).

[87] CMS, "Part D Senior Savings Model," https://innovation.cms.gov/innovation-models/part-d-savings-model. Text box is based on CMS payment example in Webinar slide link.

[88] True out-of-pocket costs are the payments that count toward an enrollee's Part D out-of-pocket threshold of $6,550 for 2021.

[89] 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.

[90] Added by §3314 of the ACA.

[91] Added by §3314 of the ACA.

toward the TrOOP, federal subsidies for brand-name or generic drugs in the doughnut hole do not count.

Examples of TrOOP Spending

Consider a non-LIS enrollee in a 2021 standard plan. To reach the initial coverage limit, the enrollee would need to incur TrOOP spending consisting of the $445 deductible and 25% coinsurance or co-payments on total drug spending up to $4,130 ($921.25 + $445 = $1,366.25). 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 on enrollee out-of-pocket spending (which includes the value of manufacturer discounts.) The beneficiary would now face about $5,183.75 of additional out-of-pocket spending in the doughnut hole before he or she would reach the catastrophic threshold (a total of $6,550 in out-of-pocket spending).

While in the coverage gap in 2021, 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 2021 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,[92] 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 × 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 × 0.25 = $5.50). The $5.50 will count as TrOOP. The government's 75% coverage portion will not count as TrOOP.

In 2018, about 8% of Part D enrollees exceeded the out-of-pocket threshold and reached the catastrophic phase of the benefit. These enrollees accounted for about 60% of total Part D spending on basic benefits that year.[93] Medicare picks up a larger share of spending (reinsurance) for enrollees who reach the catastrophic threshold. Spending for reinsurance is now the largest share of Medicare spending for the Part D program. According to MedPAC, 71% of enrollees reaching the catastrophic portion of the benefit in 2018 were receiving the LIS. 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.[94]

Low-Income Subsidies

Medicare Part D provides subsidies to assist low-income beneficiaries with premiums and cost sharing.[95] LIS cost sharing varies according to a beneficiary's assets and income and, also,

[92] Example is based on "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.

[93] MedPAC, July 2020 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.

[94] Ibid, Chart 10-20.

[95] 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.

whether a beneficiary is institutionalized, or is receiving community-based care. Full-subsidy eligibles[96] have no deductible, minimal cost sharing during the initial coverage period and coverage gap, and no cost sharing above the catastrophic threshold. Additionally, full-benefit dual eligibles who are residents of medical institutions or nursing facilities have no cost sharing. (See "Eligibility for Low-Income Assistance.")

Premium Assistance

Full-Subsidy-Eligible Individuals

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.

Partial-Subsidy-Eligible Individuals

Partial-subsidy-eligible individuals receive premium assistance based on an income sliding scale, as specified in **Table 5**.

Table 5. 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 eligibles have no deductible, minimal cost sharing during the initial coverage

[96] A full-benefit dual eligible is someone who is qualified for full Medicaid benefits. Full-benefit beneficiaries may be deemed full-subsidy Medicare Part D recipients if they meet certain guidelines. For definition of full-subsidy eligible benefit, see 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.

period and coverage gap, and no cost sharing above the catastrophic threshold. Partial-subsidy individuals have higher cost sharing. (See **Table 6**.)

Other specific policies related to cost sharing during the initial coverage period and coverage gap for dual eligibles include the following:[97]

- Full-benefit, dual eligibles who are residents of medical institutions or nursing facilities have no cost sharing, with some exceptions. The ACA expanded the LIS subsidy so that beneficiaries receiving 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 $1.30 for a generic drug prescription or preferred multiple-source drug prescription and $4.00 for any other drug prescription up to the catastrophic threshold in 2021.
- Full-subsidy-eligible individuals with incomes between 100% and 150% of FPL have cost sharing for all drug costs, up to the catastrophic limit of $3.70 for a generic drug or preferred multiple-source drug and $9.20 for any other drug in 2021.

Partial-subsidy-eligible individuals have a $92 deductible in 2021, 15% coinsurance for all costs up to the catastrophic trigger, and cost sharing above this level of $3.70 for a generic drug prescription or preferred multiple source drug prescription and $9.20 for any other drug prescription.

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. The cost-sharing amounts for all other beneficiaries, and the deductible amount 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.

[97] 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.

Table 6. Part D Standard Benefits, 2021

(by per capita drug spending category)

			Low-Income Subsidy (LIS)-Eligible Individuals			
	Non-LIS Beneficiaries		Full-Subsidy-Eligible		Other Subsidy Eligible	
Total drug Spending (Dollar Ranges)	**Paid by Part D**	**Paid by Enrollee**	**Paid by Part D**	**Paid by Enrollee**	**Paid by Part D**	**Paid by Enrollee**
$0 up to $445 Deductible	0%	$445	$445	0	$353	$92
Between Deductible and Initial Coverage Limit ($445.01-$4,130)	75%	25%	100% less enrollee cost sharing	Institutionalized duals: $0 Duals up to or at 100% of FPL: $1.30/$4.00[a] Others: $3.70/$9.20	85%	15%
Coverage Gap Between Initial Coverage Limit ($4,130) and Catastrophic Threshold (about $10,048.39)	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: $1.30/$4.00[a] Others: $3.70/$9.20[b]	85%	15%
Over Catastrophic Threshold	95%	5%	100%	$0	100% less enrollee cost sharing	$3.70/$9.20[c]

Source: CMS, "Announcement of Calendar Year (CY) 2021 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.

a. Maximum of $1.30 per prescription for generic or preferred drugs that are multiple source drugs; $4.00 per prescription for other drugs.

b. Maximum of $3.70 per prescription for generic or preferred drugs that are multiple source drugs; $9.20 per prescription for other drugs.

c. Cost sharing is the lower of 5% coinsurance or Minimum of $3.70 per prescription for generic or preferred drugs that are multiple source drugs; $9.20 per prescription for other drugs.

Employer Subsidies for Retiree Drug Coverage

The MMA included provisions designed to encourage employers to continue to offer prescription drug benefits to their Medicare-eligible retirees. Employers have several options for providing 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).[98] To qualify, an employer or union must offer drug benefits that are actuarially equivalent to, or more generous than, standard Part D prescription drug 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 who are entitled to Medicare benefits under 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. A retiree health plan cannot receive a subsidy for a current worker or an individual who is enrolled in a Part D plan. (An employer or union does have the option of sponsoring its own Part D plan [see "Employer Group Waiver Plans" section, below].)

For each retiree enrolled in a qualified plan in 2021, sponsors receive a federal subsidy equal to 28% of gross prescription drug costs between a threshold of $445 and a cost limit of $9,200.[99] The retiree subsidies are designed to encourage employers to maintain drug coverage, and have generally been less expensive for Medicare than would be enrolling these beneficiaries in a Part D drug plan. In 2020, the average annual RDS was forecast to be about $550 per beneficiary compared to average Medicare per beneficiary costs of $2,154 for Part D beneficiaries.[100]

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.[101] In addition, retiree health plans are not eligible for ACA manufacturer discounts on brand-name drugs through the coverage gap discount program. These changes, which result in higher relative costs for retiree plans, have helped prompt employers to move away from the RDS program. The Medicare Trustees predict that the share of beneficiaries covered through the retiree drug subsidy will decline from about 20% of Part D enrollment in 2010 to about 2% in 2029.[102]

Employer Group Waiver Plans

As fewer employers use the Part D retiree drug subsidy, a growing number have provided drug benefits to retirees, through Part D Employer Group Waiver Plans (EGWPs).[103] EGWPs are sponsored by large employers, state and local governments, school districts and other entities.

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[98] CMS, "Retiree Drug Subsidy," at https://www.rds.cms.hhs.gov/.

[99] CMS, "Announcement of Calendar Year (CY) 2021 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," p. 72.

[100] 2020 Medicare Trustees Report, Table IV.B9, p. 144, and Table V.D1, p. 188, at https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf.

[101] Internal Revenue Service, "Frequently Asked Questions: Retiree Drug Subsidy," at https://www.irs.gov/newsroom/frequently-asked-questions-retiree-drug-subsidy.

[102] 2020 Medicare Trustees Report, Table IV.B7, p. 144.

[103] 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.

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.

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.[104] More specifically, CMS may provide waivers of Medicare regulations to allow employers and unions to do the following:[105]

- 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;
- 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.[106] 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."[107] EGWPs instead are paid by CMS based on the 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 final rules that changed the definition of Part D supplemental benefits to exclude supplemental benefits offered through EGWPs.[108] Instead, any supplemental benefits offered as part of an EGWP are considered non-Medicare benefits and are

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[104] Specific authority for EGWPs can be found at SSA Sections 1857(i) and 1860D-22(b).

[105] CMS, "Approved Part D Waivers," https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/EGWP-Waivers.pdf.

[106] Secondary Payer Manual on the CMS website at http://www.cms.hhs.gov/Manuals/IOM/list.asp.

[107] 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.

[108] 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,* p. 22081, April 12, 2012, at https://www.govinfo.gov/content/pkg/FR-2012-04-12/html/2012-8071.htms. In its rulemaking, CMS amended 42 CFR §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.

treated instead as other health insurance that pays in a secondary position to Medicare. That means that manufacturer discounts in the coverage gap for EGWP plans are calculated based on the standard Part D benefit without taking into account the EGWP's supplemental benefits.[109] This allows sponsors to offer EGWP plans that offer lower cost sharing in the coverage gap than the standard benefit of 25% but still collect the maximum manufacturer discount. A recent MedPAC analysis found EGWPs made up about 16% of Part D enrollment in 2018 but accounted for 45% of manufacturer discounts.[110]

Drug Coverage

In order 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) 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.[111]

Some previously barred drugs are now covered. Since January 1, 2013, Part D plans have been required to include benzodiazepines in their formularies.[112] Barbiturates must be included in plan formularies for an indication of epilepsy, cancer, or chronic mental health disorders. Effective in January 2014, the ACA removed smoking cessation agents, barbiturates and benzodiazepines from the list of drugs allowed to be excluded from Medicaid coverage. The ACA provisions meant that Part D restrictions on barbiturate coverage (i.e., limiting the drugs to treatment of epilepsy, cancer, or chronic mental health disorders) were ended.[113]

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[109] 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/cciio/resources/Regulations-and-Guidance/index.html#Health Market Reforms).

[110] MedPAC, *Report to the Congress: Medicare Payment Policy*, March 13, 2020, p. 416, at http://medpac.gov/docs/default-source/reports/mar20_medpac_ch14_sec.pdf?sfvrsn=0.

[111] 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.

[112] These changes were required by Section 175 of MIPPA; P.L. 110-275.

[113] CMS, "Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," April 1, 2013, pp. 152-153, at http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/Announcement2014.pdf.

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 prescription medications 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 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).[114] As part of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act; P.L. 116-136), Congress specified that any Coronavirus Disease 2019 (COVID-19) vaccine would be covered under Medicare Part B.[115]

Formularies

Prescription drug plans operate formularies, which are lists of drugs that a plan chooses to cover and the terms under which they are covered. This means that plans can choose to cover some, but not all, FDA-approved prescription drugs, within set program standards.

A Part D sponsor's formulary must be developed and reviewed by a special CMS-approved Pharmacy and Therapeutics (P&T) Committee.[116] A majority of the committee members must be practicing physicians or practicing pharmacists and the committees must each include one physician and one pharmacist who are experts in caring for elderly or disabled individuals. Committees are to base decisions on the strength of scientific evidence and standards of practice when developing and reviewing formularies. CMS in 2016 strengthened conflict-of-interest provisions for P&T committees in Medicare Part D in response to concerns raised by the Department of Health and Human Service (HHS) Office of Inspector General.[117]

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[114] 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.

[115] CRS Report R46334, *Selected Health Provisions in Title III of the CARES Act (P.L. 116-136), Selected Health Provisions in Title III of the CARES Act (*P.L. 116-136*).* See Section 3713.

[116] 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.

[117] HHS OIG, "Gaps in Oversight of Conflicts of Interest in Medicare Prescription Drug Decisions," March 2013, at https://oig.hhs.gov/oei/reports/oei-05-10-00450.asp. See also CMS, "Medicare Program; Contract Year 2016 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs," 80 *Federal*

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.[118] (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)[119] 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.[120] 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"). This protected classes requirement, which started as CMS guidance, was 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.[121] As part of this process, the statutes allow HHS to revamp the current protected classes and

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Register, February 12, 2015, p. 7951, at https://www.federalregister.gov/documents/2015/02/12/2015-02671/medicare-program-contract-year-2016-policy-and-technical-changes-to-the-medicare-advantage-and-the/.

[118] 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).

[119] 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.

[120] 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.

[121] 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.

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 restrictions).[122] 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.[123] In May 2019, CMS announced it would not implement most of the proposed changes but instead would put into regulatory form existing sub-regulatory policy regarding utilization requirements for 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.[124] In the *Federal Register* notice announcing the final rules, CMS said it decided against a broader expansion of step therapy because the risks of inappropriately interrupting therapy for stabilized patients currently using a drug outweighed the potential clinical benefits and cost savings.[125]

Vaccines

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 also cover immunizations for patients exposed to an injury or disease, such as tetanus shots.[126] In addition, under the 2020 CARES Act, Medicare Part B will cover a vaccine for COVID-19 when a vaccine becomes available.[127] The Part B coverage designation means a COVID-19 vaccine cannot be covered under Part D.

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[122] 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*, pp. 1936 and 2063, January 10, 2014, at http://www.gpo.gov/fdsys/pkg/FR-2014-01-10/pdf/2013-31497.pdf.

[123] CMS, "Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses," Proposed Rule, 83 *Federal Register*, 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.

[124] 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.

[125] CMS, "Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses," Final Rule, 84 *Federal Register*, 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.

[126] CMS, Medicare Learning Network, "Medicare Part D Vaccines," June 2019, at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Vaccines-Part-D-Factsheet-ICN908764.pdf.

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

The Tax Relief and Health Care Act of 2006 modified the definition of a Part D drug to require plans to cover the costs for administering Part D-covered vaccines, as well as the vaccine itself. CMS considers the negotiated price for a Part D vaccine to include the vaccine ingredient cost, a dispensing fee (if applicable), sales tax (if applicable), and a vaccine administration fee.[128]

CMS policy is that Part D vaccines, including administration costs, are to be billed on one claim. The policy applies to providers both in- and out-of-network. Unlike Part B vaccines, which are billed directly to Medicare, Part D claims are paid by the insurance provider; therefore the entity/individual administering the Part D vaccine, such as a physician, may not be able to directly bill the Part D sponsor for the vaccine and administration. In some instances, patients must pay a physician for a vaccination up front, and then submit the bill to their Part D plan. CMS has issued guidance to plans regarding alternative billing options, such as allowing in-network pharmacists to administer vaccinations and to directly bill Part D, or having physicians electronically submit claims to Part D plans.[129] In an effort to increase vaccination rates, CMS has encouraged Part D sponsors to offer a $0 vaccine tier or to put vaccines on a formulary tier with low cost -sharing.[130]

Plan-Year Formulary Changes

Part D plans may alter their formularies from year to year. Plans are also allowed, in limited circumstances, to make changes to their formularies within a plan year.[131] Plans generally may not change therapeutic categories and classes of drugs within a plan year, except to account for new therapeutic uses or to 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.

Since 2019, Part D sponsors have been allowed to 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 if the generic 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. Plans are not required to give prior notice of the formulary change but (1) must generally advise enrollees in plan documents, such as annual formularies, that such changes may occur without a specific advance notice and (2) must tell affected enrollees about any substitutions that do occur.[132]

Other formulary changes may be made in the following circumstances:

- Plans may immediately remove drugs from their formularies that are deemed unsafe by the FDA or are pulled from the market by their manufacturers. Plans

[128] Ibid. p.2.

[129] Ibid.

[130] CMS, "Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," p. 230, April 2, 2018, at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.

[131] 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.

[132] 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 PACE Program," 83 *Federal Register*, April 16, 2018, p. 16604, at https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf.

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 formulary, such as replacing brand name with new generic drugs or modifying formularies as a result of 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.[133]

Transition Policies

CMS established transition standards 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.[134] In such cases, a beneficiary can request that his or her physician check to see if the 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 that the plan make an exception to its policy.

Plans are required to continue a beneficiary's previous prescription during the first 90 days of the 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.[135] 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.

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.[136] Since the Part D program began in 2006, the trend among plans has been to impose greater cost-sharing and utilization management. In addition, during the past

[133] 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.

[134] 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.

[135] 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 PACE Program," 83 *Federal Register*, 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.

[136] 42 C.F.R. §423.153.

several years, Congress and CMS have imposed more stringent 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 2021, the typical five-tier formulary design in Part D includes the following tiers: preferred generics, generics, preferred brands, non-preferred drugs, and specialty drugs.[137]

Part D plans are permitted to institute a specialty tier for expensive products (e.g., unique drugs or biologics). Beneficiaries cannot appeal cost-sharing amounts for drugs placed on a specialty tier. Plans typically charge a percentage of the cost of a drug on the specialty tier (coinsurance), rather than a flat co-payment. To ensure that beneficiaries dependent on specialty drugs are not "unduly discouraged" from enrolling in tiered plans, CMS has instituted the following conditions: (1) a plan may have only one specialty tier; (2) a plan with a standard deductible may impose coinsurance of up to 25% for specialty drugs, while a plan with a reduced or zero deductible may impose coinsurance of up to 33%, and (3) only drugs with negotiated prices exceeding a set threshold may be placed on a specialty tier ($670 for a month's supply for 2021).[138] Although specialty drugs are less than 1% of Part D prescriptions, they are nearly 20% of expenditures.

The specialty tier is not necessarily the tier with the highest coinsurance. Some Part D plans charge coinsurance greater than 33% for drugs on a non-preferred brand name formulary tier, up to the initial coverage limit. 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.[139] 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.

Under CMS guidance, plan sponsors offering alternative or enhanced plans that use tiered cost sharing can offer a non-preferred brand tier or a non-preferred drug tier, but not both. CMS has warned Part D sponsors that including a significant number of generic drugs on a tier labeled as a brand tier is misleading and could lead to beneficiary confusion. CMS set a maximum threshold

[137] Juliette Cubanski and Anthony Damico, "Medicare Part D: A First Look at Prescription Drug Plans in 2021," Kaiser Family Foundation, October 29, 2020, at https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-medicare-prescription-drug-plans-in-2021/.

[138] CMS, "Updated Contract Year (CY) 2021 Final Part D Bidding Instructions," May 22, 2020, at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2021%20mtm%20and%20specialty%20thresholds%20final%20part%20d%20bidding%2005.22.2020_7.pdf. CMS had issued a proposed rule that would have allowed plans to offer two specialty drug price tiers rather than one. CMS did not finalize the specialty tier portion of the rule, and instead issued special guidance for 2021.

[139] 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.

of 25% generic composition for a non-preferred brand tier starting in 2019.[140] CMS reviewed but did not change its policy in 2020, despite concerns from advocacy groups that placing generics on non-preferred drug tiers could increase enrollee cost sharing for those generics. CMS noted "limited instances when Part D sponsors were not including generic alternatives when available." CMS said it would continue to monitor the issue.[141]

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.

Since 2014, PDPs have been required to apply a daily cost-sharing rate to prescriptions for less than a 30-day supply of medication (with some exceptions).[142] The daily cost-sharing rate is defined as the monthly co-payment under the enrollee's Part D plan, divided by 30 or 31 and rounded to the nearest lower dollar amount. The daily cost-sharing requirement gives beneficiaries an incentive to ask physicians for shorter prescriptions when trying a medication for the first time because the Part D sponsor will charge the lower, pro-rated cost sharing when the prescription is dispensed. Shorter prescriptions are seen as a means to reduce Part D beneficiary costs and drug waste in cases where a prescribed drug is ultimately found not to be effective.[143]

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 internal 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.[144] Second, CMS has operated 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

[140] CMS, "Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," p. 229, April 2, 2018, at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.

[141] CMS, "Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," p. 210-211, April 1, 2019; https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf.

[142] 42 C.F.R. §423.153(b)(4)(i).

[143] CMS, "Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs for Contract Year 2013 and Other Changes, Final Rule," 77 *Federal Register*, April 12, 2012, p. 22126, at http://www.gpo.gov/fdsys/pkg/FR-2012-04-12/pdf/2012-8071.pdf.

[144] 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.

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.[145] Part D plans are to review drug use of beneficiaries identified through the OMS.

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.[146]

Since 2019, Part D plan sponsors have been allowed to limit an at-risk beneficiary's access to frequently abused drugs (initially defined by CMS as opioids and concurrent use of benzodiazepines) by imposing a prescription safety edit at the point of sale, and/or by requiring an at-risk enrollee to obtain opioids only from a selected pharmacy(ies) and/or prescriber(s), after case management and appropriate notice.[147] The 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.[148]

The 2019 rule[149] also seeks to reduce opioid fraud and abuse by barring Part D plans from covering prescriptions written by physicians or other health care providers who are on a special CMS preclusion list.[150] 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) requires Part D plan sponsors to implement lock-in programs.[151]

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

[145] 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/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.

[146] 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*, April 16, 2018, pp. 16442-16480.

[147] Ibid. An enrollee may ask for a redetermination of a designation as an at-risk beneficiary.

[148] CMS, "Part D Drug Management Program Policy Guidance," November 20, 2018. Available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.

[149] CMS, "Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," April 2, 2018, p. 239, at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf. The requirements also applied to the 2020 plan year.

[150] CMS, "CY 2020 Medication Therapy Management Program Guidance and Submission Instructions," April 5, 2019, at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Memo-Contract-Year-2020-Medication-Therapy-Management-MTM-Program-Submission-v-041019-.pdf. The preclusion list covers prescribers, individuals, and entities that (a) are revoked from Medicare, are under an active reenrollment bar, and for whom CMS determines that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program; or (b) have engaged in behavior for which CMS could have revoked the prescriber, individual, or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.

[151] CRS Report R45449, *The SUPPORT for Patients and Communities Act (P.L.115-271): Medicare Provisions*.

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 that is considered when CMS evaluates a sponsor's bid to participate in the Part D program for an upcoming contract year.

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 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 $4,376 in 2021.[152]

Part D sponsors also may target beneficiaries with any chronic diseases or with specific chronic diseases. If plans target beneficiaries with specific diseases, they must include at least five of the diseases CMS has defined as nine core chronic conditions:[153]

- Alzheimer's Disease;
- Chronic Heart Failure;
- Diabetes;
- Dyslipidemia;
- End-Stage Renal Disease (ESRD);
- Hypertension;
- Respiratory Disease (such as asthma or chronic lung disorders);
- Bone Disease-Arthritis; and
- Mental Health (such as depression, schizophrenia, or bipolar disorder).

In addition, the SUPPORT Act adds Part D enrollees identified as at risk for prescription drug abuse to the list of targeted MTM program enrollees, effective in plan year 2021.[154]

CMS guidelines state that, once enrolled, beneficiaries should remain in a MTM program for the course of a plan year, even if they no longer meet one or more of the eligibility criteria. The MTM program must include a comprehensive review of a beneficiary's medications, intervention with both beneficiaries and prescribers, and quarterly, targeted medication reviews.[155] In 2015, CMS announced a five-year MTM pilot program, beginning in 2017, to test whether offering Part D sponsors additional payment incentives and more regulatory flexibility would lead to improved outcomes for MTM beneficiaries.[156]

Part D Plans: Payment and Participation

Medicare Part D participants must obtain coverage through a private insurer, or other entity, that contracts with Medicare (a plan sponsor). As previously described, beneficiaries may select either

[152] CMS, "2021 Medication Therapy Management Program Information and Submission Instructions," May 22, 2020, at https://www.cms.gov/files/document/memo-contract-year-2021-medication-therapy-management-mtm-program-submission-v-052220.pdf.

[153] Ibid.

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

[155] Ibid.

[156] CMS, "Part D Enhanced Medication Therapy Management Model," at https://innovation.cms.gov/initiatives/enhancedmtm/.

a stand-alone prescription drug plan or a Medicare Advantage plan that includes prescription drug coverage along with other Medicare services.[157]

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.[158] Medicare payments to plans are determined through a competitive bidding process, and enrollee premiums are tied to plan bids. Plans bear some risk for their enrollees' drug spending. (See "Approval of PDP Plans.")

Approval of PDP Plans

Each year, CMS issues a call letter to sponsors planning to offer PDP and/or MA plans in the following year. The 2021 final call letter was issued in April 2020.[159] Potential PDP and MA sponsors are required to submit bids by the first Monday in June of the year prior to the plan benefit year. The following information must be included as part of 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. CMS reviews the information when negotiating with plan sponsors and in deciding whether to approve their program bids.

CMS may approve a drug plan only if certain requirements are met. For example, CMS must determine that the plan and sponsor 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. A contract may cover more than one Part D plan. Under the terms of a contract, the sponsor agrees to comply with Part D requirements and have satisfactory administrative and management arrangements. Beginning in 2016, CMS imposed a two-year Part D application ban on sponsors that have been approved to offer PDP plans but withdraw their bids after CMS announces the annual LIS benchmark amounts.[160]

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[157] 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.

[158] 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.

[159] CMS, "Announcement of Calendar Year (CY) 2021 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," April 6, 2020, p.71, at https://www.cms.gov/files/document/2021-announcement.pdf.

[160] 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.

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."[161]

Some Members of Congress have introduced proposals to repeal or modify the noninterference provision since the start of the Part D program, to give the HHS Secretary the 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 drug manufacturers and pharmacies than can be obtained by plan sponsors. Opponents note that Part D enrollment is concentrated in a few plan sponsors that already have substantial bargaining power. The Congressional Budget Office in previous analyses of legislation has said 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. [162]

Plan Availability

For the 2020 plan year, sponsors offered 948 PDPs and 2,799 MA-PD plans.[163] The number of PDPs per region in 2020 ranged from a low of 24 to a high of 32 across the 34 Part D regions, and beneficiaries in an average county (weighted by population) have 27 MA-PD options to choose from.[164] The number of PDPs and MA-PD plans has been increasing in recent years, as CMS has relaxed some regulations and insurers have expanded MA-PD plan offerings.[165] According to early analyses, in 2021 a total of 996 PDPs are to be offered nationwide. Medicare beneficiaries will have 30 PDPs and 27 MA-PD plans to choose from in their geographic area, on average.[166]

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 all premiums in each of the 34 PDP regions. 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.

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[161] Social Security Act, §1860D-11(i).

[162] CRS In Focus IF11318, *Negotiation of Drug Prices in Medicare Part D*.

[163] MedPAC, *Report to the Congress: Medicare Payment Policy*, March 13, 2020, p. 419, athttp://medpac.gov/docs/default-source/reports/mar20_medpac_ch14_sec.pdf?sfvrsn=0.

[164] Ibid.

[165] Ibid.

[166] Juliette Cubanski and Anthony Damico, "Medicare Part D: A First Look at Prescription Drug Plans in 2021," Kaiser Family Foundation, October 29, 2020, at https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-medicare-prescription-drug-plans-in-2021/.

In 2020, there were 244 LIS benchmark PDPs—an increase of 13% from 2019.[167] 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.") As is the case for non-LIS enrollees, enrollment for LIS enrollees has become concentrated over time. In 2020, 90% of LIS beneficiaries were in plans offered by five sponsors: CVS Health, UnitedHealth Group, Humana, WellCare, and Cigna (including its subsidiary Express Scripts).[168]

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,[169] weighted by the plans' shares of total enrollment. (The national average monthly bid is $43.07 for plan year 2021.)[170] 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. (See "Premiums.")

Reinsurance Subsidies

As previously noted, in a standard drug plan, Medicare subsidizes 80% of each plan's costs for catastrophic coverage—the reinsurance subsidy. 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 monthly basis during the year, based on either estimated or incurred costs, 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. (See "Historical Program Spending.")

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[167] MedPAC, *Report to the Congress: Medicare Payment Policy*, March 13, 2020, p. 422, at http://medpac.gov/docs/default-source/reports/mar20_medpac_ch14_sec.pdf?sfvrsn=0.

[168] Ibid, p. 423.

[169] 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.

[170] CMS, "Annual Release of Part D National Average Bid Amount and other Part C & D Bid Related Information," July 29, 2020, at https://www.cms.gov/files/document/july-29-2020-parts-c-d-announcement.pdf.

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.[171] Negotiated prices, as currently defined by CMS, 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.[172] Negotiated prices include pharmacy dispensing fees. Negotiated prices must not be rebated back to a plan sponsor in full or in part.[173]

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 PDA data to track out-of-pocket and total drug spending (plan plus beneficiary spending) as enrollees move through stages of the Part D benefit.[174]

Prescription drug 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 discounts, chargebacks or manufacturer rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies, or similar entities.[175] Plans must submit detailed DIR reports to CMS within six months after the close of a plan year.[176]

As noted, during the course of 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 annual reconciliation process, to determine whether sponsors have been overpaid or whether Medicare owes them money. (See "Reconciliation.")

Risk Corridor Payments

The MMA also 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

[171] 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.

[172] 42 C.F.R. §423.100.

[173] 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.

[174] For more CMS information on PDE data see https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PartDData.html.

[175] DIR is defined at 42 C.F.R. §423.308, under "Actually Paid."

[176] On November 20, 2020, HHS issued a final rule to bar most drug rebates, effective in plan year 2022. If the final rule takes effect, it is forecast to reduce cost sharing for some Part D enrollees who are sicker or are taking more expensive brand-name drugs, but to increase plan premiums for all enrollees, and possibly increase costs to the Medicare program. See **Appendix B**.

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 low-income subsidy payments.[177]
- 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[178] for offering the Part D drug benefit, as risk adjusted. The target amount does not include administrative expenses assumed in the plan's standardized bid.[179]

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 plan year 2021, 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. As CMS has gained more experience with Part D, the risk corridors have widened, increasing the share of insurance risk borne by the plans. Since 2012, CMS has had the authority under the MMA to either leave the corridors unchanged or to widen them. CMS has moved to keep the corridors at 2011 levels through the 2021 program year.[180] CMS does not have the authority to narrow the risk corridors.

[177] Social Security Act §1860D-15(e)(1)(B).

[178] 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.

[179] Social Security Act §1860D-15(e)(3)(B).

[180] CMS, "Advance Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2015 Call Letter," February 5, 2020, p. 42, at https://www.cms.gov/files/document/2021-advance-notice-part-ii.pdf.

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
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, "2021 Initial Call Letter."

Reconciliation

Following the close of a calendar year, CMS makes retroactive adjustments to the direct subsidy payments made to plans to reflect actual plan experience. The direct subsidy payments are adjusted based on updated data about actual beneficiary health status and enrollment. Additionally, prospective payments for reinsurance and low-income subsidy payments are compared to actual incurred costs, net of any DIR (including discounts, chargebacks, or rebates from drug manufacturers), and other related data, and appropriate adjustments are made to the plan payments. Finally, any necessary adjustments are made to reflect risk sharing under the risk corridor provisions. In general, Part D sponsors have tended to overestimate their costs for operating Part D plans in the aggregate. For example, Part D plans in most years made net risk corridor payments to CMS. (See **Table 8**.)

Table 8. Medicare Part D Risk Corridor Payments

(in billions of dollars)

Year	Net Risk-Sharing Payments
2006	-$1.6
2007	- 0.5
2008	- 0.2
2009	- 0.7
2010	- 0.1
2011	- 0.9
2012	- 1.1
2013	- 0.7
2014	- 0.1

Year	Net Risk-Sharing Payments
2015	- 1.1
2016	- 1.1
2017	-0.5
2018	0.0
2019	0.2
2020	0.9

Source: 2020 Medicare Trustees Report, Table IV.B10, and 2016 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. Figures for 2006 and 2007 include reimbursement of certain state costs under the Part D transition demonstration program. Figures for 2019 and 2020 are estimates; other years are actual data.

According to CMS, data on individual plans continue to show considerable variation in terms of risk sharing, with some plans making significant risk corridor payments to CMS and others requiring government payments.[181] In the past, MEDPac has raised questions about whether Part D plans adequately assess risk in their annual plan bids but has suggested that keeping Part D risk corridors in place, at least temporarily, would help to limit excess plan profits.[182]

Reduction of Part D Plan Payments Under Sequestration

Due to provisions in the Budget Control Act of 2011 (BCA; P.L. 112-25), most Medicare benefit related payments are to be reduced through sequestration by 2%.[183] (The CARES Act suspended these reductions from May 2020 through December 2020.) Under Part D, Medicare payments to plans for the direct subsidies and retiree drug subsidies are to be 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 beneficiary premiums or cost sharing or to reduce benefits to make up for their lower payments under sequestration.[184] The sequestration of Medicare benefit spending is scheduled to continue through FY2030.

Pharmacy Access and Payment

Part D sponsors are required to establish a pharmacy network sufficient to ensure access to covered Part D drugs for all enrollees. Sponsors must demonstrate that they provide (1)

[181] CMS, "Advance Notice of Methodological Changes for Calendar Year (CY) 2018 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2015 Call Letter," February 1, 2017, p. 39, at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents-Items/2018Advance.html.

[182] MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System*, June 2016, p. 165, at http://www.medpac.gov/docs/default-source/reports/june-2016-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf?sfvrsn=0.

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

[184] 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.

convenient access to retail pharmacies for all enrollees, (2) adequate access to home infusion pharmacies for all enrollees, (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 the sponsor's service area.

Any Willing Pharmacy

Part D sponsors are required to 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.[185] 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. A Part D sponsor may not require a network pharmacy to accept insurance risk as a condition of participation in its pharmacy network.

Since 2019, Part D plans have been required to (1) make standard pharmacy contract terms and conditions available by September 15 of each year 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 from the pharmacy.[186]

Preferred Pharmacy

While any qualified pharmacy can participate in a plan network, Part D plans, with the exception of plans offering defined, standard coverage,[187] may contract with a smaller subset of pharmacies, or pharmacy chains, to serve as preferred pharmacies.[188] Preferred pharmacies generally are marketed as having lower beneficiary cost sharing than other pharmacies in the plan network. Beneficiaries who sign up for a preferred pharmacy plan still have the option of going to any one of a number of network pharmacies in their plan region, but may face a higher cost share 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.[189] 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.

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[185] 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.

[186] 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 PACE Program," 83 *Federal Register*, 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.

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

[188] 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.

[189] Ibid.

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 by 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.[190]

CMS issued a definition of retail pharmacy, which took effect in 2019, to provide better guidance for Part D plans in determining which contracted pharmacies count toward meeting the convenient access standards.[191] The definition of retail pharmacy includes "any licensed pharmacy that is open to dispense prescription drugs to the walk-in general public from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy."[192]

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.[193] 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. However, enrollees may be charged more by Part D

[190] 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.

[191] 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 PACE Program," 83 *Federal Register*, 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.

[192] 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 PACE Program," 83 *Federal Register*, April 16, 2018, p. 16596, at https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf; 42 C.F.R. §423.100.

[193] 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.

sponsors for filling certain prescriptions at a retail pharmacy, rather than a mail-order pharmacy, within limits set by CMS.[194]

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's specialty drug tier. Specialty drug tier designation is based on cost ($670 per month in 2021), not on other special handling requirements.[195]

CMS does not have a regulatory definition of specialty pharmacy. Plans may set their own definition and fee structure for specialty pharmacies and specialty networks, including preferred specialty networks. However, Part D pharmacy 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.[196] 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 for its network LTC pharmacies. 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 that are given intravenously in a home setting. Administration of the 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 plan 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 is a hospital, ambulatory care unit, or similar facility where a patient receives

[194] Ibid, Section 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.

[195] Ibid. Section 50.3 and CMS, "Updated Contract Year (CY) 2021 Final Part D Bidding Instructions," May 22, 2020, at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2021%20mtm%20and%20specialty%20thresholds%20final%20part%20d%20bidding%2005.22.2020_7.pdf. CMS had issued a proposed rule that would have allowed plans to offer two specialty drug price tiers rather than one. CMS did not finalize the specialty tier portion of the rule, and instead issued special guidance on specialty tier pricing for 2021.

[196] Ibid. Section 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."

treatment for a serious but brief illness.) Part D plans are not expected to pay for supplies, equipment, or professional services needed for home infusion therapy. They are expected to stock drugs in a form that can be easily used, to deliver products when needed, and to ensure that enrollees have the necessary supplies and professional assistance before dispensing home-infusion drugs.

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.[197] 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).[198]

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 B** 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.[199] 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.[200] For brand-name drugs, PBMs may reimburse

[197] 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.

[198] CRS Report R46334, *Selected Health Provisions in Title III of the CARES Act (P.L. 116-136)*, coordinated by Elayne J. Heisler. See Section 3714. Requiring Medicare Prescription Drug Plans and MA-PD Plans to Allow During the COVID-19 Emergency Period for Fills and Refills of Covered Part D Drugs for Up to a 3-Month Supply.

[199] 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, physically 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.

[200] 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.

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 pricing; audit terms; and quality requirements, such as set targets for accuracy in dispensing drugs. Contracts are confidential and are not standard among Part D plans.

Part D sponsors are required to make payment for "clean claims," within 14 calendar days of the date when an electronic claim is received, and within 30 calendar days of the date that non-electronically submitted claims are received.[201] A clean claim is a claim that does not require further development or investigation (for example, 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 after a clean claim is received, the PDP sponsor or MA-PD plan will be required to 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. CMS considers such fees on network pharmacies to be a concession that reduces the cost of dispensing a Part D drug. However, because many plan sponsors, and their PBMs, impose pharmacy fees based on performance over time, sponsors often do not pass the fees on as a price reduction at point of sale but report them as DIR. According to CMS, DIR pharmacy price concessions, net of all pharmacy incentive payments, grew more than 45,000% from 2010 to 2017.[202]

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.[203] PDPs and MA-PD plans are required to provide enrollees with written information about their rights, and to institute both standard and expedited procedures for addressing coverage issues.[204]

If a Part D sponsor operates a drug management program, the sponsor must comply with special appeal procedures for issues involving beneficiaries who have been deemed at risk of prescription drug abuse. (See "Part D Opioid Overutilization Monitoring.") An at-risk determination is subject to the Part D benefit appeals process and timeframes. If an enrollee disagrees with an at-risk determination, the enrollee has the right to request a redetermination and potentially higher levels of appeal.[205]

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[201] This provision was added by MIPPA and may be found at §1860D-12(b)(4)(A)(ii) of the Social Security Act.

[202] CMS, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenditures," 83 *Federal Register* 6217, November 30, 20184, 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.

[203] CMS, *Medicare Appeals*, at https://www.medicare.gov/Pubs/pdf/11525-Medicare-Appeals.pdf.

[204] CMS, "Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance," Effective January 1, 2020, at https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.

[205] CMS, "Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance," Section

An enrollee may appoint a representative to act on his or her behalf during the 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.[206] 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.[207] (Physicians or prescribers do not have all the rights of a designated representative, however, 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;[208] (2) a decision concerning a request about a specific drug payment tier;[209] (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.[210]

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.[211] If a Part D plan sponsor denies a request for an expedited determination, it must

40.3, Effective January 1, 2020, at https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.

[206] 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.

[207] CMS, "Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance," Section 60.1, Effective January 1, 2020, at https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.

[208] 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.

[209] 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.

[210] CMS, "Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance," Section 40.2, Effective January 1, 2020, at https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.

[211] CMS, "Coverage Determinations," https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/CoverageDeterminations-.

- 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.

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.[212]

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.[213] 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.[214]

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.[215] 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.[216]

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, also

[212] 42 C.F.R. §423.570.

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

[214] CMS, "Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance," Section 50.7.1, Effective January 1, 2020, at https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.

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

[216] CMS, "Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance," Section 60.3, Effective January 1, 2020, at https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.

known as a Qualified Independent Contractor (QIC). 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.[217]

According to CMS, Medicare received 35,414 reconsideration cases in CY2016. In about 30% of the cases, the plan sponsor's decision was overturned.[218]

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 ($170 for 2020).[219] 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.[220] 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 ($1,670 for 2020).

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

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[217] Ibid.

[218] CMS, "Fact Sheet: Part D Reconsiderations Appeals Data-2016," at CMS webpage "Reconsiderations by the Independent Review Entity," at https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Reconsiderations.html. Data exclude cases that were dismissed, withdrawn, or remanded (the Part D QIC did not have jurisdiction to make a substantive decision on the case) and cases involving non-Part D drugs. The Part D QIC reversed plan decisions in 29.81% of cases.

[219] "Medicare Part D Flowchart 2020," at https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/Flowchart-Medicare-Part-D.pdf.

[220] CMS, "Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance," Section 30, Effective January 1, 2020, at https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf.

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.[221]

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.[222] (Sometimes a complaint may involve both a grievance and a coverage determination.)

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.[223] 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.[224] Quality of care grievances filed with a QIO may be filed and investigated beyond the 60-day time frame.

Program Oversight

The size, nature, and complexity of the Medicare Part D program put it at particular risk for fraud, waste, and abuse. Some examples of program vulnerabilities that have been identified include drug diversion (redirecting prescription drugs, such as opioids, for illegal purposes); billing for drugs that are not dispensed; and inappropriate plan denials of covered drugs. A variety of entities are involved in oversight activities to ensure program compliance and identify potentially fraudulent activities

CMS Oversight

CMS is responsible for preventing and detecting fraud and abuse in Medicare Part D and ensuring sponsors' compliance with applicable requirements. CMS conducts a wide variety of oversight activities, such as bid reviews, marketing reviews, financial and accounting reviews, program audits, and LIS-readiness audits.[225] Some of the management controls used in the routine operation of Medicare Part D play a primary role in the administration of the benefit and a secondary role in fraud prevention and detection.

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[221] 42 C.F.R. §423.564.

[222] 42 C.F.R. §423.564.

[223] Social Security Act, §1154(a)(14).

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

[225] The only statutorily required activity is that CMS conduct financial audits of one-third of the plans each year. Social Security Act §1860D-12(b)(3)(C).

For each plan sponsor, CMS establishes a point of contact (account manager) for all communications with the plan. The account managers are to work with plans to resolve any problems, including compliance issues. As part of its oversight strategy, CMS conducts routine *program audits* to ensure compliance with various program requirements, including such things as enrollment and disenrollment, marketing and beneficiary information, pharmacy access, coordination of benefits, claims processing and payment, and grievances and coverage determinations.[226] CMS can also conduct separate, focused audits to confirm that a previously identified deficiency has been corrected or to check into an indication of noncompliance. These audits include a combination of desk and on-site activities.

In *financial audits*, CMS looks at the accuracy and validity of data reported by the plans. These audits, normally conducted after payment reconciliation, may examine things such as possible overpayments to plans, misrepresentation of bids, underreporting of rebates, and inaccurate prescription drug event data. If financial audits identify problems, CMS would recalculate payment reconciliation for that sponsor and target the sponsor for a future audit.

If egregious problems are identified, CMS actions can range from warning letters to civil monetary penalties or removal from the program, depending on the extent to which plans have violated Part D program requirements.

Oversight Responsibilities of Part D Sponsors

CMS requires plan sponsors to monitor and correct their own behavior, as well as the behavior of those they contract with. Part D sponsors are required by law to implement a comprehensive fraud and abuse program to detect, correct, and prevent fraud, waste, and abuse. Chapter 9 of CMS's *Prescription Drug Benefit Manual* provides both interpretive rules and guidelines for sponsors to follow in developing this program.[227]

Part D sponsors are required to have, and to implement, an effective compliance plan as a condition of participation in the Medicare program. Elements of an effective plan include written policies and procedures; a designated compliance officer and committee; training and education, effective lines of communication, well-publicized disciplinary guidelines, and internal monitoring and auditing; and prompt response to detected offences and development of corrective actions.

Part D sponsors are also required to provide fraud, waste, and abuse training and education to first-tier, downstream, and related entities.[228] This includes pharmacists, pharmacy clerks, and others who are employed by entities that plans contract with to provide the Medicare drug benefit.

[226] CMS, "Program Audits, at https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits.html; and CMS, *Prescription Drug Benefit Manual*, Chapter 9, "Compliance Program Guidelines," Rev. January 11, 2013, at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf.

[227] CMS, *Prescription Drug Benefit Manual*, Chapter 9, "Compliance Program Guidelines," Rev. January 11, 2013, at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c21.pdf.

[228] Ibid.

Medicare Part D Oversight Contractors

Medicare Drug Integrity Contractor: National Benefit Integrity

CMS contracts with a private firm, Qlarant,[229] to act as the National Benefit Integrity Medicare Drug Integrity Contractor (NBI MEDIC) for Part D plans. The NBI MEDIC's responsibilities include conducting complaint investigations; performing data analysis; developing and referring cases to law enforcement, as well as supporting ongoing investigations; conducting audits; and reviewing PDP and MA-PD plan fraud and abuse compliance programs.[230]

The NBI MEDIC is also responsible for working with other entities to coordinate fraud prevention and detection efforts, including the Part D sponsors, other Medicare contractors, the HHS Office of Inspector General (OIG), the Department of Justice, and state agencies.

Medicare Drug Integrity Contractor: Outreach and Education

CMS also has contracted with Rainmakers Strategic Solutions LLC[231] to act as the Outreach and Education Medicare Drug Integrity Contractor (O&E MEDIC). The O&E MEDIC provides education on waste, fraud, and abuse for plan sponsors, pharmacists, law enforcement, as well as for Medicare advocates and enrollees. The O&E MEDIC maintains a website containing fraud and abuse related regulations and guidance, professional education materials, and relevant state and federal agency contact information.

Part D Recovery Audit Contractor

The ACA required CMS to expand its Recovery Audit Contractor (RAC) program to Medicare Part C and Part D.[232] CMS has contracted with ACLR Strategic Business Solutions to perform the Part D RAC audit functions.[233] The Part D RAC reviews Medicare payments made to plan sponsors and pharmacies to identify any over- or underpayments, provides information to CMS to help prevent future improper payments, and refers potential fraud findings to the NBI MEDIC.

Program Spending and Financing[234]

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

[229] NBI Medicare Drug Integrity Contractor, at https://www.qlarant.com/about/contracts/.

[230] CMS, *Prescription Drug Benefit Manual*, Chapter 9, "Compliance Program Guidelines," Section 50.7.4, Rev. January 11, 2013, at http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter9.pdf.

[231] CMS, "Review Contractor Directory - Interactive Map," at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs//Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/index.html. See also: Education & Outreach Medicare Drug Integrity Contractor, at http://www.rainmakerssolutions.com/.

[232] For additional information see CMS, "Review Contractor Directory - Interactive Map," at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs//Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/index.html.

[233] CMS, "Part D RAC Audit Process," at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Audit-Process.html.

[234] This section was written by Patricia A. Davis, Specialist in Health Care Financing, Congressional Research Service.

and Part D.[235] 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 2020 Medicare Trustees Report, during CY2019, total Part D expenditures were approximately $97.6 billion.[236] (See **Table 9.**) This amount included the combined costs of prescription drugs provided by Part D plans to enrollees and 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. (See the **Appendix A** for historical and projected Part D expenditures.)

Revenues

The major sources of revenue for the Part D account include general revenues, beneficiary premiums, and state contributions. In CY2019, of the $98.7 billion in total Part D income, general revenues accounted for $70.2 billion, premiums accounted for $15.8 billion, and transfers from states for $12.3 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 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

Beneficiary premiums are based on the participating plans' national average bid amounts and are defined prior to each year's operations,[237] with the average premium amounting to 25.5% of the expected per capita plan costs for basic coverage. (See "Premiums.") In 2021, the base monthly premium is $33.06; however, beneficiaries pay different premiums depending on the plan they selected (and whether they are entitled to low-income premium subsidies). Beneficiaries may have their premiums deducted from their Social Security or other federal benefit payments; these are then forwarded to Part D plans on their behalf. Alternatively, they may pay their premiums directly to the Part D plans.

As required by the ACA, since 2011, beneficiaries with higher incomes pay income-related monthly premium adjustments in addition to the premiums charged by the plans in which they

[235] 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*.

[236] 2020 Medicare Trustees Report, Table III.D3, p. 103, at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html.

[237] For example, the base premiums for 2021 were announced in July 2020. See CMS Memorandum, CMS, "Annual Release of Part D National Average Bid Amount and other Part C & D Bid Information," July 20, 2020, at https://www.cms.gov/files/document/2021-announcement.pdf.

have enrolled.[238] (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. Because individual plan premiums vary, the additional amount paid is calculated as a percentage of the base beneficiary premium, not the individual's actual premium amount. This extra amount is usually deducted from an individual's monthly Social Security payments regardless of how that person ordinarily pays the monthly prescription plan premiums. If the amount is greater than the monthly payment from Social Security, or an individual does not receive Social Security payments (e.g., the individual has not yet signed up for Social Security benefits), then CMS may directly bill the individual for this amount.

In CY2019, $5.2 billion in premium amounts were withheld from Social Security benefit checks or other federal benefit payments. (See **Table 9**.) Another $10.6 billion in premiums were paid directly to the plans by beneficiaries. As noted, premiums for the Part D program are generally set at an amount equal to 25.5% of standard benefit costs; however, as recipients of the Part D low-income subsidies are not required to pay premiums and premiums are based only on standard benefits (i.e., the premium calculation does not include such things as costs associated with the low-income subsidy and risk-corridor payments), premiums made up about 16% of total Part D program revenues in 2019.

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, low-income subsidies, net risk-sharing payments, administrative expenses, and advanced discount payments.[239] In CY2019, contributions received from the general fund of the Treasury amounted to $70.2 billion, or about 71% of total Part D revenue.

Table 9. Statement of Operations of Part D Account, CY2019

(in millions of dollars)

Assets at Beginning of Year	**$7,999.4**
Revenues	**$98,747.9**
Premiums from Enrollees	15,760.1
Premiums deducted from Social Security checks	*5,159.6*
Premiums paid directly to plans	*10,600.5*
Government Contributions	70,222.2
Prescription drug benefits	*70,162.6*
Administrative expenses	*59.7*
Payments from States	12,288.5
Interest	59.1

[238] The income thresholds are set at the same levels as those under Part B. For additional information, see CMS Memorandum, "2020 Part D Income-Related Monthly Premium Adjustment," September 27, 2019 at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/PartDIRMAA2020.pdf.

[239] 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.

Expenditures	**$97,572.9**
Benefit Payments	97,090.6
Federal Administrative Expenses	482,3
Assets at End of Year	**$9,174.4**

Source: 2020 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 low-income subsidies 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 CY2019, state payments amounted to $12.3 billion, or about 12.4% of Part D revenues.

Historical Program Spending

Actual spending for the Medicare prescription drug benefit has been lower than estimated at the beginning of the program. The 2004 Medicare Trustees Report, the first of such reports issued subsequent to the enactment of MMA, projected that total program spending would be $85 billion in CY2006 (the first year of the program) and would grow to about $162 billion by CY2013.[240] Actual Medicare expenditures for the Part D drug benefit were approximately $47 billion in CY2006 and close to $70 billion in CY2013. The difference between projected and actual spending has been due to both lower than expected enrollment and per capita spending. (See **Table 10**.) Original CBO estimates of Part D spending were also higher than actual spending for FY2004-FY2013. (See **Table 11**.)

[240] Original spending projections were made for the 10-year period 2004 to 2013. The Medicare Trustees report on a calendar year basis, while CBO reports on a fiscal year basis.

Table 10. Comparison of Projected and Actual Part D Enrollment and Spending

(CY2006-CY2013)

	Enrollment (in thousands)		Per Enrollee Spending		Total Part D Spending (in billions of dollars)	
	2004 Trustees Report (Projected)[a]	2016 Trustees Report (Actual)[b]	2004 Trustees Report (Projected)	2016 Trustees Report (Actual)	2004 Trustees Report (Projected)	2016 Trustees Report (Actual)
2006	40,736	30,560	$2,069	$1,708	$85.0	$47.4
2007	41,468	31,392	2,225	1,556	93.0	49.7
2008	42,296	32,589	2,391	1,504	101.9	49.3
2009	43,158	33,644	2,557	1,798	111.2	60.8
2010	44,069	34,772	2,725	1,775	120.9	62.1
2011	45,117	35,720	2,892	1,868	131.4	67.1
2012	46,374	37,448	3,120	1,776	145.6	66.9
2013	47,761	39,103	3,367	1,772	161.8	69.7

Source: CRS analysis of data from Tables II.A3, II.C18 and II.C19 of the 2004 Medicare Trustees Report and Tables V.B4, III.D3 and III.D4 of the 2016 Medicare Trustees Report.

a. All data from the 2004 report are projected.

b. All data from the 2016 report are actual.

Table 11. Comparison of Original CBO Estimates and Actual Part D Costs, FY2004-FY2013

(in billions of dollars)

		2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2004-2013	% Actual Different from Projected
Federal Spending	CBO Original Cost Estimate[a]	$0.6	$1.5	$32.1	$52.9	$59.9	$65.7	$72.6	$79.5	$88.5	$98.9	$552.2	
	2016 Medicare Trustees Report[b]	0.2	1.2	27.7	41.5	35.4	43.5	52.7	57.0	44.5	50.1	353.8	**35.9% less**
Total Spending	CBO Original Cost Estimate	0.6	1.5	46.8	74.8	84.2	92.0	101.3	110.6	122.8	136.8	771.4	
	2016 Medicare Trustees	0.2	1.2	33.9	52.4	47.2	56.8	63.8	71.0	61.0	68.3	455.8	**40.9% less**

Source: Congressional Budget Office, Projection of Spending for the Medicare Part D Benefit: Letter to the Honorable William "Bill" M. Thomas, February 9, 2005; and the 2016 Medicare Trustees Report, June 22, 2016, Table V.H8.

Notes:

a. The figures in this table are for fiscal years, whereas those in **Table 11** are for calendar years. Original projections were for the 10-year period FY2004 through FY2013.

b. Actual federal Medicare Part D cost is measured as total expenditures less premium income and transfers from states. Trustee report figures for FY2004-FY2013 reflect actual spending.

While aggregate Part D expenditures have increased by an average annual rate of 4.8% from 2009 to 2019, most of this growth reflects the growth in enrollment during the initial years of the program. Per capita expenditures during this time increased at a much slower annual rate of 1.4%.[241] Both the Medicare Trustees and CBO attribute the slower per capita growth rate to a high proportion of prescriptions filled with low-cost generic drugs, as well as to patent expirations of major drugs during this period.[242]

In their 2020 report, the Medicare Trustees noted that 2018 Part D per capita benefit expenditures were lower than in 2017 and attributed this decrease to reconciliation payments received from plans for their experience in 2017.[243] The Medicare Trustees reported a similar level of per capita expenditures for 2019 and attributed this to higher assumed DIR and slow reinsurance growth in plan bids. (However, in 2020, the trustees expect significant reconciliation payments to be made to plans, which would substantially increase the level of per capita benefit spending in 2020.) (See **Table 12**.)

Estimated Future Part D Expenditures

Over the 10 year period from 2020 to 2029, the Medicare Trustees project more rapid growth in Part D costs, with aggregate benefits increasing on average at 6.9% annually and per capita expenditures increasing on average by 4.2% each year.[244] This projected growth is due to expectations of a slowing in the generic drug dispensing rate and an increase in the cost of specialty drugs. (See **Table 12** and **Table 13**.)

Table 12. 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
Historical data					
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

[241] The corresponding rates for the 2008-2018 period were 6.8% for total expenditure growth and 3.2% for per capita growth. The Trustees note that this "erratic pattern" occurred primarily because of the large 2009 reconciliation payment for the 2008 plan year which had the effect of establishing a higher base level in 2009, thus reducing the 10-year annual rate for 2009-2019. 2020 Medicare Trustees Report, pp. 105-106.

[242] 2020 Medicare Trustees Report, pp. 105-106; and CBO, "Competition and the Cost of Medicare's Prescription Drug Program," July 2014, at http://www.cbo.gov/sites/default/files/cbofiles/attachments/45552-PartD.pdf.

[243] 2020 Medicare Trustees Report, p. 104.

[244] Ibid., pp. 106.

Calendar Year	Aggregate Benefits[a] (Billions)	Percentage Change	Per Capita Benefits	Percentage Change	Part D Benefits as a Percentage of GDP
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	89.5	15.1	2,140	11.5	0.49
2016	99.5	11.2	2,302	7.6	0.53
2017	100.1	0.6	2,251	−2.2	0.51
2018	94.7	−5.4	2,069	−8.1	0.46
2019	97.1	2.5	2,057	−0.6	0.45
Intermediate Estimates					
2020	106.3	9.4	2,176	5.8	0.48
2021	115.6	8.8	2,300	5.7	0.50
2022	122.3	5.7	2,361	2.7	0.50
2023	129.0	5.5	2,424	2.7	0.51
2024	138.4	7.2	2,534	4.5	0.52
2025	146.6	5.9	2,618	3.3	0.53
2026	156.6	6.8	2,731	4.3	0.55
2027	167.2	6.8	2,853	4.5	0.56
2028	178.1	6.5	2,977	4.3	0.57
2029	189.6	6.4	3,108	4.4	0.58

Source: 2020 Medicare Trustees Report, Table III.D4

Notes: Amounts shown are on a cash basis.

a. This amount does not include administrative expenses. See **Table A-1** for data on total Part D expenditures.

Table 13. Medicare Part D Reimbursement Amounts

(in billions of dollars)

Calendar Year	Direct Subsidy[a]		Reinsurance		Low-Income Subsidy		Retiree Drug Subsidy		Total[b]
	Amount	Percentage	Amount	Percentage	Amount	Percentage	Amount	Percentage	
Historical Data									
2006	$16.00	39.2%	$6.0	14.7%	$15.0	36.8%	$3.8	9.3%	$40.8
2007	17.6	38.1%	8.0	17.3%	16.7	36.1%	3.9	8.4%	46.2
2008	17.5	35.9%	9.4	19.3%	18.1	37.1%	3.8	7.8%	48.8
2009	18.2	35.1%	10.1	19.5%	19.6	37.8%	3.9	7.5%	51.8

Calendar Year	Direct Subsidy[a]		Reinsurance		Low-Income Subsidy		Retiree Drug Subsidy		Total[b]
	Amount	Percentage	Amount	Percentage	Amount	Percentage	Amount	Percentage	
2010	19.6	35.1%	11.2	20.1%	21.1	37.8%	3.9	7.0%	55.8
2011	19.2	32.7%	13.7	23.3%	22.2	37.8%	3.6	6.1%	58.7
2012	19.7	32.5%	15.5	25.5%	22.5	37.1%	3.0	4.9%	60.7
2013	19.6	30.8%	19.2	30.1%	23.2	36.4%	1.7	2.7%	63.7
2014	18.5	25.9%	27.2	38.1%	24.3	34.1%	1.3	1.8%	71.3
2015	18.1	23.2%	33.2	42.6%	25.6	32.8%	1.1	1.4%	78.0
2016	17.1	21.4%	35.5	44.4%	26.4	33.0%	1.0	1.3%	80.0
2017	14.6	18.2%	37.6	46.8%	27.3	34.0%	0.8	1.0%	80.3
2018	13.5	16.2%	40.6	48.7%	28.5	34.2%	0.8	1.0%	83.4
2019	11.6	13.1%	46.3	52.4%	29.8	33.7%	0.7	0.8%	88.4
Intermediate Estimate									
2020	10.2	11.2%	46.6	51.2%	33.5	36.8%	0.7	0.8%	91.0
2021	10.4	10.7%	50.3	51.7%	35.9	36.9%	0.7	0.7%	97.3
2022	10.3	9.9%	54.8	52.5%	38.5	36.9%	0.7	0.7%	104.3
2023	10.8	9.6%	59.1	52.7%	41.4	36.9%	0.8	0.7%	112.1
2024	11.5	9.6%	63.4	52.9%	44.2	36.9%	0.8	0.7%	119.9
2025	12.1	9.5%	67.3	53.0%	46.7	36.8%	0.8	0.6%	126.9
2026	12.7	9.4%	72.2	53.2%	49.9	36.8%	0.9	0.7%	135.7
2027	13.4	9.3%	77.2	53.4%	53.2	36.8%	0.9	0.6%	144.7
2028	14.1	9.1%	82.5	53.5%	56.7	36.7%	1.0	0.6%	154.3
2029	14.7	9.0%	88.1	53.7%	60.3	36.7%	1.1	0.7%	164.2

Source: CRS analysis based on data in the 2016 and 2020 Medicare Trustees Reports, Table IV.B10.

Notes: Amounts shown are on an incurred basis.

a. The direct subsidy amount shown is net of risk-sharing payments.

b. The total amounts do not include premiums paid by beneficiaries.

The Medicare Trustees project that total Part D expenditures will almost double between 2019 and 2029—from $97.6 billion to $190.3 billion. (See **Table A-1**.) Annual per capita Part D benefit expenditures also are projected to increase—from $2,057 in 2019 to $3,108 in 2029.[245] Over the longer term, the Medicare Trustees project that total Part D spending will grow from 0.45% of GDP in 2019 to 0.58% in 2029 and to 0.94% of GDP in 2094.[246]

[245] Ibid., Table III.D4.

[246] Ibid., Tables III.D4 and III.D6. GDP projection estimates are reported on an incurred basis.

Appendix A. Historical and Projected Part D Operations

Table A-1. Operation of the Part D Account in the SMI Trust Fund, CY2004-CY2029

(in billions of dollars)

	Income					Expenditures			Trust Fund	
Year	Premiums	General Revenue	Transfers from States	Interest and Other	Total	Benefit Payments	Admin. Expenses	Total	Net Change	Balance at End of Year
Historical Data										
2004	—	$0.4	—		$0.4	$0.4	—	$0.4	—	—
2005	—	1.1	—		1.1	1.1	—	1.1	—	—
2006	$3.5	39.2	$5.5	$0.0	48.2	47.1	$0.3	47.4	$0.8	$0.8
2007	4.1	38.8	6.9	0.0	49.7	48.8	0.9	49.7	0.0	0.8
2008	5.0	37.3	7.1	0.0	49.4	49.0	0.3	49.3	0.1	0.9
2009	6.3	47.1	7.6	0.0	61.0	60.5	0.3	60.8	0.1	1.1
2010	6.5	51.1	4.0	0.0	61.7	61.7	0.4	62.1	-0.4	0.7
2011	7.7	52.6	7.1	0.0	67.4	66.7	0.4	67.1	0.3	1.0
2012	8.3	50.1	8.4	0.0	66.9	66.5	0.4	66.9	0.0	1.0
2013	9.9	51.0	8.8	0.0	69.7	69.3	0.4	69.7	0.0	1.0
2014	11.4	58.1	8.7	0.0	78.2	77.7	0.4	78.1	0.1	1.1
2015	12.8	68.4	8.9	0.0	90.0	89.5	0.3	89.8	0.3	1.3
2016	13.8	82.4	10.0	0.0	106.2	99.5	0.5	99.9	6.3	7.6
2017	15.5	73.2	11.4	0.1	100.2	100.1	-0.1	100.0	0.2	7.8
2018	15.9	67.8	11.7	0.1	95.4	94.7	0.5	95.2	0.2	8.0
2019	15.8	70.2	12.3	0.5	98.7	97.1	0.5	97.6	1.2	9.2
Intermediate Estimates										
2020	16.1	76.4	12.6	0.1	105.1	106.3	0.7	106.9	−1.8	7.3
2021	17.1	86.5	13.4	0.1	117.1	115.6	0.7	116.3	0.8	8.2
2022	18.9	90.3	14.4	0.1	123.7	122.3	0.7	123.0	0.8	8.9
2023	20.4	94.3	15.5	0.1	130.4	129.0	0.7	129.7	0.6	9.5
2024	22.1	100.8	16.8	0.1	139.7	138.4	0.7	139.1	0.7	10.2
2025	23.6	106.1	18.0	0.1	147.8	146.6	0.6	147.2	0.6	10.8
2026	25.8	112.7	19.2	0.2	157.9	156.6	0.6	157.2	0.7	11.5
2027	27.0	121.0	20.5	0.2	168.6	167.2	0.6	167.8	0.8	12.3
2028	29.4	128.1	21.9	0.2	179.6	178.1	0.7	178.8	0.8	13.1
2029	31.6	135.9	23.4	0.2	191.2	189.6	0.7	190.3	0.9	14.0

Source: 2020 Medicare Trustees Report, Table III.D3.

Notes: Sums may not equal totals due to rounding. Some of the fluctuation in year by year spending is due to the payment structure of the Part D program. For example, in 2006, plan bids and therefore payments were higher than actual spending; the $4 billion in reconciliation payments resulted in lower per capita Part D spending in 2007 and 2008. The Medicare Trustees expect that in 2019, incurred reinsurance spending will be higher than plan bids, leading to "significant" reconciliation payments to plans in 2020.

Appendix B. Drug Rebates and PBMs in Medicare Part D

Part D plan sponsors typically work with pharmacy benefit managers (PBMs) to negotiate price concessions from drug manufacturers. PBMs also create 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. [247]

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.[248] 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 may 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. Rebates have risen from 10.4% of total Part D drug costs in 2008 to an estimated 25.3% in 2018.[249]

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.[250] 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.

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.[251] 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.

Plan sponsors mainly have used drug rebates to buy down, or reduce, plan premiums for all enrollees, rather to reduce the price of specific drugs at the point of sale. As noted, under the

[247] 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.

[248] 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*, 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.

[249] CMS, "The 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds," June 5, 2018, Table IV.B8, p. 143, at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf.

[250] HHS OIG, "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.

[251] GAO, "Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization," https://www.gao.gov/assets/710/700260.pdf.

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.[252] However, in a 2018 *Federal Register* proposal, CMS noted that less than 1% of sponsors had passed through price concessions at retail pharmacies.[253] Instead, sponsors collect and apply the vast majority of price concessions, including manufacturer rebates and pharmacy fees, after the point of sale and report them to CMS as DIR.[254]

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.

- 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 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, rising reinsurance costs, and growing 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

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

[253] 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*, 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.

[254] Ibid.

the lowest possible reimbursement a network pharmacy would receive, in total, for a particular drug.[255] No rule was published.[256]

On February 6, 2019, CMS published a proposed rule to bar most prescription drug rebates in Part D plans by ending federal anti-kickback protections for rebates.[257] CMS chose not to publish a final rule when the comment period ended. On July 24, 2020, President Trump signed an executive order directing the HHS Secretary to complete the rulemaking.[258] On November 20, 2020, HHS issued a final rule to bar most drug rebates, effective in plan year 2022.[259] If the final rule takes effect, it is forecast to reduce cost sharing for some Part D enrollees who are sicker or are taking more expensive brand-name drugs but to increase plan premiums for all enrollees and possibly to increase costs to the Medicare program.[260]

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[255] CMS, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenditures," 83 *Federal Register*, 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.

[256] Ibid, 62174.

[257] 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*, 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. The proposed rule would add an exception to the definition of "discount" so that manufacturer rebates would no longer be protected under the safe harbor. In addition, the proposed rule would create a new safe harbor under which manufacturers could provide drug price reductions to Part D or Medicaid managed care plans under certain conditions.

[258] White House, "Executive Order on Lowering Prices for Patients by Eliminating Kickbacks to Middlemen," July 24, 2020, at https://www.whitehouse.gov/presidential-actions/executive-order-lowering-prices-patients-eliminating-kickbacks-middlemen/.

[259] 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)."

[260] CBO, "Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections—Supplemental Material for Updated Budget Projections: 2019 to 2029," May 2019, Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections—Supplemental Material for Updated Budget Projections: 2019 to 2029.

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