DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 514

[CMS–5546–P]

RIN 0938–AV74

Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model to test a new Medicare payment model under section 1115A of the Social Security Act. The model proposes a test of an alternative payment method for calculating inflation rebates for certain Part D drugs and biological products. The proposed GUARD Model would test whether changing the calculation of the Part D inflation rebate would reduce costs for the Medicare program while preserving or enhancing quality of care for Part D enrollees.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by February 23, 2026.

ADDRESSES: In commenting, please refer to file code CMS–5546–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5546–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–5546–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** Section.

FOR FURTHER INFORMATION CONTACT: Vinod Mitta, 667–290–8712 or *GUARDmodel@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Information Included with Pic Comments: We encourage commenters to include supporting facts, research, and evidence in their comments. When doing so, commenters are encouraged to provide citations to the published materials referenced, including active hyperlinks. Likewise, commenters who reference materials which have not been published are encouraged to upload relevant data collection instruments, data sets, and detailed findings as a part of their comment. Providing such citations and documentation will assist us in analyzing the comments.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. The Centers for Medicare & Medicaid Services (CMS) will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at *https://www.regulations.gov/.*

I. Executive Summary

A. Background

Challenges related to the affordability of prescription drugs adversely affect taxpayers by diverting funds that could be used to improve health; such challenges also pose a direct concern for patients, with 55 percent of adults reporting that they remain concerned about medication affordability.[1] [2] High drug costs limit access to care and treatment, which in turn, can have cascading consequences that lead to poor health for patients, increased medical spending, and potentially avoidable expenditures for all payers, including Medicare.[3] Results from recent surveys show that many Americans, including Medicare beneficiaries, face significant financial burden of care that has resulted in skipping or rationing medication due to cost.[4]

Financial toxicity, or the negative impact that the monetary burden of medical care can have on patients' well-being, fiscal security, and overall health,[5] can be pronounced among the elderly population, most of whom are covered by Medicare, and among patients where the cost of treatment is high.[6] One in four adults taking prescription drugs report difficulty affording their medication, including 40 percent of those with household income of less than $40,000 per year.[7] A separate survey conducted concluded that about four in 10 older adults with Medicare reported problems accessing health care because of its costs, and that 14 percent of Medicare beneficiaries said they skipped taking or sometimes did not fill their prescription because of the expense; this can have serious health-related consequences for Medicare beneficiaries and may result in potentially avoidable costs for Medicare.[8]

[1] Sparks, G., et al. (2024). *Public Opinion on Prescription Drugs and Their Prices.* KFF. *https://www.kff.org/health-costs/public-opinion-on-prescription-drugs-and-their-prices/* (Accessed: 10 December 2025).

[2] Jones, E. & Noda, A. (2025). *Drug Costs and Their Impact on Care: Insights from Medicare Patients and Providers.* The Commonwealth Fund. *https://www.commonwealthfund.org/publications/issue-briefs/2025/feb/drug-costs-impact-care-insights-medicare-patients-providers* (Accessed: 10 December 2025).

[3] Nekui, F., et al. (2021). Cost-related Medication Nonadherence and Its Risk Factors Among Medicare Beneficiaries. *Medical Care, 59*(1):13–21. *https://doi.org/10.1097/MLR.0000000000001458.*

[4] Arnold Ventures, Commonwealth Fund, & PerryUndem. (2025). *Drug Costs and Their Impact on Care. https://www.arnoldventures.org/stories/drug-costs-and-their-impact-on-care* (Accessed: 10 December 2025).

[5] Arastu A., et al. (2020). Assessment of Financial Toxicity Among Older Adults with Advanced Cancer. *JAMA Network Open, 3*(12):e2025810. *https://doi.org/10.1001/jamanetworkopen.2020.25810.*

[6] Narang, A.K. & Nicholas, L.H. (2016). Out-of-Pocket Spending and Financial Burden Among Medicare Beneficiaries with Cancer. *JAMA Oncology, 3*(6), 757. *https://doi.org/10.1001/jamaoncol.2016.4865.*

[7] Sparks, G., et al. (2024). *Public Opinion on Prescription Drugs and Their Prices.* KFF. *https://www.kff.org/health-costs/public-opinion-on-prescription-drugs-and-their-prices/* (Accessed: 10 December 2025).

[8] Leonard, F., et al. (2023). *Medicare's Affordability Problem: A Look at the Cost Burdens Faced by Older Enrollees.* The Commonwealth Fund. *https://www.commonwealthfund.org/publications/issue-briefs/2023/sep/medicare-affordability-problem-cost-burdens-biennial* (Accessed: 10 December 2025).

Medicare Part D prescription drug costs have been rising over time, with total Part D gross drug spending increasing from $121 billion in 2014 to $276 billion in 2023, an increase of over 100 percent, as reported by the Medicare Payment Advisory Commission (MedPAC).[9] This translates to an approximately 66 percent increase in average gross spending for each beneficiary who used Part D drugs over that same period ($3,267 in 2014 to $5,429 in 2023).[10] The increase in Part D gross drug spending is consistent with overall trends in U.S. drug spending. A recent analysis shows that drug spending in the United States increased from $600 billion in 2018 to $858 billion in 2023 for all drugs (a 43 percent increase), regardless of payer source.[11] Retail prescription drug prices are expected to continue to increase over time, driven by a number of factors, including increases in the use of prescription drugs as well as increases in drug prices over time.[12]

Existing research finds that the prices of drugs sold in the United States are much higher than the prices of the same drugs sold in other countries. One study finds that overall, the U.S. health care system spends substantially more on outpatient drugs for older adults with complex conditions, such as heart failure, diabetes, and chronic obstructive pulmonary disease (COPD), who are mostly covered by Medicare, than 11 other economically similar countries (including, for example, Australia, France, Germany, Canada, and the United Kingdom).[13] The authors conclude that the United States is paying substantially higher prices for certain components of health care, including for drugs, than other countries.[14] Another study finds that prices for certain high expenditure single-source brand name prescription drugs covered under Medicare Part D in 2018 were 3 to 4 times higher in the United States, even after accounting for estimated manufacturer rebate amounts, compared to their prices in the United Kingdom, Japan, and Canada.[15] Among these countries, Japan and Canada use international reference pricing to help determine drug prices within the country.[16] Analyses by IQVIA show that per capita utilization of drugs is higher in certain regions and countries, specifically, in Western European countries and Japan, compared to North American countries, suggesting that utilization differences alone are not the drivers of the observed price differences.[17] The data also shows that U.S. brand-name prescription drug prices exceed those found in other Organization for Economic Co-operation and Development (OECD) countries.[18] [19]

The disparity between U.S. drug prices and prices in other economically comparable countries may have several drivers, but a key component is the substantial difference in the way prescription drug prices are determined in the United States and other economically comparable countries. Although there is wide variation in the way drug prices are determined in economically comparable countries, in general, many countries take a more centralized approach to drug pricing and/or have greater involvement in determining prices for drugs than the United States.[20]

In the United States, prices are set by drug manufacturers for the U.S. market and the incentives and payment mechanisms embedded within the U.S. pharmaceutical drug supply chain are complex. Drug manufacturers set a Wholesale Acquisition Cost (WAC), which is the published catalog or ''list price'' for a drug product; this represents the amount at which wholesalers are offered the drug product.[21] The manufacturer list price is not the ultimate net revenue realized by the manufacturer as there are multiple discounts and price concessions to stakeholders throughout the pharmaceutical drug supply chain; however, it may have influence throughout the pharmaceutical drug supply chain. Existing research shows that the list price of new brand-name drugs at launch have been increasing over time, with one study finding that from 2008 to 2021, the mean launch price increased by 13 percent per year; this increase was 11 percent per year for a subset of drugs for which the researchers were able to account for manufacturer rebates and drug characteristics.[22]

There are many factors that affect the amount that is ultimately paid by stakeholders for a pharmaceutical drug after discounts, rebates, and other price concessions are excluded (referred to as the 'net price'), including the degree to which the drug is subject to market competition. In general (though there may be exceptions), drugs that face more limited competition have higher net prices than drugs that have greater market competition.[23] [24] [25] Among drugs

[9] MedPAC. (2025). *Health Care Spending and the Medicare Program. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf* (Accessed: 10 December 2025).

[10] MedPAC. (2025). *Health Care Spending and the Medicare Program. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf* (Accessed: 10 December 2025).

[11] IQVIA. (2023). *The use of medicines in the U.S. 2023. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023* (Accessed: 10 December 2025).

[12] Poisal, J.A., et al. (2022). National Health Expenditure Projections, 2021–30: Growth to Moderate as COVID–19 Impacts Wane. *Health Affairs, 41*(4), 474–486. *https://doi.org/10.1377/hlthaff.2022.00113.*

[13] Figueroa, J.F., et al. (2021). International Comparison of Health Spending and Utilization Among People with Complex Multimorbidity. *Health Services Research, 56*(S3), 1317–1334. *https://doi.org/10.1111/1475-6773.13708.*

[14] Figueroa, J.F., et al. (2021). International Comparison of Health Spending and Utilization Among People with Complex Multimorbidity. *Health Services Research, 56*(S3), 1317–1334. *https://doi.org/10.1111/1475-6773.13708.*

[15] Kang, S., et al. (2019). Using External Reference Pricing in Medicare Part D to Reduce Drug Price Differentials with Other Countries. *Health Affairs, 38*(5), 804–811. *https://doi.org/10.1377/hlthaff.2018.05207.*

[16] Kang, S., et al. (2019). Using External Reference Pricing in Medicare Part D to Reduce Drug Price Differentials with Other Countries. *Health Affairs, 38*(5), 804–811. *https://doi.org/10.1377/hlthaff.2018.05207.*

[17] IQVIA. (2025). The *Global Use of Medicines 2025: Outlook to 2029—Global Webinar. https://www.iqvia.com/-/media/iqvia/pdfs/events/presentation_global-meds-webinar_public.pdf* (Accessed: 10 December 2025).

[18] Mulcahy, A.W., et al. (2024). *International Prescription Drug Price Comparisons: Estimates Using 2022 Data.* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. *https://aspe.hhs.gov/sites/default/files/documents/277371265a705c356c968977e87446ae/international-price-comparisons.pdf* (Accessed: 10 December 2025).

[19] The Organization for Economic Cooperation and Development (OECD) is a multilateral organization with 38 member countries. Comparing the United States to other OECD countries that are similar in economy, based on GDP and GDP per capita, allows for a more appropriate comparison.—*About the OECD, U.S. Mission to the Organization for Economic Co-operation and Development,* Available at *https://usoecd.usmission.gov/about-the-oecd/.*

[20] Syversen, I.D., et al. (2024). A Comparative Analysis of International Drug Price Negotiation Frameworks: An interview study of key stakeholders. *Milbank Quarterly, 102*(4), 1004–1031. *https://doi.org/10.1111/1468-0009.12714.*

[21] Mulcahy, A.W. & Kareddy, V. (2021). *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships.* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. *https://aspe.hhs.gov/reports/prescription-drug-supply-chains* (Accessed: 10 December 2025).

[22] Rome, B.N., et al. (2022). Trends in Prescription Drug Launch Prices, 2008–2021. *JAMA, 327*(21), 2145. *https://doi.org/10.1001/jama.2022.5542.*

[23] Government Accountability Office. (2023). *Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending* [GAO–23–105270]. *https://www.gao.gov/assets/gao-23-105270.pdf* (Accessed: 10 December 2025).

[24] Hernandez, I., et al. (2020). Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007–2018. *JAMA, 323*(9), 854. *https://doi.org/10.1001/jama.2020.1012.*

[25] Mulcahy, A.W., et al. (2024). *Prescription Drug Prices, Rebates, and Insurance Premiums.* RAND.

Continued

with competing therapies available, drug manufacturers have a particular incentive to compete against each other for formulary coverage by negotiating rebates with plan sponsors or their pharmacy benefit managers (PBMs). Within Part D, this generally includes drugs that are *not* in protected classes. (Centers for Medicare & Medicaid Services (CMS) protected classes are drugs for which Part D sponsors must include all or substantially all drugs within the classes on their formularies, which means that manufacturers do not have the same incentives to negotiate rebates or other price concession for these drugs.) [26] Ultimately, the negotiated rebates and other price concessions result in a ''net'' price (that is, list price net of rebates and other price concessions) for the drug that is lower than the list price.[27] Under the Part D program, this post point-of-sale compensation is included in Direct and Indirect Remuneration (DIR) [28] and is factored into CMS's calculation of final Medicare payments to Part D plans.[29] This, in turn, impacts Medicare costs under the Medicare Prescription Drug Benefit program, also known as Part D, which was created under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173, 117 Stat. 2066).[30]

Under the Part D program, drug price negotiations take place between Part D plan sponsors (or their PBMs) and pharmaceutical manufacturers. Until recently, the federal government has not been a participant in the negotiations for drug prices.[31] The Medicare program does not currently use international reference pricing, which broadly refers to the practice of taking pharmaceutical pricing data from other economically comparable countries into account in identifying domestic prices for drugs.[32] The Inflation Reduction Act of 2022 (IRA), Public Law 117–169, included a series of provisions, including the Medicare Drug Price Negotiation Program, which authorizes the Secretary of the Department of Health and Human Services (HHS) (hereafter, ''the Secretary'') to negotiate the prices of certain qualifying high expenditure single source drugs without generic or biosimilar competition with manufacturers; however, the Medicare Drug Price Negotiation Program does not consider the prices of drugs in other economically similar countries [33] in negotiating the maximum fair price (MFP).

B. Purpose

The prices of certain prescription drugs in the United States, including those covered under Part D, remain high, which contributes to increased costs under Part D. To address high spending under Part D, CMS proposes the testing of a new mandatory model under section 1115A of the Social Security Act (the Act), which authorizes the CMS' Center for Medicare and Medicaid Innovation (hereafter, ''the CMS Innovation Center'') to test innovative payment and service delivery models for the purpose of evaluating whether they will reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of such programs. The IRA included the Part D Inflation Rebate Program, which requires drug manufacturers to pay a rebate if they raise their prices for certain drugs faster than the rate of inflation. This rebate is paid to the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund and is calculated and invoiced by CMS. The CMS Innovation Center, under its statutory authority, is proposing an innovative payment model that would test an alternative approach to the IRA's Part D Inflation Rebate Program that would change the calculation of the Part D drug inflation rebates for certain Part D drugs and biological products for the purpose of evaluating whether this approach would reduce program expenditures while maintaining or enhancing quality of care for beneficiaries. CMS proposes that the model's period of performance would begin on January 1, 2027 and end on December 31, 2033 and the payment period for the model would begin on January 1, 2027 and end on December 31, 2035.

C. Summary of Major Provisions

The proposed Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model would test changes to the Part D Inflation Rebate Program, specifically testing whether an alternative calculation for the Part D inflation rebate calculation for certain drugs and biological products would reduce program spending for Medicare and taxpayers while preserving or enhancing the quality of care furnished to Medicare beneficiaries. The proposed model includes the following major provisions:

- The GUARD Model would include a subset of Part D rebatable drugs that are included in the Part D Inflation Rebate Program. Specifically, the GUARD Model would include sole-source drugs and sole-source biological products that are in the following specific therapeutic categories: Analgesics; Anticonvulsants; Antidepressants; Antimigraine Agents; Antineoplastics; Antipsychotics; Antivirals; Bipolar Agents; Blood Glucose Regulators; Cardiovascular Agents; Central Nervous System Agents; Gastrointestinal Agents; Genetic or Enzyme or Protein Disorder: Replacement or Modifiers or Treatment; Immunological Agents; Metabolic Bone Disease Agents; Ophthalmic Agents; and Respiratory Tract/Pulmonary Agents. The GUARD Model would exclude: (1) generics and biosimilar biological products; (2) sole-source drugs or sole-source biological products with annual application-level [34] total gross covered

https://www.rand.org/pubs/research_reports/RRA1820-3.html (Accessed: 10 December 2025).

[26] See section 1860D–4(b)(3)(G) of the Social Security Act. The six protected classes are: immunosuppressant, (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic. See also, *Medicare Prescription Drug Benefit Manual Chapter 6—Part D Drugs and Formulary Requirements, Centers for Medicare & Medicaid Services* (January 15, 2016) at § 30.2.5, available at *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf* (Last accessed September 24, 2025).

[27] Mulcahy, A.W. & Kareddy, V. (2021). *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships.* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. *https://aspe.hhs.gov/reports/prescription-drug-supply-chains* (Accessed: 10 December 2025).

[28] Fees, payments, or payment adjustments made after the point-of-sale that change the cost of Part D covered drugs for Part D sponsors or PBMs must be reported to CMS as Direct or Indirect Remuneration (DIR).

[29] Centers for Medicare & Medicaid Services. (2017). *Medicare Part D—Direct and Indirect Remuneration (DIR).* U.S. Department of Health and Human Services. *https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir* (Accessed: 10 December 2025).

[30] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, 117 Stat. 2066 (2003). *https://www.congress.gov/108/plaws/publ173/PLAW-108publ173.pdf* (Accessed: 10 December 2025).

[31] The exception to this is drugs that are selected for the Medicare Drug Price Negotiation Program, implemented by the Inflation Reduction Act, which authorizes Medicare to directly negotiate drug prices for certain high expenditure, single source Medicare Part B or Part D drugs.

[32] Tordrup, D., et al. (2020). *Systematic Reviews for the Update of the WHO Guideline on Country Pharmaceutical Pricing Policies.* World Health Organization (WHO). *https://www.ncbi.nlm.nih.gov/books/NBK570141/pdf/Bookshelf_NBK570141.pdf* (Accessed: 10 December 2025).

[33] Inflation Reduction Act of 2022, Public Law 117–169, 136 Stat 1818. The IRA is codified in multiple titles of the U.S. Code. The relevant sections of the Medicare Drug Price Negotiation Program are found at 42 U.S.C. 1320f–1 through 1320f–7.

[34] Application-level refers to the New Drug Application (NDA) or Biologics License application

drug costs below the GUARD minimum spend threshold; and (3) drugs that are subject to a negotiated MFP, during the price applicability period.

- Manufacturers of Part D rebatable drugs, as defined in section 1927(k)(5) of the Act and 42 CFR 428.20, that receive a Part D inflation rebate report that includes a GUARD Model drug during an applicable period that overlaps with the GUARD Model performance period would be required to participate in the GUARD Model.
- The GUARD Model would select reference countries that are economically comparable to the United States by implementing the following criteria: the country must be included as an OECD country; must have a minimum of 60 percent of the United States's purchasing power parity (PPP)-adjusted per capita gross domestic product (GDP), and must have a minimum $400 billion (PPP)-adjusted aggregate GDP. The reference countries that meet these criteria and are therefore proposed to be selected for the model are the following: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom.
- CMS proposes to test two approaches to calculating the GUARD Model international benchmark: the default international benchmark (also referred to as Method I) and the updated international benchmark (also referred to as Method II).
- For each GUARD Model drug for which data on international drug pricing in reference countries is available, CMS would calculate the GUARD Model default international benchmark. The GUARD Model default international benchmark for each GUARD Model drug would be identified as the lowest country-level average price among the set of average prices for each reference country, adjusted by the country-specific GDP based on PPP (hereafter, ''GDP (PPP)'') adjuster, where an international product that is part of a GUARD Model drug's set of international analogs is sold.[35] [36]
- CMS would provide manufacturers with the option to submit international drug net pricing[37] data for the set of reference countries where international products that are part of a GUARD Model drug's set of international analogs are sold, including the across-country average net price. This submitted across-country average net price accounts for country-specific differences using a GDP (PPP) adjuster; if the data submitted is determined to be an applicable submission, it would become the GUARD Model updated international benchmark.
- CMS would determine a GUARD Model applicable international benchmark for each GUARD Model drug that would be the greater of the GUARD Model default international benchmark and the GUARD Model updated international benchmark, unless there is only a GUARD Model default international benchmark. If there is only a GUARD Model default international benchmark, it would become the GUARD Model applicable international benchmark.
- CMS would use this information to test an alternative inflation rebate payment calculation to determine whether manufacturers owe a GUARD Model rebate payment. The alternative inflation rebate calculation tested under the GUARD Model would compare a Medicare net price against the GUARD Model applicable international benchmark.
- The GUARD Model would require manufacturers to pay a GUARD Model rebate payment if the Medicare net price is greater than the GUARD Model applicable international benchmark for a GUARD Model drug. The Medicare net price would be calculated by subtracting manufacturer rebates (obtained from DIR) and discounts (under the Manufacturer Discount Program) from the WAC of the GUARD Model drug.
- The total GUARD Model rebate amount would be equal to the product of the per unit GUARD Model rebate amount for a GUARD Model drug for the performance year and the total number of units of the GUARD Model drug dispensed under Part D and covered by Part D plan sponsors in the GUARD Model geographic areas for the performance year.
- When the per unit GUARD Model rebate exceeds the per unit Part D inflation rebate amount, CMS would waive the rebate amount described in section 1860D–14B(b) of the Act and instead apply the GUARD Model rebate amount. The GUARD Model rebate payment would be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.
- The GUARD Model evaluation would examine the main outcome, Medicare net spending, as well as additional outcomes of the GUARD Model, including the ways in which Part D plan benefits may change for GUARD Model drugs and whether and to what extent there are impacts on beneficiary cost sharing for GUARD Model drugs.

We also propose to waive program requirements that are necessary solely for the purposes of testing the GUARD Model. We propose to issue these waivers using our waiver authority under section 1115A(d)(1) of the Act. Specifically, we propose to waive the provisions in section 1860D–14B(b)(1) of the Act, which are the Medicare Part D inflation rebate calculation provisions; and, we propose to waive the provisions in section 1860D–14B(a)(1) of the Act, which describes the timing requirements for manufacturer rebates reports issued by CMS. Each of the proposed waivers is discussed in detail in section IV.R. this proposed rule.

D. Summary of Costs and Benefits

(BLA) associated with each GUARD Model drug. This means the total gross covered prescription drug costs for all Part D rebatable NDC–9s associated with the same application (NDA or BLA) as the GUARD Model drug.

[35] To be a part of the set of international analogs, an international product must have an active ingredient, route of administration, dosage form, and strength that aligns with that of the GUARD Model drug.

[36] Individual countries differ in the regulatory processes and standards governing approval of drugs and biological products. Use of international drug prices in the proposed GUARD Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved and non-U.S.-approved products.

[37] Where net pricing refers to drug prices exclusive of any discounts, rebates, or price concessions offered by manufacturers.

Provisions	Brief Description	Financial Impact
All of the GUARD Model provisions presented in this proposed rule.	As defined in detail throughout this proposed rule, the GUARD Model tests, for a specific subset of Part D rebatable drugs and biologic products, specific geographic locations, and specific Medicare Part D beneficiaries, the effects of replacing the Part D inflation rebate calculation with an alternative rebate calculation that takes into account international prices in economically comparable countries. CMS aims to understand whether the alternative payment calculation tested under the GUARD Model will reduce Medicare spending while preserving or enhancing beneficiary quality of care.	Over the 2028-2033 period, the GUARD Model is expected, in aggregate, to reduce Medicare spending by $14.1 billion. This sum would be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

II. Background

Prescription drug prices in the United States have been increasing over time, and the prices of certain drugs sold in the United States are substantially higher than prices in economically comparable countries. High prescription drug prices in the United States influence Part D spending, which has also increased over time (as we discuss later in this section).

A. Prescription Drug Prices in the United States

Medicare prescription drug costs have been rising over time, with total Part D gross drug spending increasing from $121 billion in 2014 to $276 billion in 2023, an increase of nearly 10 percent annually.[38] In 2024, Part D drug spending represented a large portion (about 40 percent) [39] of overall gross drug spending in the United States. The increase in Part D gross drug spending is consistent with overall trends in U.S. drug spending, which are rising over time. Gross drug spending has increased from $600 billion in 2018 to $858 billion in 2023 for all drugs, regardless of payer source.[40] Net drug spending increased by 11.4 percent in 2024 (from $437.1 billion in 2023 to $487 billion in 2024), more than double the increase from the previous year (4.9 percent growth in 2023, from $416.8 billion in 2022 to $437.1 billion in 2023).[41] These increases are driven by many factors; the way the United States pays for prescription drugs and the complex pharmaceutical drug supply chain also play a role.

Existing research shows that the prices of drugs in the United States are much higher than prices for the same drugs sold in other countries and this gap is increasing over time.[42] [43] In 2024, the United States accounted for less than 5 percent of the world's population (4.22) [44] and about 15 percent (14.9) of the world's real gross domestic product (GDP),[45] but U.S. gross spending on drugs accounted for over half of the world's gross spending on drugs (53.2 percent) [46] and only about 10 percent of the volume sold.[47] Among countries in the Organization for Economic Cooperation and Development (OECD), in 2024, the United States accounted for about 63 percent of spending on prescription drugs, but only 22 percent of the volume.[48]

Research from Office of Assistant Secretary for Planning and Evaluation (ASPE) and the RAND Corporation provides comparative data on U.S. prescription drug prices relative to other OECD member countries. These studies examine prescription drug pricing patterns and present findings on how U.S. prescription drug costs compare to international benchmarks. ASPE's

[38] MedPAC. (2025). *Health Care Spending and the Medicare program. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf* (Accessed: 10 December 2025).

[39] IQVIA. (2025). *Understanding the Use of Medicines in the U.S. 2025. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/understanding-the-use-of-medicines-in-the-us-2025* (Accessed: 10 December 2025).

[40] IQVIA. (2023). *The Use of Medicines in the U.S. 2023. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2023* (Accessed: 10 December 2025).

[41] IQVIA. (2025). *Understanding the Use of Medicines in the U.S. 2025. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/understanding-the-use-of-medicines-in-the-us-2025* (Accessed: 10 December 2025).

[42] Kang, S., et al. (2019). Using External Reference Pricing in Medicare Part D to Reduce Drug Price Differentials with Other Countries. *Health Affairs, 38*(5), 804–811. *https://doi.org/10.1377/hlthaff.2018.05207.*

[43] Mulcahy, A.W., et al. (2024). *International Prescription Drug Price Comparisons: Estimates Using 2022 Data.* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. *https://aspe.hhs.gov/sites/default/files/documents/277371265a705c356c968977e87446ae/international-price-comparisons.pdf* (Accessed: 10 December 2025).

[44] Data from the U.S. Census Bureau: the U.S. and World Population Clock (Population Clock) and the International Database (International Database). The U.S. and world population in 2024 according to the U.S. Census Bureau's U.S. and World Population Clock was about 340 million and 8 billion which results in the U.S. population being 4.22% of the world population in 2024.

[45] Data from the CIA World Factbook's real GDP at purchasing power parity (PPP) exchange rates (Real GDP (purchasing power parity) Comparison—The World Factbook). For 2024, the US. and world GDP in real GDP at PPP (2021 U.S. dollars) according to the CIA World Factbook was 25.7 and 172.4 trillion which results in the U.S. GDP being is 14.89% of the world GDP.

[46] Mikulic, M. (2025). *Market Share of the Leading Global Pharmaceutical Markets 2024.* Statista. *https://www.statista.com/statistics/245473/market-share-of-the-leading-10-global-pharmaceutical-markets/#:~:text=The%20United%20States%20was%20the,including%20only%20the%20hospital%20market* (Accessed: 10 December 2025).

[47] Author analysis based on IQVIA MIDAS® annual volume sales data using the kilogram measure January to December 2024 reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved. The statements, findings, conclusions, views, and opinions contained and expressed in this research article are based in part on data obtained under license from the following IQVIA information service(s): IQVIA MIDAS. Copyright IQVIA. All Rights Reserved. The statements, findings, conclusions, views and opinions contained and expressed herein are not necessarily those of IQVIA or any of its affiliated or subsidiary entities.

[48] Author analysis based on IQVIA MIDAS annual sales data using the estimated sales and kilogram measures from January to December 2024 reflecting estimated of real-world activity. Copyright IQVIA. All rights reserved.

research indicated that U.S. prescription drug prices exceeded those of non-U.S. OECD countries combined in 2018. Specifically, U.S. gross prices for brand-name drugs were 344 percent of prices in non-U.S. countries.[49] The study also found that unbranded generic drugs had lower U.S. prices compared to the prices in other OECD countries. A 2024 report revealed an even larger gap, U.S. gross prices for certain drugs are higher than other countries. Specifically, for brand-name originator drugs,[50] U.S. prices are approximately 422 percent of prices in economically comparable countries or at least 322 percent if adjusted for rebates in the United States (but not in other countries).[51] The same study showed the United States paid less for unbranded generic drugs; specifically, U.S. prices for these drugs represent approximately 67 percent of the OECD countries combined. This indicates that pricing patterns vary between brand-name originator drugs and generic drugs in the U.S. market. This body of research also suggests that U.S. drug prices for brand-name originator drugs are growing faster than drug prices in other countries.

The widening gap over time between U.S. drug prices and prices in other economically comparable countries for certain types of drugs exist for many reasons. However, one component is the substantial difference in the way the United States and other economically comparable countries approach prescription drug pricing. Although there is wide variation in the way economically comparable countries determine prices, in general, many countries take a more centralized approach to drug pricing and may have greater involvement in establishing prices for drugs than the United States.[52]

The U.S. market and the incentives and payment mechanisms embedded within the U.S. pharmaceutical drug supply chain are complex. Drug manufacturers set the list price, also known as the Wholesale Acquisition Cost (WAC), which serves as the initial anchor price for a drug throughout the complex pharmaceutical drug supply chain market in the United States.[53] The pharmaceutical drug supply chain consists of many stakeholders, each with differing, potentially complex roles. Stakeholders include drug manufacturers, drug wholesalers, pharmacies, group purchasing organizations (GPOs), payers (that is, insurance plans, including Part D plans), and pharmacy benefit managers (PBMs).[54] When payers, including Medicare Advantage organizations offering Part D prescription drug coverage and standalone Part D plans, reimburse the pharmacy for a drug, the reimbursement is based on a negotiated payment amount for the drug plus a dispensing fee. Payers, including Part D plan sponsors, often contract with PBMs, which administer the outpatient pharmacy benefit and negotiate rebates with manufacturers. For drugs in competitive therapeutic classes, PBMs often negotiate with manufacturers to receive rebates in exchange for preferred formulary placement. These rebates, which are not typically applied at point-of-sale, ultimately reduce the net price of the drug faced by the payer. Under the Part D program, the post point-of-sale compensation is included in direct and indirect remuneration (DIR), and it is factored into the Centers for Medicare & Medicaid Services (CMS) calculation of final Medicare payments to Part D plans.[55] This, in turn, impacts Medicare costs, including premiums, under the Part D program.

B. The Medicare Prescription Drug Benefit (Medicare Part D)

The Medicare Voluntary Prescription Drug Benefit Program, also known as Part D, is a federal prescription drug coverage program established under Title XVIII, Part D of the Social Security Act (hereafter, ''the Act'') (sections 1860D–1 through 1860D–43 of the Act), as added by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA); the program provides outpatient prescription drug coverage to Medicare beneficiaries.[56] Section 1860D–15 of the Act specifies the payment methodology for Part D plan sponsors, including direct subsidy payments, reinsurance, and risk corridor payments, as well as beneficiary premiums. The program is administered by private insurers through either standalone prescription drug plans (PDPs) or Medicare Advantage prescription drug (MA–PD) plans.[57] The prices of prescription drugs covered by a Part D plan are negotiated between the plan sponsor or its PBM and pharmaceutical drug manufacturers.[58]

Under the program, Medicare typically subsidizes a portion of the Part D basic benefit costs for enrollees through reinsurance and direct subsidy payments made to Part D plans, and provides additional premium and cost sharing subsidies for low-income enrollees through the low-income subsidy (LIS) program.[59] Beneficiaries who voluntarily enroll in a Part D plan typically pay a monthly premium, and depending on their specific plan and drug utilization, may have to pay an annual deductible, copayments, and coinsurance.

The Inflation Reduction Act of 2022 (IRA), Public Law 117–169, made several additions and amendments to the Act that affected the structure of the defined standard Part D drug benefit. Currently, the Part D defined standard benefit consists of three phases that enrollees go through depending on their use and cost of drugs: the deductible phase, the initial coverage phase, and the catastrophic coverage phase. Plans are responsible for setting the specific

[49] Mulcahy, A., et al. (2021). *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies.* RAND. *https://www.rand.org/pubs/research_reports/RR2956.html* (Accessed: 16 December 2025).

[50] The 2024 ASPE report defines brand-name originators as ''the original drugs developed and licensed or approved via 351(a) or a New Drug Application (NDA) pathway.'' The authors of the study are solely responsible for how brand-name originator drugs were defined for the study.

[51] Mulcahy, A.W., et al. (2024). *International Prescription Drug Price Comparisons: Estimates Using 2022 Data.* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. *https://aspe.hhs.gov/sites/default/files/documents/277371265a705c356c968977e87446ae/international-price-comparisons.pdf* (Accessed: 10 December 2025).

[52] Syversen, I.D., et al. (2024). A Comparative Analysis of International Drug Price Negotiation Frameworks: An interview study of key stakeholders. *Milbank Quarterly, 102*(4), 1004–1031. *https://doi.org/10.1111/1468-0009.12714.*

[53] Mulcahy, A.W. & Kareddy, V. (2021). *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships.* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. *https://aspe.hhs.gov/reports/prescription-drug-supply-chains* (Accessed: 10 December 2025).

[54] Mulcahy, A.W. & Kareddy, V. (2021). *Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships.* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. *https://aspe.hhs.gov/reports/prescription-drug-supply-chains* (Accessed: 10 December 2025).

[55] Centers for Medicare & Medicaid Services. (2017). *Medicare Part D—Direct and Indirect Remuneration (DIR).* U.S. Department of Health and Human Services. *https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir* (Accessed: 10 December 2025).

[56] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, 117 Stat. 2066 (2003). *https://www.congress.gov/108/plaws/publ173/PLAW-108publ173.pdf* (Accessed: 10 December 2025).

[57] MA–PD plans offer both medical and prescription benefits (Medicare Part D) through Medicare Part C. Standalone PDP plans offer only Part D coverage.

[58] The exception to this is drugs that are selected for the Medicare Drug Price Negotiation Program, implemented by the Inflation Reduction Act, which authorizes Medicare to directly negotiate drug prices for certain high expenditure, single source Medicare Part B or Part D drugs.

[59] MedPAC. (2024). *Part D Payment System. https://www.medpac.gov/wp-content/uploads/2024/10/MedPAC_Payment_Basics_24_PartD_FINAL_SEC.pdf* (Accessed: 10 December 2025).

deductible, up to a maximum of $615 in 2026.[60] In the 2026 defined standard benefit, enrollees are responsible for 25 percent of drug costs until their true out-of-pocket (TrOOP) spending reaches $2,100, after which they enter the catastrophic coverage phase. Once enrollees reach the catastrophic coverage phase, they are not responsible for any further out-of-pocket payments for a covered Part D drug. The deductible and $2,100 annual out-of-pocket cap in effect for 2026 will be adjusted each year based on the annual percentage increase in average expenditures for covered Part D drugs among Part D eligible individuals in the United States.[61] In the defined standard benefit initial coverage phase, manufacturers are typically responsible for 10 percent of costs for certain brand drugs and biologics under the Manufacturer Discount Program and Part D plans are typically responsible for 65 percent.[62] In the catastrophic coverage phase, Part D plans are typically responsible for 60 percent of drug costs, drug manufacturers are typically responsible for 20 percent, and Medicare pays the remaining 20 percent for brand-name drugs and biologics.[63]

Under section 1860D–2(a)(1) of the Act, each Part D plan is required to offer either the defined standard benefit, as described previously, or an alternative coverage structure that is actuarially equivalent to the defined standard benefit. In addition, under section 1860D–2(a)(2) of the Act, Part D plan sponsors may offer enhanced or supplemental benefits. Analysis of the landscape files available on *CMS.gov* reveal that for 2026, 49 percent of standalone Part D plan offerings include enhanced benefits and 98 percent of MA–PD plans have enhanced benefits.[64] This flexibility allows Part D plans to compete for enrollees based on the benefit design and premiums. It also leads to differences between plans' specific design (for example, whether they require a deductible and, if so, the deductible amount); coverage (for example, the specific drugs covered and tier placement of covered drugs); beneficiary cost sharing (for example, whether a drug is subject to coinsurance or copayment); and other components. Each plan maintains its own formulary, consistent with Medicare formulary requirements in 42 CFR 423.120(b)(2) and 423.272(b)(2). CMS evaluates formularies based on requirements, including sufficiency of categories and classes, tier placement, and utilization management restrictions. These requirements include, for example, that each plan must cover at least two drugs within each therapeutic category and class and generally, all drugs within the six protected classes (immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics)[65] as well as selected drugs under the Medicare Drug Price Negotiation Program for which a negotiated maximum fair price (MFP) is in effect. The Medicare Payment Advisory Commission (MedPAC) has reported that in 2023, Part D covered 54.9 million enrollees, of which about 14 million were enrolled in LIS;[66] Part D enrollees had total gross spending of about $276 billion, which translates to about $5,429 per Part D enrollee who used a Part D covered drug.[67] Previous research by ASPE has found that in 2019, about 5.7 million Medicare beneficiaries did not have prescription drug coverage.[68]

To offer the Part D benefit, under section 1860D–11(b) of the Act, each Part D plan sponsor must submit an annual bid to CMS for each plan it intends to offer, including the plan's benefit design, service area, and the sponsor's actuarial estimate of the expected cost of covering the standard benefit for an average enrollee.[69] These bids, which are due to CMS annually in June, use actuarial methods to project gross drug costs at the point of sale and subtract expected manufacturer rebates, other price concessions, and other components to estimate the net plan liability. As part of the process of bid development, Part D plan sponsors consider the price of a drug, the estimated rebate payments and price concessions from various entities, including pharmacies and drug manufacturers, and other factors. Manufacturer rebates represent the majority of these rebates received by Part D plans and substantially reduce Part D plans' net drug costs.[70] Part D plan bids are used to calculate the Part D National Average Monthly Bid Amount (NAMBA) and derive the base beneficiary premium (BBP) amount. Although the BBP does not represent the actual premiums paid by Part D enrollees, which is dependent on individual Part D plan offerings, this estimate influences the average level of enrollee premiums across the Part D plan market. Typically, Medicare subsidizes 74.5 percent of the average cost of basic benefits in the form of direct subsidies and reinsurance. However in 2025, MedPAC reports that the Medicare subsidy increased to about 83 percent of the average cost of basic benefits due to the IRA's premium cap that institutes a 6 percent cap on annual increases in the BBP.[71]

C. Recent Drug Pricing Policy Reforms

The IRA's amendments to Part D of Title XVIII of the Act included provisions that change the Part D benefit. As part of these changes, the IRA included several provisions that directly changed manufacturer liability under the Part D program.

[60] *Medicare.gov*. (n.d.). *Medicare Part D Costs.* Centers for Medicare and Medicaid Services (CMS), U.S Department of Health and Human Services. *https://www.medicare.gov/health-drug-plans/part-d/basics/costs* (Accessed: 10 December 2025).

[61] Centers for Medicare & Medicaid Services. (2025). *Final CY 2026 Part D Redesign Program Instructions.* U.S. Department of Health and Human Services. *https://www.cms.gov/newsroom/fact-sheets/final-cy-2026-part-d-redesign-program-instructions* (Accessed: 10 December 2025).

[62] Under the Manufacturer Discount Program, there is a multi-year phase-in period for applicable discounts for certain manufacturers' applicable drugs. See section 1860D–14C(g)(4) of the Act.

[63] This is the Part D standard benefit for brand-name drugs and biologics. There are some differences in the Part D standard benefit for generic drugs.

[64] Centers for Medicare & Medicaid Services. (2025). *Prescription Drug Coverage (Part D).* U.S. Department of Health and Human Services. *https://www.cms.gov/medicare/coverage/prescription-drug-coverage* (Accessed: 10 December 2025).

[65] See also: Medicare Prescription Drug Benefit Manual Chapter 6—Part D Drugs and Formulary Requirements, Centers for Medicare & Medicaid Services (January 15, 2016) at § 30.2, Available at *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf* (Last accessed September 24, 2025).

[66] For eligible enrollees whose income and resources are limited, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 established Extra Help (a subsidy) for prescription drugs, which provides financial assistance for prescription drugs (premiums, deductibles, and co-payments). Under the IRA, beginning in 2024, the LIS program is expanded to individuals with limited financial resources and incomes up to 150 percent of the Federal Poverty Limit (FPL).

[67] MedPAC. (2025). *Health Care Spending and the Medicare program. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf* (Accessed: 10 December 2025).

[68] Tarazi, W., et al. (2022). *Medicare Beneficiary Enrollment Trends and Demographic Characteristics.* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. *https://aspe.hhs.gov/sites/default/files/documents/b9ac26a13b4fdf30c16c24e79df0c99c/medicare-beneficiary-enrollment-ib.pdf* (Accessed: 10 December 2025).

[69] MedPAC. (2024). *Part D Payment System. https://www.medpac.gov/wp-content/uploads/2024/10/MedPAC_Payment_Basics_24_PartD_FINAL_SEC.pdf* (Accessed: 10 December 2025).

[70] MedPAC. (2023). *Assessing postsale rebates for prescription drugs in Medicare Part D, Report to the Congress: Medicare and the Health Care Delivery System. https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch2_MedPAC_Report_To_Congress_SEC.pdf* (Accessed: 10 December 2025).

[71] MedPAC. (2025). *Chapter 4: Part D Outlook, Medicare Payment Advisory Commission. https://www.medpac.gov/wp-content/uploads/2025/06/Jun25_Ch4_MedPAC_Report_To_Congress_SEC.pdf* (Accessed: 10 December 2025).

Section 11102(a) of the IRA added new section 1860D–14B of the Act, which establishes requirements for drug manufacturers to pay inflation rebates for certain Part D drugs. Specifically, pharmaceutical drug manufacturers that increase the price for a Part D rebatable drug faster than the rate of inflation (as measured by changes in the Consumer Price Index for all Urban Consumers, CPI–U), as described in section 1860D–14B of the Act, are required to pay Part D drug inflation rebates to the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund for each 12-month applicable period.

Under these provisions, a ''Part D rebatable drug'' is defined as a drug or biological described at section 1860D–14B(g)(1)(C) of the Act and is: (1) a drug approved under a New Drug Application (NDA) under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 301 *et seq.*); (2) a drug approved under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act that meets the criteria in section 1860D–14B(g)(1)(C)(ii) of the Act; or (3) a biological licensed under section 351 of the Public Health Service (PHS) Act (42 U.S.C. 201 *et seq.*). In general, the statute excludes multi-source generic drugs from the definition of a Part D rebatable drug and limits generics that may be Part D rebatable drugs to sole-source generics—that is, generic drugs for which (1) the reference listed drug approved under section 505(c) of FD&C Act, including any ''authorized generic drug'' (as that term is defined in section 505(t)(3) of the FD&C Act), is not being marketed, as identified in the Food and Drug Administration's (FDA's) National Drug Code (NDC) Directory; (2) there is no other drug approved under section 505(j) of the FD&C Act that is rated as therapeutically equivalent and that is being marketed, as identified in FDA's NDC Directory; (3) the manufacturer is not a ''first applicant'' during the 180-day exclusivity period; and (4) the manufacturer is not a ''first approved applicant'' for a competitive generics therapy. The Part D Inflation Rebate Program also excludes drugs or biological products with an average annual total cost under Part D of less than $100 per individual using such drug or biological product for the first applicable period; this amount is adjusted by percentage changes in the CPI–U annually thereafter.

The Part D inflation rebate calculation examines year-over-year changes to determine whether an inflation rebate is owed for a Part D rebatable drug. Specifically, the Part D inflation rebates are calculated, as reported under section 1927(b)(3) of the Act [72] and further clarified in a December 2023 guidance,[73] for each Part D rebatable drug by establishing a historical benchmark price and comparing this price against the price for an applicable 12-month period. The inflation rebate amounts are based on the difference between the drug's volume weighted annual average manufacturer price (AnMP) in a given 12-month applicable period and the inflation-adjusted volume weighted annual average manufacturer price of the benchmark period. This means if the Part D rebatable drug's AnMP in an applicable period exceeds the drug's inflation adjusted payment amount, an inflation rebate amount would be due. The average manufacturer price (AMP) represents the average price paid to the manufacturer for the drug in the United States by wholesalers.

The statute defines an ''applicable period'' to mean a 12-month period beginning with October 1 of a year (beginning with October 1, 2022). As such, October 1, 2022 was the beginning of the first 12-month period for which drug manufacturers will be required to pay rebates to Medicare if a Part D rebatable drug's price increases faster than the rate of inflation over the 12-month period. December 31, 2025 is the date by which CMS is required to begin invoicing pharmaceutical drug manufacturers for the Part D inflation rebates they owed Medicare for the 12-month applicable periods that began on October 1, 2022 and October 1, 2023.[74] For subsequent applicable periods, CMS must invoice pharmaceutical drug manufacturers for any Part D inflation rebates they owe Medicare by no later than 9 months after the end of the applicable period.

Section 11201 of the IRA, as codified in sections 1860D–14C and 1860D–43 of the Act, established a new Manufacturer Discount Program, which became effective January 1, 2025. The Manufacturer Discount Program replaced the Medicare Coverage Gap Discount Program (CGDP), which was enacted into law in section 3301 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 1101 of the Health Care and Education Reconciliation Act (HCERA) of 2010 (Pub. L. 111–152) (referred to collectively as the Affordable Care Act) and codified in sections 1860D–14A and 1860D–43 of the Act. Effective January 1, 2011, the CGDP made manufacturer discounts for brand name drugs and biologic products (with biosimilars included starting in 2019) available to applicable beneficiaries at the point of sale. The CGDP provided non-low-income subsidy beneficiaries in the coverage gap phase of the Part D benefit, a 50 percent discount on the negotiated price of the drug at point of sale. For an applicable drug to be covered under Part D, the manufacturer had to sign a manufacturer agreement with the Secretary.

Section 53116 of the Bipartisan Budget Act of 2018 (BBA) (Pub. L. 115–123), changed the CGDP amount from 50 to 70 percent for applicable beneficiaries beginning in 2019. The BBA also reduced beneficiary cost sharing in the coverage gap phase to 25 percent in 2019 and subsequent years. The CGDP was sunset effective December 31, 2024, and the new Manufacturer Discount Program became effective January 1, 2025. The Manufacturer Discount Program differs from the CGDP in several important ways. First, the Manufacturer Discount Program discount is applied to applicable drugs dispensed to beneficiaries who receive a low-income subsidy as well as those who do not. Also, discounts are applied in the initial coverage and catastrophic phase of the benefit at 10 and 20 percent, respectively. The IRA outlined a method to identify certain specified manufacturers and specified small manufacturers, as defined in statute, and set forth a multiyear phase-in period to phase-in the full discount percentages for these manufacturers. Finally, unlike the CGDP, Manufacturer Discount Program discounts do not count towards a beneficiary's TrOOP [75] costs (meaning that manufacturer payments made under the Manufacturer Discount Program will not accrue to a beneficiary's incurred costs).

The IRA also established the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198

[72] Social Security Act, Payment for Covered Outpatient Drugs (section 1927 of the Act, 42 U.S.C. 1396r–8). *https://www.ssa.gov/OP_Home/ssact/title19/1927.htm* (Accessed: 10 December 2025).

[73] Centers for Medicare & Medicaid Services. (2023). *Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Revised Guidance, Implementation of Section 1860D–14B of the Social Security Act.* U.S. Department of Health and Human Services. *https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-revised-guidance.pdf* (Accessed: 10 December 2025).

[74] Centers for Medicare & Medicaid Services. (2024). *Fact Sheet: Medicare Prescription Drug Inflation Rebate Program Policies in the Calendar Year 2025 Physician Fee Schedule Final Rule.* U.S. Department of Health and Human Services. *https://www.cms.gov/files/document/medicare-prescription-drug-inflation-rebate-program-final-fact-sheet.pdf* (Accessed: 10 December 2025).

[75] See sections 1860D–2(b)(4)(C)(iii) and (E) of the Social Security Act).

of the Act, which gave the Secretary authority to negotiate a MFP for certain high expenditure, single source drugs and biologics without generic or biosimilar competition with participating drug manufacturers. The program began with a set of drugs covered under Part D and expands over time to include drugs payable under Part B that meet the criteria. On August 29, 2023, CMS published the list of 10 drugs covered under Part D selected for initial price applicability year 2026; the negotiated MFPs for these drugs will go into effect on January 1, 2026.[76] The second set of 15 drugs covered under Part D that were selected for negotiation for 2027 were announced on January 17, 2025, and the MFPs, if agreed upon by the manufacturers and CMS, for these drugs are expected to go into effect on January 1, 2027.[77]

D. High Drug Costs Under Part D

Although the provisions under the IRA included a series of changes to the Part D benefit, including allowing Medicare to negotiate for certain drugs, they do not fully address the issue of high drug spending in the Part D program. High drug prices affect Part D spending, particularly for certain types of drugs (for example, single-source brand-name drugs), and influence overall program spending. Moreover, enrollees may ration their prescription drugs due to cost, which can have serious health-related consequences for Medicare enrollees and may result in avoidable costs for Medicare.[78]

Part D gross drug spending has risen over time (from $348 gross drug spending per month per LIS enrollee in 2010 to $765 gross drug spending per month per LIS enrollee in 2023 and $163 per month per non-LIS enrollee in 2010 to $309 per month per non-LIS enrollee in 2023).[79] Analyses show that Part D gross spending is concentrated among certain types of drugs, particularly certain types of brand name drugs such as specialty drugs. One study examined trends in total gross drug spending under Part D between 2012 to 2021 specifically for drugs with the top 1 percent, 5 percent, and 10 percent of spending. Findings showed that gross drug costs increased by 103 percent from 2012 to 2021, driven both by increases in the number of prescriptions as well as increases in prices for existing drugs. Drugs in the top 1 percent of spending in Part D accounted for an increasing share of total gross drug costs over time, increasing from 31.4 percent to 41.1 percent from 2012 to 2021. Spending specifically for specialty drugs increased by over 500 percent over the study period and accounted for 71.1 percent of total gross drug costs in 2021, even though specialty drugs accounted for 6.2 percent of prescriptions in 2021.[80]

In 2023, MedPAC reported that Medicare gross spending on brand-name drugs was about $171.2 billion and spending on biologics was about $60 billion, collectively representing about 84 percent of the total gross drug spending.[81] Generic drugs represented the remaining 15 percent of spending.[82] Additionally, although there were more prescriptions filled for generic drugs (about 82 percent across the top 15 therapeutic classes, including diabetic therapy, antineoplastics, anticoagulants, asthma/chronic obstructive pulmonary disease (COPD) agents, and others in 2023), the majority of gross spending (91 percent) was for brand-name products within these therapeutic classes.[83]

Enrollee out-of-pocket costs for drugs covered under Part D vary based on several factors. Research by ASPE finds that in 2022, Part D enrollees who do not receive LIS had greater average out-of-pocket costs than their LIS enrollee counterparts ($464 per non-LIS enrollee vs. $52 per LIS enrollee); these differences are particularly pronounced for enrollees who reached the catastrophic coverage phase of the Part D benefit ($3,093 per non-LIS enrollee vs. $87 per LIS enrollee). ASPE analysis also finds that, prior to the IRA's out-of-pocket cap going into effect, among enrollees who reached the catastrophic coverage phase of the Part D benefit, annual out-of-pocket prescription drug costs were highest for enrollees with certain health conditions (such as enrollees with cystic fibrosis, metabolic and immune disorders, certain types of cancers, and those who have undergone major organ transplant) and those who take certain types of medications. For example, enrollees who took certain brand name single source drugs used to treat cancers had significantly higher out-of-pocket costs than the average Part D enrollee.[84]

The IRA caps enrollees' out-of-pocket costs for prescription drugs at $2,100 in 2026 (and this cap is adjusted annually based on the annual percentage increase in average expenditures for covered Part D drugs in the United States for Part D eligible individuals in the previous year), which reduces the out-of-pocket costs for certain Part D enrollees who take expensive medications covered under the Part D program. However, although the provision has gone into effect, there remain concerns about the affordability of prescription drugs covered under Part D. Specifically, there is concern that Part D plan sponsors are shifting from a fixed copayment model for high-cost brand-name drugs to a coinsurance-based model, where the enrollee pays a percentage of the price at the point-of-sale in the pharmacy, potentially exposing Part D enrollees who take certain drugs to higher costs.[85] Additionally, CMS analysis of the Medicare Current Beneficiary Survey (MCBS) finds that nine percent of Medicare beneficiaries reported that they decided *not* to fill a prescription in

[76] Centers for Medicare & Medicaid Services. (2024). *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026.* U.S. Department of Health and Human Services. *https://www.cms.gov/newsroom/fact-sheets/medicare-drug-price-negotiation-program-negotiated-prices-initial-price-applicability-year-2026* (Accessed: 10 December 2025).

[77] Centers for Medicare & Medicaid Services. (2015). *HHS Announces 15 Additional Drugs Selected for Medicare Drug Price Negotiations in Continued Effort to Lower Prescription Drug Costs for Seniors.* U.S. Department of Health and Human Services. *https://www.cms.gov/newsroom/press-releases/hhs-announces-15-additional-drugs-selected-medicare-drug-price-negotiations-continued-effort-lower* (Accessed: 10 December 2025).

[78] Leonard, F., et al. (2023). *Medicare's Affordability Problem: A Look at the Cost Burdens Faced by Older Enrollees.* The Commonwealth Fund. *https://www.commonwealthfund.org/publications/issue-briefs/2023/sep/medicare-affordability-problem-cost-burdens-biennial* (Accessed: 10 December 2025).

[79] MedPAC. (2025). *Health Care Spending and the Medicare program. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf* (Accessed: 10 December 2025).

[80] Niu, S., et al. (2024). Concentration of spending and share of specialty drug spending in Medicare Part D over a 10-year period. *Journal of Managed Care & Specialty Pharmacy, 30*(12), 1355–1363. *https://doi.org/10.18553/jmcp.2024.30.12.1355.*

[81] MedPAC. (2025). *Health Care Spending and the Medicare program. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf* (Accessed: 10 December 2025).

[82] MedPAC. (2025). *Health Care Spending and the Medicare program. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf* (Accessed: 10 December 2025).

[83] MedPAC. (2025). *Health Care Spending and the Medicare program. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf* (Accessed: 10 December 2025.

[84] Sayed, B.A., et al. (2024). Inflation Reduction Act Research Series, Medicare Part D Enrollee Out-Of-Pocket Spending: Recent Trends and Projected Impacts of the Inflation Reduction Act. Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. *https://aspe.hhs.gov/reports/medicare-part-d-enrollee-out-pocket-spending* (Accessed: 10 December 2025).

[85] Trish, E. & Blaylock, B. (2025). *Shifting Cost-Sharing Burden to Beneficiaries in Medicare Part D.* U.S.C. Schaeffer Center White Paper Series. White Paper No. 2025–06. *https://schaeffer.usc.edu/research/cost-sharing-burden-medicare-part-d/* (Accessed: 10 December 2025).

2025 due to cost.[86] All of this suggests that Part D enrollees with certain health conditions and particularly those who take certain brand-name drugs or biologics may still experience high out-of-pocket spending.

In addition to out-of-pocket costs for their prescription drugs, enrollees also pay monthly premiums for their Part D coverage, which may impact whether a Medicare beneficiary elects to enroll in a Part D plan. Previous ASPE research finds that in 2019, about 5.7 million Medicare beneficiaries did not have any prescription drug coverage.[87] From 2024 to 2025, MedPAC found a decrease in the average premiums paid by enrollees, from $27 to $23. This decline is largely attributed to the IRA's 6 percent cap on base beneficiary premiums, which remains in effect through 2029 and to the voluntary Part D Premium Stabilization Demonstration. This demonstration, which began in 2024 for calendar year 2025, is testing an approach to stabilize the year-over-year changes in premiums for standalone PDPs during the implementation of the Part D redesign.[88] MedPAC analysis shows that average monthly premiums are higher for standalone PDPs than MA–PD plans. This is driven in part by the additional tools and flexibilities available to MA–PD plans (for example, MA–PD sponsors that submit MA bids that are below the applicable benchmark can use MA rebates to reduce Part D premiums) compared to PDPs.[89]

E. Rationale and Need for GUARD Model Test

Within the United States, the prices of certain types of drugs have been increasing over time, which impacts spending in Part D and affordability of Part D coverage for Medicare beneficiaries. Brand-name drugs and biologics, in particular, represent a large portion of Part D spending in spite of the fact that generic drugs have a higher volume of use.[90] [91] The IRA addresses certain high drug costs under Part D. However, the IRA provisions—specifically the Drug Price Negotiation Program—focuses on a small set of drugs and only after they are available in the market for a period of time. The current Part D Inflation Rebate Program requires manufacturers to pay a rebate for certain drugs based on price changes over time within the United States. While this approach is useful for curbing post-launch increases in drug prices, the Part D Inflation Rebate Program does not address the high launch prices of drugs, which continue to increase over time and contribute to high Medicare drug spending. One way to address high Part D spending is to test a change in the IRA's Part D inflation rebate calculation by using a benchmark that takes into account drug pricing information from economically comparable countries. The benchmark could then be subtracted from a net price that uses the manufacturer's starting point for negotiations (for example, the publicly available list price); manufacturer rebates and discounts could be netted from this figure (to give credit to manufacturers for rebates that have been paid). This approach is different from the current Part D Inflation Rebate Program, which compares each applicable drug's current year price (based on the applicability period as described previously in this Section of the proposed rule) to the inflation adjusted benchmark period price, and in so doing, evaluates changes in prices *within* the United States over time.[92]

Under the CMS Innovation Center's statutory authority under section 1115A of the Act, we propose to address this key issue of persistent high domestic Medicare drug spending for certain drugs and biologics through the GUARD Model, which tests changes to the Part D inflation rebate provision by implementing an innovative alternative payment method for the purpose of reducing Medicare drug spending and preserving or improving quality of care for Part D enrollees.

III. Summary Provisions Proposed in the Guard Model

The proposed GUARD Model would test changes to the Part D Inflation Rebate Program, specifically testing whether an alternative for the Part D inflation rebate calculation for certain drugs and biological products would reduce program spending for Medicare and taxpayers while preserving or enhancing the quality of care furnished to Medicare beneficiaries. The proposed model includes the following major provisions:

- The GUARD Model would include a subset of Part D rebatable drugs that are included in the Part D Inflation Rebate Program. Specifically, the GUARD Model would include sole-source drugs and sole-source biological products that are in the following specific therapeutic categories: Analgesics; Anticonvulsants; Antidepressants; Antimigraine Agents; Antineoplastics; Antipsychotics; Antivirals; Bipolar Agents; Blood Glucose Regulators; Cardiovascular Agents; Central Nervous System Agents; Gastrointestinal Agents; Genetic or Enzyme or Protein Disorder: Replacement or Modifiers or Treatment; Immunological Agents; Metabolic Bone Disease Agents; Ophthalmic Agents; and Respiratory Tract/Pulmonary Agents. The GUARD Model would exclude (1) generics and biosimilar biological products; (2) sole-source drugs or sole-source biological products with annual application-level [93] total gross covered drug costs below the GUARD minimum spend threshold; and (3) drugs that are subject to a maximum fair price (MFP), during the price applicability period. For a more detailed discussion, see section IV.B. of this proposed rule.
- The Centers for Medicare & Medicaid Services (CMS) proposes in section IV.D. of this proposed rule that manufacturers of ''Part D rebatable drugs,'' as defined in section 1927(k)(5) of the Act and 42 CFR 428.20, that receive a Part D inflation rebate report that includes a GUARD Model drug for an applicable period that overlaps with the GUARD Model performance period

[86] Internal CMS analysis of Medicare Current Beneficiary Survey data collected May–July 2025 (Office of Enterprise Data and Analytics).

[87] Tarazi, W., et al. (2022). *Medicare Beneficiary Enrollment Trends and Demographic Characteristics.* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. *https://aspe.hhs.gov/sites/default/files/documents/b9ac26a13b4fdf30c16c24e79df0c99c/medicare-beneficiary-enrollment-ib.pdf* (Accessed: 10 December 2025).

[88] Centers for Medicare & Medicaid Services. (2025). *2026 Medicare Part D Bid Information and Part D Premium Stabilization Demonstration Parameters.* U.S. Department of Health and Human Services. *https://www.cms.gov/newsroom/fact-sheets/2026-medicare-part-d-bid-information-and-part-d-premium-stabilization-demonstration-parameters* (Accessed: 10 December 2025).

[89] Suzuki, S., et al. (2025). *Structural differences between the Part D PDP and MA–PD markets.* MedPAC. *https://www.medpac.gov/wp-content/uploads/2025/04/Tab-D-Structural-issues-in-Part-D-April-2025.pdf* (Accessed: 10 December 2025).

[90] Trish, E. & Blaylock, B. (2025). *Shifting Cost-Sharing Burden to Beneficiaries in Medicare Part D.* U.S.C. Schaeffer Center White Paper Series. White Paper No. 2025–06. *https://schaeffer.usc.edu/research/cost-sharing-burden-medicare-part-d/* (Accessed: 10 December 2025).

[91] MedPAC. (2025). *Health Care Spending and the Medicare program. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf* (Accessed: 10 December 2025).

[92] In addition, unlike the Medicare Drug Price Negotiation Program, which has requirements for the number of years a drug has been on the market before it is eligible to be selected for negotiation, under the GUARD Model, if a drug meets the criteria, it would be included and potentially be subject to a rebate regardless of how long it has been on the market.

[93] Application-level refers to the New Drug Application (NDA) or Biologics License application (BLA) associated with each GUARD Model drug. This means the total gross covered prescription drug costs for all Part D rebatable NDC–9s associated with the same application (NDA or BLA) as the GUARD Model drug.

would be required to participate in the GUARD Model.

• CMS proposes in section IV.E. of this proposed rule that the GUARD Model would select reference countries that are economically comparable to the United States. Reference countries must meet the following criteria: they must be a part of the Organization for Economic Cooperation and Development (OECD), have a minimum of 60 percent of the United States's purchasing power parity (PPP)-adjusted per capita gross domestic product (GDP), and a minimum $400 billion (PPP)-adjusted aggregate GDP. The reference countries that meet these criteria and are therefore proposed to be selected for the model are the following: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom.

• As part of the GUARD Model, CMS proposes to test two approaches to calculating the GUARD Model international benchmark: the default international benchmark (also referred to as the Method I benchmark) and the updated international benchmark (also referred to as the Method II benchmark).

• For each GUARD Model drug for which data on international drug pricing in reference countries are available, CMS would calculate the GUARD Model default international benchmark. The GUARD Model default international benchmark for each GUARD Model drug would be identified as the lowest country-level average price among the set of average prices for each reference country, adjusted by the country-specific GDP based on PPP (hereafter, ''GDP (PPP)'') adjuster, where an international product that is part of a GUARD Model drug's set of international analogs [94] is sold. Please see section IV.G. of the proposed rule.

• CMS would provide manufacturers with the option to submit international drug net pricing data for the set of reference countries where international products that are part of a GUARD Model drug's set of international analogs are sold, including the across-country average net price. This submitted across-country average net price accounts for country-specific differences using a GDP (PPP) adjuster; if the data submitted is determined to be an applicable submission, it would become the GUARD Model updated international benchmark. Please see section IV.F. of this proposed rule.

• CMS would determine a GUARD Model applicable international benchmark for each GUARD Model drug that would be the greater of the GUARD Model default international benchmark and the GUARD Model updated international benchmark, unless there is only a GUARD Model default international benchmark. If there is only a GUARD Model default international benchmark, it would become the applicable international benchmark. Please see section IV.G. of this proposed rule.

• CMS would use this information to test an alternative inflation rebate payment calculation to determine whether manufacturers owe a GUARD Model rebate payment. The alternative inflation rebate calculation tested under the GUARD Model would compare a Medicare net price against the applicable international benchmark. Please see section IV.H. of this proposed rule.

• The GUARD Model would require manufacturers to pay a GUARD Model rebate payment if the Medicare net price is greater than the GUARD Model applicable international benchmark for a GUARD Model drug. The Medicare net price would be calculated by subtracting manufacturer rebates (obtained from direct and indirect remuneration (DIR)) and discounts (under the Manufacturer Discount Program) from the wholesale acquisition cost (WAC) of the GUARD Model drug. Please see section IV.H. of this proposed rule.

• The total GUARD Model rebate amount would be equal to the product of the per unit GUARD Model rebate amount for such GUARD Model drug for the performance year and the total number of units of the GUARD Model drug dispensed under Part D and covered by Part D plan sponsors in the GUARD Model geographic areas for the performance year. Please see section IV.H. of this proposed rule.

• When the per unit GUARD Model rebate exceeds the per unit Part D inflation rebate amount, CMS would waive the rebate amount described in section 1860D–14B(b) of the Act and instead apply the GUARD Model rebate amount. The GUARD Model rebate payment would be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.

• The evaluation would examine the main outcome, Medicare net spending, as well as additional outcomes of the GUARD Model, including the ways in which Part D plan benefits may change for GUARD Model drugs and whether and to what extent there are impacts on beneficiary cost sharing for GUARD Model drugs.

[94] To be a part of the set of international analogs, an international product must have an active ingredient, route of administration, dosage form, and strength that aligns with that of the GUARD Model drug.

IV. Detailed Description of Provisions in the Proposed Guard Model

In this Section, CMS proposes our policies for testing and implementing the GUARD Model, including model-specific definitions and the general framework for implementation of the GUARD Model. The proposed model-specific terms are described in applicable Sections of this proposed rule. We propose to codify these model-specific terms at proposed 42 CFR part 514. In addition, for purposes of this proposed rule and the proposed GUARD Model, we propose that the following terms would have the same meaning as set forth in 42 CFR 428.20: ''applicable period''; ''Consumer Price Index for All Urban Consumers'' (CPI–U); ''applicable threshold''; ''average manufacturer price'' (AMP); ''manufacturer''; ''national drug code'' (NDC) ; ''Part D rebatable drug''; and ''unit.'' We also propose that ''covered Part D drug'' has the same meaning as set forth in 42 CFR 423.100, and ''line extension'' has the same meaning as set forth in 42 CFR 428.200.

The remaining sections of this proposed rule are organized as follows: In section IV.A. of this proposed rule, we describe the proposed model performance and test period. In section IV.B. of this proposed rule, we present the Part D covered drugs that would be included in the GUARD Model. In section IV.C. of this proposed rule, we present the model test design, geographic selection, and beneficiary population that would be included in the GUARD Model. In section IV.D. of this proposed rule, we present the GUARD Model participants, including the requirement that participation is mandatory as well as requirements for participants during the GUARD Model performance period and after the ending of the performance period. In section IV.E. of this proposed rule, we present the existing international drug pricing data that CMS proposes to use to generate the GUARD Model default international benchmark as well as CMS' proposed data sources and methods to identify the reference countries for the GUARD Model. In section IV.F. of this proposed rule, we present the option for manufacturers to submit international drug net pricing data, if they choose to do so; the requirements for such data submission; and the process to elect this option if preferred for the purpose of determining the updated international benchmark. In section IV.G. of this proposed rule, we

present the proposal to determine the GUARD Model applicable international benchmark based on the set of reference countries, including the default international benchmark and the updated international benchmark (which only applies if the manufacturer elects to submit international drug net pricing data, and it is deemed applicable by CMS). In section IV.H. of this proposed rule, we propose the methods to determine the GUARD Model rebate payment, including the data inputs and the calculation steps for the GUARD rebate payment amount. Section IV.I. of this proposed rule presents the proposals for reports of rebate amounts and timing of reports for GUARD Model participants. In section IV.J. of this proposed rule, we present the proposed reconciliation process for a GUARD rebate payment and the suggestion of error process. In section IV.K. of this proposed rule, we present the enforcement mechanisms that would be used to ensure manufacturer payment of rebates are paid in a timely manner. Section IV.L. of this proposed rule presents the proposed quality and monitoring strategy for the GUARD Model, and section IV.M. of this proposed rule presents the proposed beneficiary protections and compliance related activities that CMS would require under the GUARD Model. Section IV.N. of this proposed rule presents the GUARD Model's interaction and coordination with other models and programs and CMS' approach for taking these into account. Section IV.O. of this proposed rule presents the proposed evaluation approach for the GUARD Model, including the key outcomes that would be examined. Section IV.P. of this proposed rule presents information on the limitations on review that apply to CMS Innovation Center Models, including the GUARD Model. Section IV.Q. of this proposed rule presents program waivers that CMS proposes to apply to the GUARD Model. Section IV.R. of this proposed rule denotes that the GUARD Model and its provisions are severable from other CMS programs. Section IV.S. of this proposed rule presents information on the termination of the GUARD Model. Section IV.T. of this proposed rule presents the process for response to comments on this proposed rule.

A. Proposed Model Performance and Test Period

CMS is proposing in § 514.1(c) that the GUARD Model would have a 7-year overall test period, which would consist of 5 performance years, during which GUARD Model rebate payments would apply, and 7 payment years during which CMS calculates, invoices, collects, and reconciles the GUARD Model rebates for a performance year, unless the model is terminated sooner, in accordance with proposed § 514.910(a).

In § 514.5, we propose to define ''payment year'' as a 12-month period beginning on January 1 and ending on December 31 during the GUARD Model test period. As such, we propose to define ''GUARD Model payment period'' as the 7-year period beginning on January 1, 2027 through December 31, 2033, as specified in § 514.1(c). We propose a 7-year payment period to allow for sufficient time for payments to be invoiced and collected after the end of the 5 performance years of the GUARD Model.

In § 514.5, we propose to define the ''GUARD Model performance period'' as the 5-year period, beginning on January 1, 2027, through December 31, 2031, as specified in § 514.1(c). We propose to define at § 514.5, the ''performance year'' (PY) as the 12-month period beginning on January 1st and ending on December 31st during the GUARD Model performance period, and in alignment with the GUARD Model duration as specified in § 514.1(c). We propose to utilize a 5-year performance period because it would allow for sufficient time and duration to test an alternative to the Part D inflation rebate calculation under the Medicare Part D Inflation Rebate Program, using the applicable international benchmark price, as described in section IV.G. of this proposed rule, and for the purpose of understanding the impacts of the GUARD Model. A 5-year performance period would allow CMS to examine whether the Model reduces expenditures under Part D and maintains or improves quality of care for Part D enrollees; that is, whether the GUARD Model—(1) maintains spending while improving quality; (2) maintains quality while reducing spending; or (3) reduces spending and improves quality. We believe this is sufficient time to evaluate the way the GUARD Model impacts Medicare net spending for the GUARD Model drugs. Within this time horizon, we would also be able to observe short-, intermediate-, and some long-term impacts of the GUARD Model, such as manufacturer and other stakeholder responses as well as changes in cost sharing for beneficiaries. See section IV.L. of this proposed rule for the quality and monitoring approach and section IV.O. of this proposed rule for the evaluation strategy of the GUARD Model.

CMS proposes in § 514.110(c) that it would be necessary to continue GUARD Model processes for payment beyond the end of the GUARD Model performance period and reconciliation activities beyond the GUARD Model payment period. CMS believes the reconciliation activities beyond the end of the GUARD Model payment period would pose minimal burden to manufacturers. Examples of reconciliation activities that could take place after the end of the GUARD Model payment period are responses to reconciliation reports, suggestion of error processes, and payment of any reconciled rebate amounts due or owed.

B. GUARD Model Drugs

1. Proposed Identification of GUARD Model Drugs

From among the Part D rebatable drugs included in the Part D Inflation Rebate Program, as defined in 42 CFR 428.20 and identified in 42 CFR 428.101, CMS proposes at § 514.120(a) that GUARD Model drugs would be defined as sole-source drugs and biological products identified at the NDC–9 level, except those that meet certain exclusions, as described in section III.B.2. of this proposed rule. This means that for every performance year, only sole-source drugs and sole-source biological products included in the Part D Inflation Rebate Program would be considered for the GUARD Model.

CMS proposes at § 514.120(a) that identification of drugs and biological products would be at the NDC–9 level because this is the same unique prescription drug product number that is used to identify a Part D rebatable drug in accordance with 42 CFR 428.20 and 428.101. We would use the NDC–9 level at which to identify the drugs in the Medicare Part D Prescription Drug Event (PDE) data. At § 514.5 CMS defines ''PDE data'' to mean records submitted by a Part D plan to CMS each time a beneficiary fills a prescription under Medicare Part D. A PDE record is data summarizing the final adjudication of a Part D dispensing event that is reported to CMS by the Part D sponsor using a CMS-defined file layout.

We propose at § 514.100 that for the purposes of the GUARD Model test, a ''sole-source drug'' will be defined as a drug approved by the Food and Drug Administration (FDA) under a New Drug Application (NDA) under section 505 of the Food Drug and Cosmetics Act (FD&C Act) for which there are no

generic(s),[95] as defined at § 514.5, rated as therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations''). The generic rated as therapeutically equivalent to the drug must be recognized as a therapeutic equivalent in the FDA's Orange Book and be identified as marketed in the FDA's NDC Directory. From this definition, it follows that a multi-source drug, which is a drug with at least one therapeutically equivalent generic approved and marketed, is not a GUARD Model drug.

We propose at § 514.100 that a ''sole-source biological product,'' for purposes of the GUARD Model test, will be defined as a biological product licensed by the FDA under a Biologics License Application (BLA) under section 351(a) of the Public Health Service (PHS) Act that is not the reference biological product, as defined at 42 U.S.C. 262(i)(4), for a biosimilar biological product licensed by FDA in a BLA under section 351(k) of the PHS Act. The biosimilar biological product [96] must have the biological product as its reference product as defined at 42 U.S.C. 262(i)(4) in the FDA's Purple Book and be identified as marketed in the FDA's NDC Directory. From this definition, it follows that a multi-source biological product, which is a biological product with at least one biosimilar biological product licensed and marketed that has said biological product as their reference product, is not a GUARD Model drug.

At the time of evaluating inclusion of a drug into the GUARD Model (based on being sole-source drugs or biological products) for each performance year, CMS would use the FDA's NDC Directory, including historical information from NDC Directory files such as discontinued, delisted, and expired listings, provided by the FDA or published on the FDA website to identify whether the generic or biosimilar biological products are being sold or marketed for purposes of the GUARD Model. Additionally, CMS proposes at § 514.120(a) that should a sole-source drug or sole-source biological product become multi-source at any point during a performance year, it would only be subject to the GUARD Model for the period of the performance year during which it was sole-source.

CMS recognizes that based on the definitions of sole-source previously described, authorized generics and unbranded biological products could potentially be GUARD Model drugs. Authorized generics are drugs sold without their brand name by the original manufacturer or a third party under the NDA of the original drug. Unbranded biological products are biological products sold without their brand name by the original manufacturer or a third party licensed by the BLA 351(a) of the original biological product.[97] Since both authorized generics and unbranded biological products are, directly or indirectly, sponsored by the original pharmaceutical drug manufacturer, CMS believes that if their NDC–9 is included in the Part D Inflation Rebate Program, then subject to the exclusions described in section III.B.2. of this proposed rule, they would be included in the GUARD Model.

Under the proposed policies, the GUARD Model drugs would consist of a subset of Part D rebatable drugs. CMS believes that focusing the GUARD Model test on a subset of the Part D rebatable drugs, rather than all Part D rebatable drugs, would allow CMS to understand the GUARD Model's impacts with a smaller set of drugs. For example, testing the GUARD Model on a select subset of drugs would allow CMS to understand how the Part D plan market would respond to the alternative rebate payment methodology tested under the GUARD Model. In § 514.120(a), we propose sole-source drugs and sole-source biological products for inclusion in the GUARD Model because generally, these drugs face similar market dynamics. By including only sole-source drugs and sole-source biological products in the GUARD Model, we expect that learnings from the test would not be influenced by the very different market dynamics that exist for other types of drugs included in the Part D Inflation Rebate program.

When determining the scope of drugs included in our proposal for the GUARD Model, we considered two key characteristics related to market dynamics for sole-source drugs and sole-source biological products. First, sole-source drugs and sole-source biological products experience different competitive forces than multi-source drugs and multi-source biological products. The entry of a generic drug, which changes a sole-source drug into a multi-source one, has been shown to shift utilization from the original drug to the generic by 75 percent within a year,[98] with prices falling on average by more than half for the sole-source drug.[99] [100] Biosimilar biological product entry, which changes a sole-source biological product into a multi-source biological product, has been shown to shift utilization from the original biological product to the biosimilar biological product by 40 percent within a year, with prices falling by up to 25 percent.[101] These shifts and prices in multi-source drug [102] and multi-source biological product [103] markets varies by market size, product form, therapeutic area, distribution channel, and other idiosyncratic characteristics. Therefore, by only including sole-source drugs and sole-source biological products, the GUARD Model test can focus on understanding the impacts on these types of drugs without having to account for confounding factors that may arise due to the entry of generics or biosimilars, which fundamentally alters market dynamics.[104]

Second, pharmaceutical drug manufacturer rebates and discounts are significantly different for sole-source

[95] At § 514.5 we define ''generic'' to mean, for the United States, a marketed drug submitted in an ANDA and approved under an ANDA under section 505(j) of the FD&C Act.

[96] At § 514.5 we define ''*biosimilar biological product*'' to mean, for the United States, a marketed biological product submitted in a BLA under section 351(k) of the PHS Act.

[97] It is possible for there to be an unbranded biological product derived from a biosimilar biological product, which would have been licensed under section 351(k) of the PHS Act. Given that at § 514.120 CMS proposes to exclude generics and biosimilar biological products and that biosimilar biological products are defined at § 514.5 as those licensed under section 351(k), it follows that these specific unbranded biological products would be excluded from the GUARD Model.

[98] Grabowski, H., et al. (2016). Updated Trends in US Brand-name and Generic Drug Competition. *Journal of Medical Economics, 19*(9), 836–844. *https://doi.org/10.1080/13696998.2016.1176578.*

[99] Darling P., et al. (2024) *Economic Considerations Related to Biosimilar Market Entry.* American Bar Association. *https://www.americanbar.org/groups/antitrust_law/resources/newsletters/economic-considerations-biosimilar-market-entry/* (Accessed: 10 December 2025).

[100] Aitken, M. (2016). *Price Declines after Branded Medicines Lose Exclusivity in the U.S.* IQVIA. *https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf* (Accessed: 10 December 2025).

[101] Maini L. et al. (2021). Biosimilar Entry and the Pricing of Biologic Drugs. *SSRN. https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3760213.*

[102] Frank, R.G., et al. (2021). The Evolution of Supply and Demand in Markets for Generic Drugs. *The Milbank quarterly, 99*(3), 828–852. *https://doi.org/10.1111/1468-0009.12517.*

[103] McGeeney, J.D., et al. (2025). Measuring the First Mover Advantage in US Biosimilar Markets. *Value Health. https://doi.org/10.1016/j.jval.2025.07.011.*

[104] Bosworth, A., et al. (2023). *Changes in the List Prices of Prescription Drugs, 2017–2023.* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. *https://www.aspe.hhs.gov/reports/changes-list-prices-prescription-drugs* (Accessed: 10 December 2025).

and multi-source drugs and biological products. Although there are many factors that influence the net price of a drug, which is exclusive of rebates, discounts, and other price concessions, in general (though there are exceptions), drugs that face more limited competition (such as sole-source drugs and sole-source biological products) maintain higher net prices than drugs that have market competition (such as multi-source drugs and multi-source biological products).[105] [106] [107] This occurs for multiple reasons, but one reason is due to the specific features of the sole-source drug market. Part D plan sponsors or their pharmacy benefit managers (PBMs) negotiate with pharmaceutical drug manufactures for rebates in exchange for favorable formulary placement, which includes assigning drugs into tiers with different cost sharing requirements (for example, coinsurance vs. copayment); prior authorization requirements; utilization management approaches, and other aspects. Although Part D plan sponsors or their PBMs negotiate with pharmaceutical drug manufactures for formulary placement for both sole-source drugs and sole-source biological products as well as multi-source drugs and biological products, negotiation is fundamentally different due to the different characteristics of these types of drugs.

These two key differences illustrate how market dynamics vary between sole-source drugs and biological products and multi-source drugs and biological products, and the way these differences directly impact their pricing dynamics. CMS believes that the focus of the GUARD Model on sole-source drugs and sole-source biological products mitigates the potential confounding factors that would arise if the full set of Part D rebatable drugs were included in the GUARD Model test.

Further, CMS proposes in § 514.120(a) to limit the subset of sole-source drugs and sole-source biological products to those classified by the United States Pharmacopeia (USP) Drug Classification as belonging to certain categories selected by CMS. The categories selected by CMS, hereinafter referred to as ''USP selected categories'' are proposed at § 514.120(e) and include the specific categories from the USP Drug Classification that correspond to all of the Part D protected classes and additional categories based on several considerations. The primary reasons for selection of these categories are that Medicare beneficiaries taking these drugs have conditions for which deficits in care exist and they represent a meaningful amount of spending under Part D.

a. Approach for Selecting Categories From the United States Pharmacopeia

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, 117 Stat. 2066 (2003), section 1860D–4(b)(3)(C)(ii) of the Act, the USP is required to develop and revise the Medicare Model Guidelines, which is a classification system used for the purpose of supporting Part D formulary development and submission. The Medicare Model Guidelines include a list of categories and classes that may be used by prescription drug plans; USP revises them on a continuous basis based on changes in therapeutic uses of covered Part D drugs and the additions of new covered Part D drugs.[108]

CMS proposes at § 514.120(d) to use the 'category' field of the USP Drug Classification because CMS believes this field is sufficient to identify drugs and biological products for conditions where Medicare beneficiaries may experience deficits of care, while allowing for differences in mechanism of action and molecular or biological targets for products that treat the same therapeutic area. We recognize that a drug or biological product may be listed in more than one USP category. We propose at § 514.120(d) that as long as one of the categories selected for inclusion in the GUARD Model applies to the drug or biological product, it will be considered to have met this criterion and would be included in the GUARD Model.

CMS proposes at § 514.120(d) to identify the Part D rebatable drugs classified as belonging to one of the categories listed later in this Section of this proposed rule using their RxNorm [109] Concept Unique identifier,[110] active ingredient(s), NDC–9, or the FDA approved indication. Using the current guidelines, the USP Medicare Model Guidelines v9.0,[111] CMS proposes at § 514.120(a) that a drug or biological product whose listed USP categories include at least one of the following USP selected categories (as defined at § 514.120(e)) would be included in the GUARD Model if they meet all other inclusion criteria and limited to the exclusion criteria proposed at § 514.120(c): Analgesics; Anticonvulsants; Antidepressants; Antimigraine Agents; Antineoplastics; Antipsychotics; Antivirals; Bipolar Agents; Blood Glucose Regulators; Cardiovascular Agents; Central Nervous System Agents; Gastrointestinal Agents; Genetic or Enzyme or Protein Disorder: Replacement or Modifiers or Treatment; Immunological Agents; Metabolic Bone Disease Agents; Ophthalmic Agents; and Respiratory Tract/Pulmonary Agents.

The proposed list of USP categories includes categories that correspond to the six Medicare Protected Classes (anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants) identified by CMS as those for which ''all or substantially all'' drugs must be covered by Part D plans.[112] The USP categories that correspond to the Medicare Protected Classes are Anticonvulsants, Antidepressants, Antineoplastics, Antipsychotics, Antivirals, Bipolar Agents, and Immunological Agents, as defined at § 514.5. The Bipolar Agents USP category has significant overlap with the Medicare Protected Classes of antidepressants and antipsychotics; thus, CMS considers Bipolar Agents to correspond with the Medicare protected classes and this category would be included in the GUARD Model. These USP categories that correspond to the protected classes are included because of their relevance for vulnerable

[105] Government Accountability Office. (2023). *Medicare Part D: CMS should monitor effects of rebates on plan formularies and beneficiary spending* (GAO–23–105270). *https://www.gao.gov/assets/gao-23-105270.pdf.*

[106] Hernandez, I., et al. (2020). Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007–2018. *JAMA, 323*(9), 854–862. *https://doi.org/10.1001/jama.2020.1012.*

[107] Mulcahy, A.W., et al. (2024). *Prescription Drug Prices, Rebates, and Insurance Premiums.* RAND. *https://www.rand.org/pubs/research_reports/RRA1820-3.html* (Accessed: 10 December 2025).

[108] Historically, every 3 years, the USP publishes an updated version of the Medicare Model Guidelines. The current guidelines can be found following this link *https://www.usp.org/health-quality-safety/usp-medicare-model-guidelines.*

[109] The National Library of Medicine (NLM) produces RxNorm. RxNorm provides normalized names and unique identifiers for medicines and drugs. The goal of RxNorm is to allow computer systems to communicate drug-related information efficiently and unambiguously. See *https://www.nlm.nih.gov/research/umls/rxnorm/index.html.*

[110] An RXCUI is a machine-readable code or identifier that points to the common meaning shared by the various source names grouped and assigned to a particular concept. A concept is a fundamental unit of meaning in RxNorm. *https://www.nlm.nih.gov/research/umls/rxnorm/overview.html.*

[111] The current guidelines can be found here: *https://www.usp.org/health-quality-safety/usp-medicare-model-guidelines.*

[112] Centers for Medicare & Medicaid Services. (2016). *Medicare Prescription Drug Benefit Manual: Chapter 6—Part D drugs and formulary requirements* (Rev. 18, Issued Jan. 15, 2016). U.S. Department of Health and Human Services. *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf* (Accessed: 10 December 2025.

beneficiaries that depend on these drugs for serious conditions. Except for Anticonvulsants, among the Part D rebatable sole-source drugs and sole-source biological products, all of the USP selected categories that correspond to Medicare protected classes have 2024 total covered gross drug costs above $1 billion.[113] The top three spending categories that correspond to Medicare Protected Classes in 2024 are Immunological Agents, Antineoplastics, and Antivirals; for these categories, among Part D rebatable sole-source drugs and sole-source biological products, the total covered drug costs are $32, $30, and $10 billion, respectively.

The proposed list also includes additional categories that correspond to drugs that are used for conditions for which Medicare beneficiaries experience deficits of care and that are within the top spending categories for the Part D Inflation Rebate Program based on previous spending trends. The additional USP selected categories (as defined at § 514.120(e)) are Analgesics; Antimigraine Agents; Blood Glucose Regulators; Cardiovascular Agents; Central Nervous System Agents; Gastrointestinal Agents; Genetic or Enzyme or Protein Disorder: Replacement or Modifiers or Treatment; Metabolic Bone Disease Agents; Ophthalmic Agents; and Respiratory Tract/Pulmonary Agents. Among the Part D rebatable sole-source drugs and sole-source biological products, in 2024, all of these USP selected categories have total covered gross drug costs above $1 billion.[114] The top two spending categories in 2024 were Blood Glucose Regulators and Respiratory Tract/Pulmonary Agents.

CMS proposes at § 514.120(d) that once CMS has identified the drug or biological product's category, it should remain in that category for the entire GUARD Model performance period. Accordingly, drugs or biological products will retain their category, while newly added drugs or biological products will retain the category assigned at the time of their identification, based on the USP Medicare Model Guidelines available at the time. Additionally, as defined at § 514.5, any change to the definition of Medicare Protected Classes in Chapter 6 section 30.2.5 from the Medicare Prescription Drug Benefit Manual would be carried over.

[113] CMS analysis using preliminary list of Part D rebatable drugs for 2024 and PDE data as of October 1, 2025.

[114] CMS analysis using preliminary list of Part D rebatable drugs for 2024 and PDE data as of October 1, 2025.

b. Addressing Deficits of Care Among Part D Enrollees

We propose these categories partly because Part D enrollees who take these drugs have conditions for which deficits of care are documented. For example, Part D beneficiaries who have immunological diseases (and therefore may take immunological agents), endocrine diseases (and therefore may take blood glucose regulators and metabolic bone disease agents), neurological diseases (and therefore may take analgesics, anticonvulsants, antimigraine agents, central nervous system agents) and chronic diseases (and therefore may take cardiovascular agents, gastrointestinal agents, respiratory tract and pulmonary agents), may experience affordability challenges related to their treatment.[115] [116] [117] There is evidence that patients with autoimmune diseases such as rheumatoid arthritis and systemic lupus erythematosus, neurological disease such as multiple sclerosis and myasthenia gravis, and endocrine diseases such as diabetes mellitus, continue to experience financial burden.[118] [119] [120]

Additionally, CMS analysis of the Medicare Current Beneficiary Survey (MCBS) finds that nine percent of Medicare beneficiaries reported that they decided *not* to fill a prescription in 2025 due to cost.[121] Financial distress associated with cost coping behaviors, such as rationing or skipping medicines or delaying care that could worsen health outcomes continues to raise concerns for providers treating a range of conditions. This includes, for example, providers treating autoimmune diseases such as systemic lupus erythematosus [122] and neuromyelitis optical spectrum disorder,[123] endocrine diseases such as diabetes mellitus,[124] neurological diseases such as multiple sclerosis [125] [126] and myasthenia gravis,[127] and chronic diseases such as cardiovascular diseases [128] [129] and inflammatory bowel disease.[130]

Although the GUARD Model does not directly impact Part D enrollees' out-of-pocket costs for these drugs, we believe the GUARD Model has the capacity to address deficits of care experienced by the populations who take the drugs that fall within these categories. The GUARD Model test requires a GUARD Model

[115] Dusetzina, S.B., et al. (2022). Many Medicare Beneficiaries Do Not Fill High-Price Specialty Drug Prescriptions. *Health Affairs, 41*(4), 487–496. *https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2021.01742.*

[116] San-Juan-Rodriguez, A., et al. (2019). Trends in Prices, Market Share, and Spending on Self-administered Disease-Modifying Therapies for Multiple Sclerosis in Medicare Part D. *JAMA Neurology, 76*(11), 1386–1390. *https://doi.org/10.1001/jamaneurol.2019.2711.*

[117] Tarazi, W., et al. (2022). *Prescription Drug Affordability among Medicare Beneficiaries.* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. *https://aspe.hhs.gov/sites/default/files/documents/1e2879846aa54939c56efeec9c6f96f0/prescription-drug-affordability.pdf* (Accessed: 15 December 2025).

[118] Sandoval-Heglund, D., et al. (2024). Economic Insecurities and Patient-Reported Outcomes in Patients with Systemic Lupus Erythematosus in the USA: a cross-sectional analysis of data from the California Lupus Epidemiology Study. *Lancet Rheumatology, 6*(2), e105–e114. *https://doi.org/10.1016/S2665-9913(23)00296-5.*

[119] Weinstein, D.R., et al. (2022). Multiple Sclerosis: Systemic Challenges to Cost-Effective Care. *American Health & Drug Benefits, 15*(1), 13–20. *https://pubmed.ncbi.nlm.nih.gov/35586614/.*

[120] Khan, S., et al. (2025). Insulin Rationing Persists Despite Policy Changes: Repeated Cross-Sectional Studies, 2017 vs 2024. *Journal of General Internal Medicine,* 10.1007/s11606–025–09886–9. Advance online publication. *https://doi.org/10.1007/s11606-025-09886-9.*

[121] Internal CMS analysis of Medicare Current Beneficiary Survey data collected May–July 2025 (Office of Enterprise Data and Analytics).

[122] Sandoval-Heglund, D., et al. (2024). Economic Insecurities and Patient-Reported Outcomes in Patients with Systemic Lupus Erythematosus in the USA: a cross-sectional analysis of data from the California Lupus Epidemiology Study. *Lancet Rheumatology, 6*(2), e105–e114. *https://doi.org/10.1016/S2665-9913(23)00296-5.*

[123] Wingerchuk, D.M., et al. (2022). Aligning Payer and Provider Strategies with the Latest Evidence to Optimize Clinical Outcomes for Patients with Neuromyelitis Optica Spectrum Disorder. *Journal of managed care & specialty pharmacy, 28*(12–a Suppl), S3–S27. *https://doi.org/10.18553/jmcp.2022.28.12-a.s1.*

[124] Patel, M.R., et al. (2022). Measurement and Validation of the Comprehensive Score for Financial Toxicity (COST) in a Population with Diabetes. *Diabetes Care, 45*(11), 2535–2543. *https://doi.org/10.2337/dc22-0494.*

[125] Singer, B.A., et al. (2024). Early Use of High-Efficacy Therapies in Multiple Sclerosis in the United States: benefits, barriers, and strategies for encouraging adoption. *Journal of Neurology, 271*(6), 3116–3130. *https://doi.org/10.1007/s00415-024-12305-4.*

[126] Mizell, R. (2024). The Impact of Insurance Restrictions in Newly Diagnosed Individuals with Multiple Sclerosis. *International Journal of MS Care, 26*(1), 17–21. *https://doi.org/10.7224/1537-2073.2022-069.*

[127] Choi, S.A., et al. (2025). Health Care Costs and Resource Utilization Among Patients with Myasthenia Gravis in the United States. *Journal of Managed Care & Specialty Pharmacy, 31*(5), 472–481. *https://doi.org/10.18553/jmcp.2025.31.5.472.*

[128] Sukumar, S., et al. (2023). Financial Toxicity of Medical Management of Heart Failure: JACC Review Topic of the Week. *Journal of the American College of Cardiology, 81*(20), 2043–2055. *https://doi.org/10.1016/j.jacc.2023.03.402.*

[129] Wang, S.Y., et al. (2021). Out-of-Pocket Annual Health Expenditures and Financial Toxicity from Healthcare Costs in Patients with Heart Failure in the United States. *Journal of the American Heart Association, 10*(14), e022164. *https://doi.org/10.1161/JAHA.121.022164.*

[130] Nguyen, N.H., et al. (2021). National Estimates of Financial Hardship from Medical Bills and Cost-related Medication Nonadherence in Patients with Inflammatory Bowel Diseases in the United States. *Inflammatory Bowel Diseases, 27*(7), 1068–1078. *https://doi.org/10.1093/ibd/izaa266.*

rebate payment, as described in Section IV.H. of this proposed rule, if a GUARD Model drug's Medicare net price is greater than an international benchmark. It is possible that in response to the alternative payment strategy tested under the model, manufacturers reduce their net price for a given drug, for instance by reducing launch prices for drugs that are likely to become GUARD Model drugs. If manufacturers decrease launch prices for GUARD Model drugs for the purpose of reducing their liability under the GUARD Model, it may have cascading effects. For example, such a response may benefit Part D plans, who may then change their benefit design and offerings for Part D plan enrollees and potentially reduce cost sharing for the drugs included in the GUARD Model.

It is also possible manufacturers respond to the GUARD Model by reducing the list prices of the drugs included in the model. A reduction of list prices would reduce a manufacturer's rebate liability under the GUARD Model. Given that the list price of drugs is used as a starting point for negotiations in the pharmaceutical drug supply chain, it is possible that a reduction in list prices may lead to a reduction in the out-of-pocket costs paid by Part D enrollees who take these drugs, particularly if the out-of-pocket cost is based on coinsurance instead of a flat copayment.

In sum, CMS proposes at § 514.5 that ''GUARD Model drug'' means, subject to the exclusions set forth in § 514.120(c), a Part D rebatable drug, as set forth in section 1860D–14B(g)(1) of the Act and defined in 42 CFR 428.20 and determined in 42 CFR 428.101, that is a sole-source drug or sole-source biological product as defined in § 514.100, has a USP category classification that includes at least one of the USP selected categories, as defined in § 514.120(e), and is identifiable by a unique NDC–9 for which a payment was made under Medicare Part D. This means that CMS proposes to limit the GUARD Model test to the subset of sole-source drug and sole-source biological products belonging to USP selected categories among the Part D rebatable drugs, with some exclusions. Focusing the GUARD Model test on sole-source drugs and source biological products allows the GUARD Model test to identify the impact of the model without having to consider and potentially adjust for the very different market dynamics between these different types of drugs. Additionally, selecting drugs in specific USP categories with deficits of care and high costs means the GUARD Model focuses on drugs with the greatest potential for savings for the Medicare program and Part D enrollees. Moreover, the proposed approach allows for testing of the GUARD Model on a smaller subset of Part D rebatable drugs, which would generate learnings and insights that can help CMS understand how stakeholders may respond, even for drugs that are not included in the GUARD Model.

2. Proposed Exclusion of Certain Part D Rebatable Drugs

CMS proposes in § 514.120(a) to test the GUARD Model with a subset of Part D rebatable drugs, specifically, sole-source drugs and sole-source biological products belonging to the proposed selected therapeutic USP categories.[131] CMS proposes to exclude from the GUARD Model, generics and biosimilar biological products. At § 514.5 we propose ''generic'' to mean, for the United States, a drug approved and marketed under an Abbreviated New Drug Application (ANDA) under section 505(j) of the FD&C Act; and ''biosimilar biological product'' to mean, for the United States, a biological product approved and licensed under a BLA under section 351(k) of the PHS Act. Given that the only generics that are Part D rebatable are sole-source generics, another way of stating the exclusion is that sole-source generics and any (sole- or multi-source) biosimilar biological products are excluded from the GUARD Model.

CMS proposes this exclusion because sole-source generics and biosimilar biological products experience very different market dynamics than sole-source drugs (the original drug product approved under an NDA)[132] and sole-source biological products (the original biological product licensed under section 351(a) of the PHS Act).[133] This is consistent with our proposed policy to only include sole-source drugs (which excludes multi-source drugs due to them having generics) and sole-source biological products (which excludes multi-source biological products due to them having biosimilar biological products).

As explained in this Section previously, sole-source generics experience different market dynamics than sole-source original drugs. Specifically, their existence necessitates that patent protections on the original drugs have expired; their original counterparts may have ceased to be marketed (usually discontinued due to business reasons); they are typically at higher risk for disruptions in their supply; and they tend to be older drugs.[134] [135] For instance, sole-source generics have been singled out by FDA via the Competitive Generic Therapies pathway (created under the FDA Reauthorization Act of 2017); this pathway seeks to facilitate approval of sole-source generics with the goal being to impact their market dynamics via increased competition. CMS believes that it does not strengthen the GUARD Model test to include sole-source generics in the model because of their specific market dynamics.

Biosimilar biological products also experience different market dynamics compared to the original biological product. As stated earlier in this Section of this proposed rule, the entry of a biosimilar biological product results in a multi-source biological product market which results in competitive forces that shift consumption patterns, prices, and overall utilization of both the original biological product and other biosimilars (if they exist). As such, CMS proposes at § 514.120(c) that biosimilar biological products would be excluded from the GUARD Model. For sole-source biosimilar biological products, this would mean that the original biological product would have to no longer be marketed according to the FDA's NDC Directory. At time of this writing, there is no clear case of a sole-source biosimilar biological product in the United States; however, there is also no reason to believe that sole-source biosimilar biological products would behave any differently from sole-source

[131] From the USP Medicare Model Guidelines v9.0: Analgesics, Anticonvulsants, Antidepressants, Antimigraine Agents, Antineoplastics, Antipsychotics, Antivirals, Bipolar Agents, Blood Glucose Regulators, Cardiovascular Agents, Central Nervous System Agents, Gastrointestinal Agents, Genetic or Enzyme or Protein Disorder: Replacement or Modifiers or Treatment, Immunological Agents, Metabolic Bone Disease Agents, Ophthalmic Agents, and Respiratory Tract/Pulmonary Agents.

[132] Could also be referred to as the reference listed drug to the generic, where ''reference listed drug'' means the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA according to 21 U.S.C. 314.3(b).

[133] Could also be referred to as the reference product to the biosimilar biological product, where ''reference product'' means the single biological product licensed under section 351(a) against which a biological product is evaluated in an application submitted under section 351(k) according to 42 U.S.C. 262(i)(4).

[134] McGeeney, J.D., et al. (2025) *Drug Shortages, 2018–2023*. Eastern Research Group, Inc. & Office of the Assistant Secretary of Planning and Evaluation, U.S. Department of Health and Human Services. *https://aspe.hhs.gov/reports/drug-shortages-2018-2023* (Accessed: 10 December 2025).

[135] Food and Drug Administration. (2019). *Drug Shortages: Root Causes and Potential Solutions*. U.S. Department of Health and Human Services. *https://www.fda.gov/media/131130/download* (Accessed: 10 December 2025).

generics in the market. For a sole-source biosimilar biological product to exist, patent protections on the original product would had to have expired; their original biologic products may have been discontinued; and we would expect them to be older drugs. As such, CMS believes that inclusion of sole-source biosimilar biological products would not strengthen the GUARD Model test.

CMS proposes at § 514.120(c) that the second exclusion would be based on whether a sole-source drug or biological product's application-level total gross covered prescription drug costs are below the GUARD Model minimum spend threshold, as discussed below in this Section of this proposed rule. ''Application-level total gross covered prescription drug costs'' is defined at § 514.100 as the sum of total gross covered prescription drug costs, as defined in 42 CFR 428.100, from Medicare Part D PDE data for all rebatable Part D drugs belonging to the same FDA application.

CMS believes that by using an application-level total gross covered prescription drug costs, the risk of gaming to keep a specific Part D rebatable drug below the threshold by, for example, applying for a new NDC–9 to reduce the total gross covered prescription drug spend of the original NDC–9 or by shifting formulary placement, is mitigated. At the same time, the approach considers total spending incurred by the Medicare Program on a GUARD Model drug by a manufacturer.[136]

CMS proposes at § 514.100 that the ''GUARD minimum spend threshold'' means for the performance year beginning on January 1, 2027, an amount equal to $69 million and for subsequent performance years, the minimum spend threshold is equal to the GUARD Model minimum spend threshold for the prior performance year increased by the percentage increase in the CPI–U [137] for the 12-month period beginning with January of the previous performance year, where a ''subsequent performance year'' means every performance year after the first. There are four, starting January 1 and ending on December 31 of 2028, 2029, 2030, and 2031, as defined at § 514.5. This means that for each subsequent performance year, the GUARD minimum spend threshold would increase with inflation. CMS would use PDE data to check whether a potential GUARD Model drug is excluded from the GUARD Model due to the minimum spend threshold. CMS proposes at § 514.120(c) to examine PDE data for the application-level total gross covered prescription drug costs for the corresponding performance year. CMS proposes at § 514.120(c) that once a GUARD Model drug has exceeded the GUARD Model minimum spend threshold for a performance year during the GUARD Model performance period, they would no longer be subject to this exclusion for subsequent performance years. This means that a GUARD Model drug's minimum spend would *not* be checked annually.

CMS believes that setting a GUARD minimum spend threshold and comparing application-level total gross covered prescription drug costs against it reduces the risk of access-related challenges associated with the drug. In our analysis, we find that on average, across the 2024 Part D rebatable drugs that would be included in the GUARD Model if the model had been implemented in 2024 [138] (using an application-level total gross covered drug cost above $69 million), the included drugs would be associated with approximately $188 million per drug in Part D spending.[139] Therefore, we believe applying a threshold of $69 million that is adjusted for inflation annually thereafter means that manufacturers of GUARD Model drugs would have significant revenue from the Medicare Program and thus would likely remain in the Medicare program during the GUARD Model test.

CMS also believes that a threshold of $69 million in the first performance year of the GUARD Model that is adjusted for inflation annually thereafter allows us to evaluate impacts to drugs above and below the threshold as part of the GUARD Model test. Specifically, applying the $69 million GUARD minimum threshold to 2024 Part D rebatable drugs that would be included if the model had been implemented in 2024 [140] results in 38 percent [141] of sole-source drugs and sole-source biological products included in the GUARD Model test. Among the 2024 Part D rebatable drugs [142] with an application-level total gross covered drug cost above $69 million, each drug that would be included in the GUARD Model is associated with an average wholesale acquisition cost (WAC) of approximately $47; and each drug excluded is associated with an average WAC of approximately $14.[143] This analysis suggests that the GUARD minimum threshold, as applied to 2024 Part D rebatable drugs, results in the GUARD Model test directed towards more expensive drugs and biological products whose average gross covered prescription drug costs are significantly higher than the GUARD minimum threshold.

CMS believes that this threshold, in addition to the Part D Inflation Rebate Program applicable threshold [144] defined in 42 CFR 428.101, minimizes risk of disrupting access to drugs for several reasons. The GUARD minimum threshold supports the goal of having sufficient inclusion to adequately test the alternate payment strategy on a set of specific type of drugs (sole-source, high-expenditure drugs in specific USP selected categories). The Part D Inflation Rebate Program applicable threshold ensures that drugs with low per beneficiary gross drug costs which—given the low volume or price—could be affected disproportionately with a

[136] While it is possible for an application to change sponsor, during or after approval, there is one responsible party (the sponsor) for an application at a time. Any shifts in application ownership are notified to FDA, thus reflected in Orange or Purple Book, and would require a new NDC–9 and NDC codes are manufacturer-specific.

[137] If for a subsequent performance year, the resulting amount is not a multiple of $10, CMS rounds that amount to the nearest multiple of $10.

[138] 2024 Part D rebatable sole-source drugs and sole-source biological products whose USP category is a USP selected category excluding generics, biosimilar biological products, and those subject to an MFP during the price applicability period.

[139] CMS analysis using 2024 total gross drug costs and preliminary list of Part D rebatable NDC–9s (as of October 1, 2025).

[140] 2024 Part D rebatable sole-source drugs and sole-source biological products whose USP category is a USP selected category excluding generics, biosimilar biological products, and those subject to an MFP during the price applicability period.

[141] CMS analysis using 2024 total gross drug costs and preliminary list of Part D rebatable NDC–9s (as of October 1, 2025). According to the GUARD Model drug definition and in alignment with the Part D Inflation Rebate Program, drugs are defined at the NDC–9 level, thus the percentage represents the number of NDC–9s included in the GUARD Model.

[142] 2024 Part D rebatable sole-source drugs and sole-source biological products whose USP category is a USP selected category excluding generics, biosimilar biological products, and those subject to an MFP during the price applicability period.

[143] CMS analysis using 2024 total gross drug costs and preliminary list of Part D rebatable NDC–9s (as of October 1, 2025). The averages are a weighted average using total quantity dispensed as weights at the NDC–9 level.

[144] For the applicable period beginning October 1, 2022, the applicable threshold is equal to $100. For the applicable period beginning October 1, 2023, the applicable threshold is equal to $100 increased by the percentage increase in CPI–U for the 12-month period beginning October 1, 2023. For subsequent applicable periods, the applicable threshold is equal to the applicable threshold for the prior applicable period increased by the percentage increase in the CPI–U for the 12-month period beginning with October of the previous period.

change in payment strategy, are excluded from the GUARD Model because they are not Part D rebatable drugs.

In § 514.120(c), CMS proposes, as a third exclusion, that when the Part D payment is based on a maximum fair price (MFP) (as defined in section 1191(c)(3) of the Act), the Part D rebatable drug would be excluded from the GUARD Model. This means that drugs that are selected for the Medicare Drug Price Negotiation program (under Part E of Title XI of the Act (sections 1191 through 1198)) would be excluded from the GUARD Model when the negotiated MFP is in effect. Specifically, this proposal would mean that a GUARD Model drug that is selected for negotiation of an MFP would be removed from the GUARD Model on the date that the MFP goes into effect. For example, because the prices of the drugs selected for initial price applicability year 2028 go into effect on January 1, 2028, these set of drugs would not be included as GUARD Model drugs as of January 1, 2028.

Should a drug no longer have a negotiated MFP in effect, but still be covered under Medicare, and to the extent it continues to fulfill the GUARD Model inclusion requirements, the drug would be included in the GUARD Model. CMS believes that excluding drugs when the Medicare Part D payment is based on a negotiated MFP is appropriate because these drugs are subject to different market dynamics within the United States, and we believe that including them could confound the GUARD Model test. As such, we do not propose a waiver under this model related to the Medicare Drug Price Negotiation Program.

To maintain consistency with the definition of a Part D rebatable drug at 42 CFR part 428, we propose at § 514.120(e) that any changes to the definition of Part D rebatable drug at 42 CFR part 428 would be automatically carried over to the definition of a GUARD Model drug at Part 514.

In summary, for the purposes of the GUARD Model, CMS is defining a GUARD Model drug as proposed at § 514.120(a) as a Part D rebatable sole-source drug or biological product identified based on the Part D Inflation Rebate Program and whose assigned USP categories are within one of the USP selected categories listed previously in this Section of the proposed rule with some exclusions. The proposed exclusions are: (1) sole-source generics and any biosimilar biological products; (2) sole-source drugs or sole-source biological products whose annual application-level total gross covered prescription drug costs are below the GUARD minimum spend threshold; and (3) sole-source drugs or sole-source biological products that are subject to an MFP during the price applicability period when the MFP is in effect. CMS believes that the proposed identification approach, along with the proposed exclusions covered in this Section of this proposed rule, would result in the inclusion of drugs and biological products that are used to treat a variety of conditions in the Part D enrollee population and are frequently sold at retail pharmacies, mail order pharmacies, and long-term care pharmacies.

We invite public comment on our proposed approach for defining a GUARD Model drug as discussed in this proposed rule. We are seeking comment on the inclusion and exclusion criteria for GUARD Model drugs, including the GUARD minimum spend threshold and the proposal to include drugs in the GUARD Model if they are included in one of the USP selected categories included in the GUARD Model.

3. Alternatives Considered

CMS considered including multi-source drugs and biological products, sole-source generic drugs, and biosimilar biological products in the GUARD Model. However, CMS believes that their market dynamics and pricing behaviors, as discussed previously, would generate variability that would hinder precision in the evaluation of the alternate payment strategy tested under the GUARD Model.

CMS also considered including additional USP categories beyond the ones proposed. Specifically, we considered including some additional categories based on their 2024 Part D total gross drug costs. For instance, CMS considered including the following additional USP categories due to each category having 2024 total covered gross drug costs for Part D rebatable sole-source drugs and sole-source biological products above $1 billion: Blood Products and Modifiers, Dermatological Agents, Antibacterials, Electrolytes/Minerals/Metals/Vitamins, and Genitourinary Agents.[145] We also considered including all USP categories with Part D rebatable sole-source drugs and sole-source biological products that had any amount of Medicare Part D gross covered drug spending in 2024. This would result in the additional inclusion, besides the five USP categories already mentioned, of the following USP categories: Antiparasitics, Dental and Oral Agents, Otic Agents, Antimycobacterials, Contraceptives, and Antispasticity Agents. These additional six USP categories only amount to 1.6 percent of spending among Part D sole-source rebatable drugs and sole-source biological products. Finally, CMS also considered including in the USP selected categories list others such as Antidementia Agents, Inflammatory Bowel Disease Agents, and Skeletal Muscle Relaxants; and even considered not limiting inclusion for the GUARD Model by USP category and including all Part D rebatable drugs regardless of their USP category. However, CMS believes prioritizing the USP selected categories proposed at § 514.120(a)(2) is necessary because these categories represent drugs with high Part D gross drug spending and they treat conditions for populations that experience care deficits. We also considered excluding some of the proposed USP selected categories from the GUARD Model. For example, we considered excluding categories that correspond to the Medicare Protected Classes such as Anticonvulsants, or other categories such as Antimigraine Agents, Gastrointestinal Agents, and Metabolic Bone Disease Agents. However, we decided inclusion better serves the GUARD Model as the drugs in these categories are taken by populations that experience deficits of care. CMS seeks feedback on our approach, including whether additional categories should be included (and if so, which ones) or if there are any categories proposed that should be excluded. We also seek feedback on whether there are other approaches to identify the categories that we should consider.

CMS considered using the total gross covered prescription drug costs for an NDC–9 instead of the application-level total gross covered prescription drug costs to identify the GUARD minimum spend threshold. However, we decided not to propose any thresholds at the NDC–9 level due to concerns regarding gaming, particularly the possibility of a new NDC–9 being introduced without a significant change in the drug. CMS also considered basing the minimum spend threshold on the total gross covered drug costs accrued over a calendar year for all Part D rebatable drugs with the same combination of certain characteristics. These characteristics could include all or some of active ingredient, route of administration, and dosage form. However, this would mean the total summed covered gross drug costs would not necessarily all

[145] CMS analysis using preliminary list of Part D rebatable drugs for 2024 and PDE data as of October 1, 2025.

correspond to the same manufacturer. Therefore, CMS does not believe this is the best approach for identifying the GUARD minimum spend threshold.

Additionally, CMS considered determining the application-level or other aggregate levels of total covered gross costs for comparison with the GUARD minimum spend threshold using all Part D drugs not just those that qualify for the Part D Inflation Rebate Program. However, CMS believes that, given that the GUARD Model is testing an alternative calculation for the Part D inflation rebate calculation, it is appropriate to use the total covered gross costs from Part D rebatable drugs.

CMS also considered evaluating whether a GUARD Model drug's application-level total covered gross costs exceeds the GUARD Model minimum spend threshold for every performance year instead of only for the first performance year that the drug is being considered for inclusion as a GUARD Model drug. However, in the interest of stability and transparency regarding which drugs or biological products are GUARD Model drugs and given the modest 5-year duration of the GUARD Model performance period, CMS decided against this. CMS welcomes comments on the proposed approach and the alternatives considered.

In proposing the GUARD minimum spend threshold, CMS considered all amounts between $24.4 and $127 million since these amounts would result in 50 and 30 percent of Part D rebatable sole-source drugs and sole-source biological products after GUARD Model exclusions being included.[146] A GUARD minimum spend threshold lower than $24.4 million would result in the set of drugs and biological products included being too broad and CMS believes that it benefits the GUARD Model to focus the model test on a narrower set of drugs for conditions with observed deficits of care and those with higher costs. A GUARD minimum spend threshold higher than $127 million would result in a set of drugs included too narrow; CMS believes this is an insufficient number of drugs and biological products for the GUARD Model test to be informative.

CMS also considered not inflation adjusting the $69 million GUARD minimum threshold for each subsequent performance year after the first performance year; however, we believe that given the specific characteristics of the Part D program, inflation adjustment is necessary.

Additionally, CMS considered beginning the GUARD Model with a limited set of drugs, ranging from only a set number of top spending drugs or starting with a small subset of drugs and phasing drugs in over time. Concerns around administrative burden, competitive disadvantages, operational complexity, and insufficient sample for evaluation of the model contributed to our decision not to employ these alternative approaches. CMS believes that beginning the GUARD Model with a subset of Part D rebatable drugs that allows for exclusions is a transparent, consistent, and clear approach that would provide sufficient opportunity for CMS to observe a wide range of manufacturer behavior with respect to drug pricing, increasing the generalizability of the evaluation findings.

We believe the benefits of including a subset of Part D rebatable drugs in the GUARD Model with some exclusions, as discussed in this Section of this proposed rule, outweigh the benefits of initiating the GUARD Model with greater or fewer Part D rebatable drugs. We seek comments on our proposed approach, including the inclusion of only sole-source drugs and biological products from selected therapeutic areas;[147] the exclusion of sole-source generics and biosimilar biological products; the exclusion of drugs whose annual application-level total gross covered prescription drug cost are below the GUARD minimum spend threshold; and the exclusion of drugs subject to an MFP during the price applicability period.

4. GUARD Model Drug Units

We propose at § 514.125(a) that the GUARD Model include every GUARD Model drug unit, with some exceptions, as defined at 514.5 and described in this section of the proposed rule, dispensed based on Part D PDE records for GUARD Model drugs that are furnished to Part D enrollees who reside in ''GUARD Model geographic areas'' as defined by § 514.5, which means the geographic areas, defined by Zonal Improvement Plan Code Tabulation Areas (hereinafter ZCTAs; see Section IV.C. of this proposed rule for details), selected for participation in the GUARD Model in accordance with § 514.110(d), and who are part of the GUARD Model beneficiary population (as described in section IV.C. of this proposed rule). We propose to use the PDE data to identify GUARD Model drug and drug units because it is the prescription drug cost and payment data that enables CMS to administer the Part D benefit and records all prescription drug events for drugs covered under the Part D program.

We propose at § 514.125(b) that the following drug units would be excluded from the GUARD Model: drug units for which payment is subject to an agreement under 340B.

C. Proposed Model Test Design, Geographic Selection, and Beneficiary Population

Section 1115A(b) of the Act gives the Secretary discretion in the design of models, including the geographic reach of models. Section 1115A(a)(5) of the Act states that the Secretary may elect to limit testing of a model to certain geographic areas. In this section, we describe the proposed model test design, including the geographic selection approach, and the defined beneficiary population that would be included in the GUARD Model.

1. Proposed Model Test Design and Identification of Geographic Areas

At § 514.110(d), we propose a randomized design in which the GUARD Model geographic approach will be determined by selection of geographic areas where GUARD Model beneficiaries reside, as determined by CMS. Model test geographic areas would be randomly selected to balance the Part D population and Medicare expenditures nationwide. Later in this Section of the proposed rule, we propose the process by which CMS would identify the model cohort and propose that, prior to the model start, CMS would randomly identify the model geographic areas. We also propose at § 514.130(e) that the identification of included beneficiaries and the timing of such identification, as well as the identification of a comparison group, would be performed by CMS and would not be subject to administrative or judicial review.

CMS proposes to establish the unit of geography for evaluation of GUARD Model impacts based on identifying existing well-defined geographic units that are sufficiently numerous to

[146] CMS analysis using 2024 total gross drug costs and preliminary list of Part D rebatable NDC–9s (as of October 1, 2025). Part D rebatable sole-source drugs and sole-source biological products whose USP category is a USP selected category excluding generics, biosimilar biological products, and those subject to an MFP during the price applicability period. Drugs and biological products analyzed at the NDC–9 level.

[147] From the USP Medicare Model Guidelines v9.0: Analgesics, Anticonvulsants, Antidepressants, Antimigraine Agents, Antineoplastics, Antipsychotics, Antivirals, Bipolar Agents, Blood Glucose Regulators, Cardiovascular Agents, Central Nervous System Agents, Gastrointestinal Agents, Genetic or Enzyme or Protein Disorder: Replacement or Modifiers or Treatment, Immunological Agents, Metabolic Bone Disease Agents, Ophthalmic Agents, and Respiratory Tract/Pulmonary Agents.

support statistical analysis. Based on CMS' review of existing defined geographic units that are suitable for statistical purposes, CMS, after consideration of alternatives, proposes at § 514.110(d) that ZCTAs would be an appropriate geographic unit to randomly select geographic areas included in the GUARD Model. At § 514.100, CMS defines ''ZCTAs'' to mean approximate area representations of U.S. Postal Service 5-digit Zonal Improvement Plan (ZIP) Code service routes that the U.S. Census Bureau creates using whole blocks to present statistical data from censuses and surveys, where ''ZIP Code'' means a trademark of the USPS created to coordinate mail handling and delivery. The USPS assigns ZIP Code ranges to regional post offices, which in turn assign ZIP Codes to delivery routes. ZCTA's are a geographic product of the U.S. Census Bureau, created to allow mapping, display, and geographic analyses. They are both numerous and small in size. ZCTAs are generalized and real representations of the geographic extent and distribution of the U.S. Postal Service 5-digit ZIP Code service routes that the U.S. Census Bureau creates using whole blocks to present statistical data from censuses and surveys. The ZIP Code used for beneficiary enrollment in Medicare can be linked to ZCTAs.

CMS believes that because of their small size and large numbers, the random assignment of ZCTAs to define the GUARD Model geographic area and the associated GUARD Model beneficiaries would enable CMS to achieve the desired balance in the counts of beneficiaries, Part D spending, and prescription drug utilization between the intervention and comparison arms of the GUARD Model within the country, within the Part D Plan regions, and within Part D plans. In addition, ZCTAs are small enough to allow CMS to randomly select the GUARD geographic area and the associated GUARD Model beneficiaries to ensure balance in the number of beneficiaries included in the GUARD Model for each Part D plan.

The proposed design of the model would reduce the potential for unintended interactions resulting from the geographic selection approach. Under this proposed design, the beneficiary is assigned to the GUARD geographic area based upon the ZCTA linked to their enrollment data and not where the beneficiary would fill their prescription, limiting beneficiary incentives to switch pharmacies. For example, when a beneficiary is assigned to a non-GUARD Model geographic area, their prescription fill, even if for a GUARD rebatable drug at a pharmacy located in a GUARD Model geographic area, would not be subject to the intervention. Also, because beneficiary assignment to a GUARD Model geographic area or non-GUARD Model geographic area would not change with a change in residence, the measurement of outcomes to be evaluated in the proposed model would not be dependent upon the size of the geographic area. Therefore, randomizing a geographic area that is small and numerous, such as a ZCTA, would enable balance of measured and unmeasured characteristics of the geography, the associated resident population, and pharmacies and other dispensing entities that may be associated with this model.

CMS has considered the variation in GUARD Model drugs with respect to cost and use in the Medicare population and proposed at § 514.110(d) that the ideal allocation between GUARD Model and non-GUARD Model regions for operational fairness is to allocate based on a 1:3 ratio. That is, the GUARD Model should be tested with approximately 25 percent of Medicare beneficiaries. A simple random selection of 25 percent of ZCTAs would result in the selection of approximately 25 percent of Medicare Part D enrollees representing approximately 25 percent of Medicare Part D spending. The geographic area would be varied, and a representative selection of urban and rural areas are expected to be included. CMS proposes this policy because a simple random selection at the ZCTA level would enable about a quarter of nearly every Part D plan sponsors' beneficiaries to be in the GUARD Model and three-quarters would be in the comparison group (and therefore, not subject to the GUARD Model test).

2. Proposed Unit of Analysis and Defined Population

In designing the proposed GUARD Model, CMS determined that conducting the proposed GUARD Model test in the population of beneficiaries residing in GUARD Model geographic areas would provide the best means for testing the alternative rebate mechanism.

CMS proposes in § 514.130(a) to identify a GUARD Model beneficiary as a Part D enrollee who ''*resides within the GUARD Model geographic area*'', which means according to § 514.100, that the beneficiary's home address as recorded in CMS' Medicare Enrollment Database [or CMS' Medicare Beneficiary Database (MDB) System] is within the set of ZIP Codes linked to ZCTAs selected for the GUARD Model geographic areas in the U.S., excluding U.S. territories as identified in § 514.110. In § 514.5, CMS proposes to define a ''GUARD Model beneficiary'' as an individual who is enrolled in a Part D plan, either in a standalone prescription drug plan (PDP) or Medicare Advantage prescription drug (MA–PD) plan, but not in an Employer Group Waiver Plan (EGWP), and who resides in a GUARD Model geographic area as determined by the beneficiary's address of record with Medicare. CMS proposes at § 514.130(a) that Part D enrollees who do not have Medicare as their primary payer or are enrolled in EGWPs would be excluded from the GUARD Model. Therefore, the ''GUARD Model beneficiary population'' is defined in this proposed rule at § 514.5, to include all Part D enrollees (with the exception of those who are enrolled in an EGWP) who are furnished with a GUARD Model drug as identified in Medicare Part D PDE data within the GUARD Model performance period and who reside within a GUARD Model geographic area.

CMS proposes in § 514.130(b) that 30 calendar days prior to the start of the model, CMS would identify a beneficiary as a GUARD Model beneficiary. Periodically thereafter, but no more than weekly, CMS would identify eligible GUARD Model beneficiaries who would be subsequently aligned to the model. GUARD Model beneficiaries would be aligned to the model until the model ends, or the beneficiary is no longer enrolled in Part D. If a GUARD Model beneficiary's address as recorded in CMS' MBD changes (that is, they no longer reside within the GUARD Model geographic areas) they would continue to be aligned to the model, as proposed in § 514.110(d). Beneficiaries who become newly enrolled in Medicare Part D plans and are identified by CMS as GUARD Model beneficiaries (because all criteria are met) would be aligned to the GUARD Model; these beneficiaries (and any relevant drug units) would be included in the GUARD Model rebate payment calculations from the time that they newly enroll in Medicare Part D, if all criteria are met. Beneficiaries for whom Medicare switches from being a secondary payer to being the primary payer and are identified by CMS as a GUARD Model beneficiary (because all criteria are met) would be aligned to the model cohort at the time that they switch, according to § 514.130(c). No other beneficiaries would be aligned to the GUARD Model after the model starts. For example, the following changes would not enable beneficiary

alignment to the GUARD Model after the model starts: (1) beneficiaries who were enrolled in Medicare at the time CMS identifies the initial cohort prior to the start of the model and had an MBD address in a non-GUARD Model geographic area then had an address change to a GUARD Model geographic area; and (2) newly enrolled Medicare Part D beneficiaries with an address with a new ZIP Code that did not exist at the time that the GUARD Model geographic areas were identified.

Defining the population broadly and in a manner that fosters a stable and consistent model cohort would allow CMS to observe the implications of an alternative approach to determining the GUARD Model rebate payment for GUARD Model drugs across a broad set of manufacturers and beneficiaries. If this proposed rule is finalized, the GUARD Model geographic areas would be identified in a table that lists the model test areas, total number of Medicare beneficiaries at the time of analysis, and any other relevant information no later than 60 calendar days in advance of the beginning of the GUARD Model performance period. This table would be shared on the GUARD Model website. Defining the population in this manner would allow CMS to assess if the GUARD Model payment test reduced Medicare costs while preserving or enhancing quality of care, in line with section 1115A(b)(2) of the Act, across a broad set of pharmacies and other dispensing entities and Part D enrollees, as well as a large set of manufacturers. Lessons learned from the GUARD Model would inform CMS and other interested parties about the effect of applying the proposed alternative rebate approach to a broader set of drugs on Part D enrollees and to the Medicare program.

3. Alternatives Considered

CMS considered initiating the model with a greater number of geographic areas to include up to approximately 50 percent of Part D beneficiaries in the model beneficiary cohort instead of our proposal to test the model with approximately 25 percent of Part D beneficiaries. We also considered an approach of initially testing the model with approximately 25 percent of Part D beneficiaries and then after initial monitoring observations are assessed, increasing the model beneficiary cohort to include up to approximately 50 percent of Part D beneficiaries. We note that these alternatives would likely necessitate selection of the initial and potentially additional geographic areas at the same point, prior to model start. These approaches would have the benefit of enhancing the model evaluation as a random selection of approximately 50 percent of the Medicare Part D population would enable a 1:1 allocation of treatment to comparison. We also considered approaches that CMS could follow to identify when and how the included geographic areas and beneficiary cohort could be increased to include up to 50 percent of Part D beneficiaries. One option is that CMS could increase the beneficiary cohort at different points throughout the model, depending on observed data. For example, based on the first 6 months of data, if new patient access or supply chain constraints do not appear or do not appear to be attributed to the GUARD Model, CMS could increase the size of the model cohort later in the model test period. CMS could continue to periodically monitor available data and consider whether to increase the geographic areas included in the model. However, we decided against these approaches because we believe testing the GUARD Model with 25 percent of Medicare Part D enrollees across randomly selected geographic areas is sufficient for CMS to glean learnings on the impacts of the model. We seek feedback on this approach.

We also considered the following geographic areas as the geographic unit from which beneficiaries would be included in the model requirements: (1) ZIP Codes; (2) counties; (3) states; (4) Census-defined Core Based Statistical Areas (CBSAs) or Combined Statistical Areas (CSAs); and (5) Part D Plan regions. ZIP Codes were considered because they are the basis for determining beneficiary residence. However, ZIP Codes, unlike ZCTAs are not technically geographic areas, but delivery routes for the U.S. Postal Service, and they are not Census-designated regions. Counties, states and CBSAs were determined to be too heterogeneous in their size and population to achieve the desired balance between intervention and comparison groups for the proposed design. Part D Plan regions were considered to reduce operational complexity but also were determined to be too large and heterogeneous. CMS determined that these candidates would likely fail to achieve the desired balance in the counts of beneficiaries, Part D spending, and prescription drug utilization between the intervention and comparison arms of the GUARD Model within the country, within the Part D Plan regions, and within Part D plans. We welcome comment on this proposal and the alternatives considered.

We considered including the ZCTAs of U.S. territories among the geographic regions from which the randomly selected model geographic area would be selected. However, due to operational considerations, we decided to exclude U.S. territories. We seek feedback on this exclusion.

We also considered randomly selecting plans as the unit from which Part D drugs would be subject to the model requirements. This would enable plans to have a uniform consideration of how rebates would apply across all their beneficiaries. This, however, could reduce operational fairness across plans nationally so we decided against this approach. We welcome comment on our proposal to select ZCTAs as our geographic unit of analysis.

In addition, we considered whether to include beneficiaries who are enrolled in an EGWP. We decided against this, however, because there are differences in the data that is available for these enrollees compared to beneficiaries enrolled in standalone PDPs and MA–PDs and because we believe this group could serve as an important counterfactual for subgroup analysis in the evaluation. We seek feedback on this proposed policy.

We welcome comment on all of our policy proposals presented here, including proposals to test the model in geographic areas to cover 25 percent of Part D beneficiaries in the GUARD Model beneficiary population and whether CMS should test the model with an alternative approach that would include additional geographic areas, different geographic selection units, U.S. territories, and additional beneficiaries in the model.

D. GUARD Model Participants

1. Proposed Participants

At § 514.110(a), CMS proposes that manufacturers would be the participants of the GUARD Model. CMS proposes at § 514.5 that ''manufacturer'' would have the same meaning as that term is defined and used in § 428.20 and section 1927(k)(5) of the Act. We note that this is consistent with how CMS defines manufacturer for the purposes of the Part D Inflation Rebate Program. We propose to define at § 514.5 ''GUARD Model participant'' as a manufacturer of a GUARD Model drug that receives a Part D inflation rebate report for an applicable period that overlaps with the GUARD Model performance period.

At § 514.110(a), CMS proposes that all manufacturers that receive a Part D inflation rebate report including a GUARD Model drug for an applicable period that overlaps with the GUARD

Model performance period would be required to participate in the GUARD Model. There would be no specific enrollment activities for GUARD Model participants; rather, their participation will be effectuated through the requirements under the Part D Inflation Rebate Program, and where applicable, the application of the proposed GUARD Model rebate payment, as described in section IV.H. of this proposed rule.

CMS believes that this proposal to require participation of manufacturers is necessary to conduct the GUARD Model test and comprehensively understand the potential impacts of the model. Mandatory participation can enhance the generalizability of model results, as mandatory model participants may be more broadly representative of all organization types that could be affected by a model. With a mandatory participation policy, CMS would be able to observe the experience of manufacturers with a diverse range of characteristics—including, for example, large and small manufacturers—as well as manufacturers with varying corporation structures; difference in penetration within the United States and global markets; differences in global pricing approaches; and differences in marketing strategies. Additionally, CMS believes that despite the potential opportunity under the GUARD Model to lower the Part D program's financial liability and potentially reduce Part D enrollees' financial barriers to access GUARD Model drugs, which could, in turn, increase U.S. sales of such drugs, manufacturers of the proposed GUARD Model drugs would likely not volunteer to participate in the GUARD Model, which would threaten the model test. Therefore, CMS believes that mandatory participation of manufacturers is essential to carrying out the GUARD Model test.

CMS invites comment on our proposal for mandatory participation in the GUARD Model by manufacturers of GUARD Model drugs. We also seek feedback on whether manufacturers of proposed GUARD Model drugs would voluntarily participate in the proposed GUARD Model absent a mandatory participation requirement while still allowing for a robust test and evaluation during performance year 1 and thereafter.

2. Mandatory Participation Requirements

CMS proposes that model participation would be mandatory for all manufacturers that receive a Part D inflation rebate report including a GUARD Model drug during an applicable period that overlaps with the GUARD Model performance period. In § 514.110(b) and (c), we propose the GUARD Model participant requirements during and after the GUARD Model performance period and payment years.

During the GUARD Model performance period and payment years, CMS proposes that GUARD Model participants must—

- Adhere to the proposed GUARD Model rebate invoicing and payment instructions as proposed in § 514.610 and established by CMS and its contractors responsible for providing GUARD Model rebate reports and invoices and processing GUARD Model rebates, including without limitation those described in proposed § 514.640 to ensure appropriate and accurate GUARD Model rebate payments.
- Participate in GUARD Model monitoring and evaluation activities in accordance with 42 CFR 403.1110(b), including collecting and reporting of information as the Secretary determines is necessary to monitor and evaluate the GUARD Model.
- If voluntarily electing to submit manufacturer reported international drug net pricing data, adhere to the requirements set forth in § 514.310 and the GUARD Model data agreement set forth in § 514.310(b)(1).

After the GUARD Model performance period and payment years, we propose that GUARD Model participants must—

- Adhere to the proposed GUARD Model rebate invoicing and payment instructions as proposed in proposed § 514.610 and established by CMS and its contractors responsible for providing GUARD Model rebate reports, processing GUARD Model rebates, including without limitation those described in proposed § 514.640 to ensure appropriate and accurate GUARD Model rebate payments.
- Participate in GUARD Model monitoring and evaluation activities in accordance with 42 CFR 403.1110(b), including collecting and reporting of information as the Secretary determines is necessary to monitor and evaluate the GUARD Model.
- If electing to submit international net drug pricing data, adhere to the requirements set forth in § 514.310 and the GUARD Model data agreement set forth in § 514.310(b)(1).
- Continue GUARD Model rebate payment reconciliation activities as proposed in § 514.640.

We seek comment on our proposal for model participation requirements for GUARD Model participants.

E. Proposed Existing International Drug Pricing Data and Reference Countries

Under the GUARD Model, as described in section IV.G. of this proposed rule, CMS will test two approaches to calculating the GUARD Model international benchmark: Method I referred to as the GUARD Model default international benchmark, and Method II, referred to as the GUARD Model updated international benchmark. This Section of this proposed rule discusses the existing sources for international drug pricing data and the selection process of an international drug pricing data source that CMS proposes to use, if available, to calculate the GUARD Model default international benchmark for each GUARD Model drug. We also describe our proposals to identify the set of reference countries that would be used to identify the GUARD Model international benchmark, both for the default and the updated international benchmarks.

1. Existing Data Sources for International Drug Pricing Data

CMS proposes that the selected data source for a specific GUARD Model drug must contain international drug pricing data for that specific GUARD Model drug's set of international analogs. We propose, at § 514.5, to define ''set of international analogs'' to mean, for each GUARD Model drug, the set of international products sold in all reference countries, identified in § 514.220(d) and as discussed later in this Section of this proposed rule; and, we define ''international product'' to mean a drug or biological product, sold in a reference country (where ''reference country'' means the countries identified in § 514.220(d) and discussed later in this Section of this proposed rule), that is aligned across its identifying characteristics with a GUARD Model drug. The identifying characteristics are specific to each GUARD Model drug (which in accordance with § 514.120(a), is identified at the NDC–9 level) and include active ingredient(s), route of administration, dosage form, and strength. Alignment across identifying characteristics, according to § 514.410 and as discussed in section IV.G. of the proposed rule, allows for adjustments that do not materially modify the nature of the drug but account for country-specific differences, such as differences due to language, units of measurement, labeling standards, or differences in dosage form or strength. The international drug pricing data for international analogs would then be used to determine, for each GUARD

Model drug, the GUARD Model default international benchmark, as described in section IV.G. of this proposed rule, which would be used to calculate the GUARD Model rebate payment, which is described in section IV.H. of this proposed rule.

To calculate the GUARD Model default international benchmark as described in section IV.G. of this proposed rule and proposed at § 514.410, CMS proposes to use existing data sources as proposed in § 514.210 available to CMS that contain international drug pricing data, including coordinated prices and volume data, coordinated sales and volume data, or only prices.

Within the available data sources with international drug pricing data that CMS proposes to use, sales may be based on ex-manufacturer prices (sometimes referred to as ex-factory price) that represent actual or calculated prices paid to the manufacturer by wholesalers and other distributors, retail prices, prices for other distribution channels, or a combination thereof. Confidential manufacturer rebates to payers and other off-invoice payments would not likely be accounted for within this data as this data does not typically represent net prices. Therefore, existing sources for international drug sales data may differ from net prices realized by manufacturers. However, CMS believes the existing data sources are adequate for purposes of identifying country-level average prices. At § 514.5, ''country-level average price'' is defined for a reference country identified in § 514.220(d), as the average or weighted-average unitary price for the international products sold in the specific reference country that are part of a GUARD Model drug's set of international analogs, where the unit is the lowest dispensable amount of the GUARD Model drug expressed in terms of National Council for Prescription Drug Program (NCPDP) units.[148] If the selected data source (according to the requirements and selection criteria proposed at § 514.210(b) and (c)) includes international drug pricing information on volume, then the country-level average price is a weighted-average where the weights are the corresponding volume for a price expressed in the terms of the NCPDP unit corresponding to the GUARD Model drug. The country-level average prices would serve as the basis for the GUARD Model default international benchmark, as described in section IV.G. of this proposed rule, and CMS would select, among these, the lowest country-level price, as described in section IV.G. of this proposed rule. In addition, manufacturers would have the option to voluntarily submit international drug net pricing data to CMS that would potentially be used to identify the GUARD Model updated international benchmark, as described in sections IV.F and IV.G. of this proposed rule.

We identified and assessed several existing data sources to confirm the availability and sufficiency of international drug pricing data for the implementation of the GUARD Model. Specifically, we reviewed proprietary global drug pricing data sources that include drug pricing data for a large diverse set of pharmaceutical products, including the types of pharmaceutical products that could be covered under Part D, for more than 30 countries. These data sources vary with respect to the scope (such as products, manufacturer level, market level data, countries), and periodicity of updates (such as daily, monthly, quarterly).

One existing data source evaluated by CMS was IQVIA's MIDAS®,[149] which is an IQVIA proprietary information service which integrates IQVIA's national audits into a globally consistent view of the pharmaceutical market, and provides estimated product volumes of registered medicines, trends and market share through retail and non-retail channels. IQVIA MIDAS [150] includes detailed drug product information such as brand name, molecule, strength, dosage form, pack characteristics, manufacturer, regulatory approval, and intellectual property protection statuses. For each of the drug products, it also has sales and volume amounts by country, distribution channel (for example, retail or hospital), and calendar quarter. IQVIA's MIDAS is updated monthly and retains extensive historical data for over 90 countries.

Another potential data source we assessed is Global Data Pharmaceutical Prices (POLI) [151] data which includes prices for at least 80 countries at the pack level (pharmaceutical name, generic name, dosage form, strength, and number of units). POLI includes drug product information (such as drug descriptor, molecule type, dosage form, strength, and classification as brand or generic) and market information (such as therapeutic area and geography). POLI is updated monthly and provides historic data since 2016. Eversana NAVLIN's Price & Access database,[152] includes pricing data for more than 100 countries, as well as tools to compare international pricing (specifically, pricing across countries), and is another potential data source.

CMS believes any of these three data sources would provide adequate information in a timely way to inform CMS' determination of the GUARD Model default international benchmark for the vast majority of proposed GUARD Model drugs. Therefore, CMS has confirmed the availability and sufficiency of at least three international drug pricing data sources for the implementation of the GUARD Model and we acknowledge that it is possible for other international drug pricing data sources to be utilized for the determination of the GUARD Model default international benchmark.

CMS proposes at § 514.210(a) to identify data sources of international drug pricing data for each GUARD Model drug's set of international analogs that are sold in the reference countries identified in § 514.220(d) for purposes of calculating the GUARD Model default international benchmark, prior to the GUARD Model rebate payment calculation for the first performance year. During subsequent performance years, for any GUARD Model drug that was not a GUARD Model drug in any of the previous performance years, CMS proposes to identify data sources of international drug pricing data for each of these GUARD Model drug's set of international analogs that are sold in the reference countries identified in § 514.220(d) for purposes of calculating the GUARD Model default international benchmark, prior to the GUARD Model rebate payment calculation for the corresponding subsequent performance year.

[148] To assist in consistent and accurate billing of pharmaceutical products, NCPDP developed the Billing Unit Standard (BUS). The standard contains three billing units: EA, ML and GM. CMS also requires reporting of unit type for purposes of rebates in the Medicaid Drug Rebate Program. When possible, the NCPDP billing unit and CMS unit type should be aligned. *https://standards.ncpdp.org/Standards/media/pdf/BUS_fact_sheet.pdf.*

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[150] IQVIA. (n.d.) *IQVIA MIDAS Overview. https://www.iqvia.com/solutions/commercialization/data-and-information-management/midas* (Accessed: 10 December 2025).

[151] Global Data. (n.d.) *Data Lake—Pharmaceutical Prices (POLI). https://marketaccess.globaldata.com/product-solutions/data-lake-pharmaceutical-prices-poli/* (Accessed: 10 December 2025).

[152] NAVLIN by Eversana. (n.d.). *Navlin. https://www.navlin.com/* (Accessed: 10 December 2025).

CMS proposes in § 514.210(c), for each GUARD Model drug, to select a data source that CMS has access to, has international drug pricing information and fulfills the following five criteria (proposed at § 514.210(b)).

First, the data source(s) must incorporate and apply standardized approaches within and between countries to consistently define drug products in terms of their active ingredient(s), route of administration, dosage forms, and strengths. This criterion means a data source must have the following elements.

- A standardized active ingredient naming scheme, such as using an internationally recognized set of scientific (nonproprietary) names (for example, International Nonproprietary Names [153] (INN) names).
- A standardized method to differentiate between dosage forms (including route of administration) of drug products such as using an internationally recognized nomenclature for pharmaceutical dosage forms like the New Form Code classification.
- A standardized method for differentiating between different dosage strengths of drug products in terms of different strength units that can reliably be converted to and expressed in terms of NCPDP units—the units used in Part D.

This first criterion is necessary because the process that CMS proposes to calculate the GUARD Model default international benchmark, as discussed in section IV.G. of this proposed rule, requires international drug pricing data to be aligned with each GUARD Model drug across active ingredient, route of administration, dosage form, and strength.

Second, the data source(s) must use and apply a standardized approach based on country-specific regulatory approval pathways that, at a minimum, distinguishes international generics and international biosimilar biological products [154] At § 514.5 CMS proposes ''international generic'' to mean, for a reference country identified in § 514.220(d), a drug approved and marketed in a reference country under that reference country's regulatory framework under a pathway similar to section 505(j) of the FD&C Act in the United States; and ''international biosimilar biological product'' to mean, for a reference country identified in § 514.220(d), a biological product approved and licensed in a reference country under that reference country's regulatory framework under a pathway similar to section 351(k) of the PHS Act in the United States. If the data source does not directly differentiate approval pathways but has other factors that can allow for this differentiation to be implemented, CMS will evaluate the specific case and may consider the criterion fulfilled. For instance, it is possible that the data source includes a standardized approach based on country-specific regulations to identify products with or without brand names, with or without intellectual property protection (for example, patents), or as single-source or multi-source products depending on the extent of competition in each market.

Third, the data source(s) must contain either: (1) coordinated international drug price data and volume data; (2) coordinated international drug sales and volume data that can be used to calculate prices; or (3) drug price data. Such data must be expressed in a standardized manner (for example, with appropriate and clearly defined volume and monetary units). For volume data, this means the quantity of units where the lowest dispensable amount is or can be converted into NCPDP units. For price or sales data, this means a price or sales amount corresponding to a volume that is recorded in a standardized currency across countries within that data source. Such data must also be accompanied by written or other structured descriptions of the methods underlying the generation of the data, including conversion and projection factors.

Fourth, the data source must have a process for data cleaning and validation, including but not limited to checking errors, identifying outliers, and where possible, comparing with other relevant information as part of the validation process.

Fifth, the data source(s) must be maintained by organizations that seek to limit the lag inherent in data to no more than 90 calendar days from the end of the period for which drug pricing data is compiled to the time that the organization makes such updates available to users of the data source. We believe the limit of no more than 90 calendar days provides sufficient time for organizations to collect data, perform data quality checks, and update their data sources, and for CMS to obtain and use the data available.

In addition, we propose at § 514.210(c) to use international drug pricing information for international products that are part of the set of international analogs for each GUARD Model drug in reference countries from no earlier than January 1, 2024 to increase the likelihood that GUARD Model drugs are included in international drug pricing data sources, as well as to mitigate incentives to limit the availability of international drug pricing data during the GUARD Model performance period.

We seek feedback on our approach to existing sources for international drug pricing data.

2. Proposed Hierarchy for Using Existing Data Sources

For each GUARD Model drug, CMS would apply the approach proposed in § 514.210(c) to determine the international drug pricing data source that would be used to obtain international drug pricing data for a specific GUARD Model drug's set of international analogs. The data source that is selected would then be used to calculate the GUARD Model default international benchmark, as discussed in section IV.G. of this proposed rule.

Among the existing international drug pricing data sources that CMS is able to access, for the GUARD Model's first performance year, we propose a hierarchy in § 514.210(c) for identifying and selecting which international drug pricing data source to use in obtaining international drug pricing data for each GUARD Model drug's set of international analogs. CMS would select the data source at the highest level of the following hierarchy:

- First level: The data source with coordinated sales and volume data for the set of international analogs in the highest number of reference countries, identified in § 514.220(d), for any duration of the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year. If data for the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year is not available, data for any duration of the most recently available prior 12-month period beginning on or after January 1, 2024, would be used.
- Second level: The data source with coordinated prices and volume data for the set of international analogs in the highest number of reference countries, identified in § 514.220(d), for any duration of the 12-month period corresponding to the 12-month calendar

[153] World Health Organization. (n.d.). *International Nonproprietary Names (INN). https://www.who.int/teams/health-product-and-policy-standards/inn* (Accessed: 10 December 2025).

[154] Individual countries differ in the regulatory processes and standards governing approval of drugs and biological products.Use of international drug pricing information in the proposed GUARD Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved or licensed and non-U.S.-approved or licensed products.

year prior to the start of the first performance year. If data for the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year is not available, data for any duration of the most recently available prior 12-month period beginning on or after January 1, 2024, would be used.

- Third level: The data source with price data for the set of international analogs in the highest number of reference countries, identified in § 514.220(d), for any duration of the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year. If data for the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year is not available, data for any duration of the most recently available prior 12-month period beginning on or after January 1, 2024, would be used.

CMS believes using a 12-month period is appropriate because this mirrors the duration of the performance year and gives sufficient time for an international product to accrue transactions that are captured by the selected data source. Regardless of the period of time used by the selected data source to measure pricing information, CMS proposes at 514.410(c)(3) to aggregate data to the 12-month period, regardless of the duration of time for which observations are available within the 12-month period. For instance, if the data source has pricing information reported on a monthly basis and there is data for 7 of the 12 months, the 7 monthly data points would be used.

In cases when there is more than one data source meeting the requirements proposed in § 514.210(b) and they are all equal on the level of the hierarchy noted previously, CMS proposes to select a single data source based on an assessment of the relative reliability and generalizability of the data from each available data source. This assessment and CMS' resulting decision will be based on the technical characteristics of the data source rather than on the relative magnitude of prices from one source or another. CMS' assessment may consider, among others, the following factors: the share of national reference country markets reflected in the data source, the specificity of price information to specific international analog products, the number of data points available, methods to identify and address any errors, and data validation processes.

For the GUARD Model's subsequent performance years, we propose in § 514.210(c) that the same hierarchy approach as the one noted previously would apply, except that instead of first performance year it would apply to the subsequent performance year.

Under this proposal, for each GUARD Model drug, CMS would use an existing data source with international drug pricing data that CMS can access to calculate the GUARD Model default international benchmark, as described in section IV.G. of this proposed rule, once during the GUARD Model performance period. This means that the GUARD Model default international benchmark would not be revised over time with more recent international pricing data. Table B1 illustrates this proposal. We propose this policy to limit the possibility that a data source that meets CMS' criteria would experience challenges in collecting data about GUARD Model drugs in the future. We considered the possibility of using the most recent international pricing data to update the GUARD Model default international benchmark annually to correspond to each performance year. However, we believe that doing so increases the risk that a drug (for which a GUARD Model default international benchmark had been previously identified) would not have the available data to construct a benchmark in future years. We welcome comments on this policy proposal.

TABLE B1: ILLUSTRATION OF CMS' PROPOSED TIMEFRAME FOR INTERNATIONAL PRICING DATA SOURCE SELECTION FOR A GUARD MODEL DRUG'S SET OF INTERNATIONAL ANALOGS

	GUARD Model PY 1	GUARD Model PY 2	GUARD Model PY 3	GUARD Model PY 4	GUARD Model PY 5
Timeframe for international pricing data source selection for *New* GUARD Model drugs (or those that do not yet have a default international benchmark)	12 months prior to PY1 which corresponds to January – December 2026; Or, if not available, any preceding 12-month period after January 1, 2024.	12 months prior, which corresponds to January – December 2027; Or, if not available, any preceding 12- month period after January 1, 2024.	12 months prior, which corresponds to January – December 2028; Or if not available, any preceding 12-month period after January 1, 2024.	12 months prior, which corresponds to January – December 2029; Or if not available, any preceding 12-month period after January 1, 2024.	12 months prior, which corresponds to January – December 2030; Or if not available, any preceding 12-month period after January 1, 2024.
Timeframe of Data for *Existing* GUARD Model drugs	Not applicable.	No update or change to the GUARD Model default international benchmark.	No update or change to the GUARD Model default international benchmark.	No update or change to the GUARD Model default international benchmark.	No update or change to the GUARD Model default international benchmark.

Notes: PY stands for performance year, as defined at § 514.5. This proposed timeframe applies to each GUARD Model drug. These data would be used to calculate the GUARD Model default international benchmark for a GUARD Model drug. As discussed in this Section of this proposed rule, the 12-month periods referred to in this table require pricing data for any duration of the 12-month period to qualify as the selected data source.

An example of how the proposed selection process would apply is presented in Table B2 It illustrates how the hierarchy would function. Table B2 also illustrates that for data sources within the same proposed level of hierarchy (having the same pricing data available), selection would be made in the following way: first, by choosing the data source with the highest number of reference countries and second, by choosing the data source with the most recent 12-month period with respect to the start of the first performance year (January 1, 2027). We seek feedback on our proposed selection process.

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TABLE B2: ILLUSTRATION OF CMS' PROPOSED HIERARCHY FOR SELECTION OF AN INTERNATIONAL PRICING DATA SOURCE FOR A GUARD MODEL DRUG

For GUARD Model drug X in PY 1 (begins January 1, 2027)									
Data Source	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**
Pricing data	Sales and volume*	Sales and volume*	Sales and volume*	Price and volume*	Price and volume*	Price and volume*	Prices	Prices	Prices
Number of reference countries	10	5	10	10	5	10	8	5	8
Timeframe	Jan-Dec 2026	Jan-Dec 2026	Jan-Dec 2025	Jan-Dec 2026	Jan-Dec 2026	Jan-Dec 2025	Jan-Dec 2026	Jan-Dec 2026	Jan-Dec 2025
Proposed hierarchy level	**1**	**1**	**1**	**2**	**2**	**2**	**3**	**3**	**3**
Selection preference within the same proposed hierarchy level	1	3	2	1	3	2	1	3	2

Notes: Jan stands for January; Dec stands for December; PY stands for performance year, as defined at § 514.5. *The pricing information must be coordinated (sales and volume or price and volume). Proposed hierarchy refers to the hierarchy for data source selection proposed in § 514.210.

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3. Proposed Criteria and Process for Identifying the Set of Reference Countries

In this Section of this proposed rule, we propose the criteria and process that CMS would use to identify the non-U.S. countries that would be included in the set of reference countries for the GUARD Model for purposes of calculating the GUARD Model default international benchmark, as described in section IV.G. of this proposed rule.

Our proposed approach aims to select a large set of countries that are economically similar, have reasonably comparable purchasing power to the United States, and generally have existing international drug pricing information available. In § 514.220(b), CMS proposes to identify a set of reference countries that are non-U.S. Organization for Economic Cooperation and Development (OECD) members as of October 1, 2025 with: (1) purchasing power parity (PPP)-adjusted per capita gross domestic product (GDP) that is at least 60 percent of the corresponding U.S. level, as estimated and available in the Central Intelligence Agency (CIA) World Factbook; and (2) annual (PPP)-adjusted aggregate GDP that is at least $400 billion (as measured in U.S. dollars) as estimated and available in the CIA World Factbook.

For each country, CMS proposes at § 514.220(b) to use (PPP)-adjusted per capita GDP and (PPP)-adjusted aggregate GDP, as estimated and available in the CIA World Factbook, to identify the reference countries. We note that while the CIA online World Factbook is updated daily, the underlying data such as GDP and PPP are reported no more frequently than annually, based on a July 1 mid-point. Therefore, our proposal is to identify the set of reference countries using data available as of October 1, 2025, in the CIA World Factbook. There are other existing sources for GDP per capita data besides the CIA World Factbook, including the World Bank, and the International Monetary Fund. Upon examining these sources, we found that the GDP data across these sources are highly associated with one another. and include data for countries that are economically comparable to the United States. We propose using the CIA World Factbook as our source for GDP data as it is issued by a U.S. government agency.[155]

We believe that applying a minimum of 60 percent of the United States's (PPP)-adjusted per capita GDP and a minimum $400 billion (PPP)-adjusted aggregate GDP strikes a balance between having too low (PPP)-adjusted per capita GDP and (PPP)-adjusted aggregate GDP thresholds and including data from countries with economies that are substantially different from the United States, while also not having such high (PPP)-adjusted per capita GDP and (PPP)-adjusted aggregate GDP thresholds that the set of reference countries would be very small. Therefore, we believe that our proposed approach is appropriate and would result in a set of reference countries that are economically similar, have reasonably comparable purchasing power to the United States, and generally have existing international drug pricing data that is available.

We propose that CMS would identify the set of reference countries using CIA World Factbook data that is available to CMS as of October 1, 2025. We propose that the identified set of reference countries would remain the same throughout the GUARD Model performance period, even if a country would not meet the criteria for the set of reference countries during any performance year of the model. Considering the relatively short duration of the performance period (5-years), CMS believes that this approach yields increased stability for the GUARD Model test, affords manufacturers stability, and reduces substantial administrative burden for manufacturers.

4. Set of Reference Countries for the GUARD Model Identified Using the Proposed Methodology

Using the criteria to identify the set of reference countries for the GUARD Model that CMS proposes in § 514.220(b), CMS identified the set of reference countries by applying our proposed criteria to non-U.S. OECD-member countries using CIA World Factbook data that was available on October 1, 2025; this results in the following set of reference countries: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom. All 19 countries are economically comparable to the United States with (PPP)-adjusted per capita GDP in 2024 (the most recent data available) falling between 61 and 153 percent of U.S (PPP)-adjusted per capita GDP in 2024 and have an aggregate (PPP)-adjusted GDP in 2024 exceeding $400 billion. We propose that the set of reference countries listed previously would be the GUARD Model's reference countries and remain the same throughout the 5 years of the model's performance period. Table B3 presents the (PPP)-adjusted per capita GDP, (PPP)-adjusted aggregate GDP, and GDP (PPP) adjuster for the United States and the proposed reference countries.

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[155] Central Intelligence Agency. (2025). *The World Factbook. https://www.cia.gov/the-world-factbook/* (Accessed: 10 December 2025).

TABLE B3: GDP RELATED INDICATORS FOR THE UNITED STATES AND THE SET OF REFERENCE COUNTRIES IDENTIFIED AS ECONOMICALLY COMPARABLE TO THE UNITED STATES FOR THE GUARD MODEL

OECD Member Country	2024 Aggregate (PPP)-Adjusted GDP (billion)	2024 (PPP)-Adjusted Per Capita GDP	Percent of U.S. (PPP)-Adjusted Per Capita GDP	GDP (PPP) Adjuster
United States	$25,676	$75,500	100%	1.000
Canada	$2,341	$56,700	75%	1.332
France	$3,732	$54,500	72%	1.385
Germany	$5,247	$62,800	83%	1.202
Italy	$3,133	$53,100	70%	1.422
Japan	$5,715	$46,100	61%	1.638
United Kingdom	$3,636	$52,500	70%	1.438
Australia	$1,635	$60,100	80%	1.256
Korea, South	$2,607	$50,400	67%	1.498
Netherlands	$1,276	$70,900	94%	1.065
Spain	$2,361	$48,400	64%	1.560
Austria	$581	$63,300	84%	1.193
Belgium	$749	$63,100	84%	1.197
Czechia	$522	$48,000	64%	1.573
Ireland	$621	$115,300	153%	1.000*
Norway	$508	$91,100	121%	1.000*
Sweden	$669	$63,300	84%	1.193
Switzerland	$741	$82,000	109%	1.000*
Denmark	$441	$73,700	98%	1.024
Israel	$472	$47,300	63%	1.596

Notes: OECD stands for Organization for Economic Co-operation and Development; PPP stands for purchasing power parity; GDP stands for gross domestic product, as defined at § 514.5. The GDP (PPP) adjuster is necessary to account for differences in the economic capacity between the countries. In this case the GDP (PPP) adjuster accounts for differences between the reference countries' (PPP)-adjusted per capita GDP and the U.S. (PPP)-adjusted per capita GDP. The GDP (PPP) adjuster is obtained by dividing the 2024 (PPP)-adjusted per capita GDP of the United States by the reference country's 2024 (PPP)-adjusted per capita GDP. In cases marked with a *, where the reference country has a greater (PPP)-adjusted per capita GDP than the United States, the adjusted is kept at one (not allowed to go below one).

Source: CIA World Factbook.[156]

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We seek comment on whether there are any inclusion or exclusion policies we should consider after identifying the set of reference countries using the proposed criteria. CMS also welcomes comments on any of the proposed policies in this Section of this proposed rule.

5. Alternatives Considered

For the policy proposals presented in this Section of this proposed rule, CMS considered a number of alternatives, including alternatives related to the proposed existing data sources and the proposed hierarchy as well as the proposed criteria and process for identifying the set of reference countries.

a. Alternatives Related to Data Sources and the Proposed Hierarchy

In cases when there is more than one data source meeting the requirements for a GUARD Model drug and using the hierarchy proposed in § 514.210(c), CMS considered using the data source at the highest level of the hierarchy with the lowest country-level average price. However, CMS believes that selecting based on the relative reliability and quality of the data from each available data source better serves the model test.

Other hierarchy arrangements were also considered. One proposal CMS considered was to not differentiate between data sources based on the number of reference countries for which they have data. This would mean that a data source with one reference country would be considered at the same hierarchy level as a data source with multiple reference countries if they had the same timeframe and pricing data available. Under this option, ties between data sources would be resolved by selecting the data source with the lowest country-level average price, in absolute terms, regardless of the number of reference countries contained in the data source. We also considered a hierarchy arrangement that prioritized recency of timeframe for the data over the type of pricing information available. For this potential proposal, a data source that contained only prices, but with data for a more recent timeframe, would be selected over a data source with sales and volume data with a less recent timeframe. However, CMS believes that by prioritizing the data source according to: (1) type of

[156] Central Intelligence Agency. (2025). *The World Factbook, Real GDP (Purchasing Power Parity)—Country Comparison. https://www.cia.gov/the-world-factbook/field/real-gdp-purchasing-power-parity/country-comparison/* (Accessed: 10 December 2025).

pricing data; (2) number of reference countries with data; [157] and (3) recency of data, the selected data source is the best possible in terms of completeness, quality, and recency. Therefore, CMS believes that the proposed approach is appropriate for determining the GUARD Model default international benchmark.

CMS also considered an even broader approach. Under this potential proposal, CMS would allow each GUARD Model drug to have more than one data source contribute to its corresponding international drug pricing information. CMS would make no adjustments for differences between the data sources. This means that for one GUARD Model drug, international drug pricing information could be from data source A for three reference countries, data source B for two different reference countries, data source C for four other different reference countries, and so on; the reference country-level average prices obtained for each of those reference countries would be compared to select the lowest without any data source specific adjustment. This broad approach would allow for more reference countries to be included in the calculation of the GUARD Model default international benchmark. However, the potential drawback of this approach is that there would be differences with respect to the type of international pricing information between the data sources for the same GUARD Model drug. For instance, one data source could have a price that incorporates retail and non-retail prices; another data source has only in-patient prices; and another has only government prices. There would be no clear standard way of adjusting the prices to make them directly comparable, thus CMS would have proposed making no adjustments. While this approach would have maximized the number of reference countries available to select the lowest country-level average price, CMS believes that the drawbacks outweigh the benefits and so we did not propose this policy.

CMS also considered adding a hierarchy level at the end that would allow CMS to consider pricing data in the form of prices made public in any other source even if they do not comply with the data source requirements outlined in § 514.210(b) when there is no compliant and available data source. However, CMS believes it unlikely that this approach would yield sufficient detail for alignment of international analogs to the GUARD Model drug. Therefore, we did not propose this policy.

We also considered using all the available data sources for a GUARD Model drug and calculating the average of the pricing information available across all the data sources. Because this alternative approach could result in cases where different types of pricing information for a drug from a reference country would be combined, we are not proposing this at this time and may reconsider the potential value of this approach based on feedback from interested parties and further information gathering.

We are interested in better understanding the existing data sources for international drug pricing data that may be available and steps we could follow to best use such data sources for the GUARD Model. CMS solicits feedback on the proposed policies as well as alternative proposals for the hierarchy of data sources that would be used in calculating the GUARD Model default international benchmark. CMS welcomes comments on the methods or processes that we should consider when more than one existing data source is available at the highest level of the hierarchy for the purpose of determining which data source to use when there are multiple potential sources available. We also seek comments on how CMS might refine the hierarchy for potential use of more than one data source for a GUARD Model drug or for ways in which we might be able to incorporate new data sources that may become available during the GUARD Model performance period. We also welcome comments on how CMS should weigh data sources that include fewer reference countries, but which incorporate discounts, rebates, or other price concessions.

b. Alternatives Related to Identifying the Set of Reference Countries

We considered different criteria to identify a country's economy size based on minimum percentages of U.S. (PPP)-adjusted per capita GDP. For example, a (PPP)-adjusted per capita GDP threshold of 80 percent of the corresponding U.S. level would result in the set of reference countries only including eight countries (Austria, Belgium, Germany, Ireland, the Netherlands, Norway, Sweden, and Switzerland), all of which are in Western Europe. We also considered different criteria to identify economy size based on different (PPP)-adjusted aggregate GDP. For example, $300 billion, $1 and $2 trillion. Again, this resulted in either including countries significantly different from the United States or too few countries. For instance, an aggregate (PPP)-adjusted GDP level of $2 trillion results in only three non-U.S. OECD member countries—Canada, Germany, and Japan—being included. We welcome feedback on our proposals to include only OECD reference countries that have a (PPP)-adjusted per capita GDP of 60 percent and an annual (PPP)-adjusted aggregate GDP of at least $400 billion.

We also considered alternative approaches to our proposed criteria for identifying the set of reference countries. Specifically, we considered including all non-U.S. OECD member countries or including countries based on factors such as having a national regulatory authority recognized as a Stringent Regulatory Authority by the World Health Organization (WHO) (to be replaced by the WHO-listed authority or WLA) [158] [159] and intellectual property protections. We also considered including only countries that may represent large markets for drug manufacturers such as all countries in the European Union, Canada, Japan, and United Kingdom. However, we do not believe that these approaches would be as optimal for purposes of identifying the GUARD Model default international benchmark because they would result in either too few countries or countries with economies too different from the United States being included as reference countries for the GUARD Model.

We also considered alternatives that would phase-in countries or would adjust the set of reference countries over time based on a defined set of characteristics, such GDP per capita or average drug prices. However, we believe that phasing in countries over time or adjusting the set of reference countries periodically would create instability within the GUARD Model test and could confound implementation, monitoring, and evaluation activities as well as cause potential negative impacts on GUARD Model participants (for example, creating confusion regarding voluntary data submission). In addition, if we adopted a phase-in of countries or an adjustment to the set of countries during the GUARD Model performance period, it would mean that we would also need

[157] Pricing information may be coordinated sales and volume, coordinated prices and volume, or just prices.

[158] World Health Organization. (2025). *List of WHO Listed Authorities (WLAs). https://www.who.int/publications/m/item/list-of-who-listed-authorities-wlas* and *https://cdn.who.int/media/docs/default-source/medicines/regulatory-systems/wla/list_of_wla.pdf* (Accessed: 10 December 2025).

[159] World Health Organization. (n.d.). *WHO-Listed Authority (WLA). https://www.who.int/initiatives/who-listed-authority-reg-authorities* (Accessed: 10 December 2025).

to consider whether to change our proposal to maintain the GUARD Model default international benchmark for the duration of the model test if we determine that the phase-in would apply to all GUARD Model drugs, regardless of when they became a GUARD Model drug, which creates additional complexity. For all these reasons, we propose to maintain a stable set of reference countries for the duration of the GUARD Model.

Although we have concerns about the potential negative impacts that could occur if the set of reference countries is not held constant during the 5-year GUARD Model performance period, as discussed in this Section of this proposed rule, we welcome comment on the potential benefits and drawbacks of establishing a threshold for adding or removing a country from the set of reference countries at certain points during the model performance period. Specifically, we seek comment on whether a country should be removed from the set of reference countries if the CIA World Factbook data for a calendar year after 2024 shows that, for 2 consecutive calendar years, the country does not meet the criteria for inclusion in the set of reference countries that are finalized in a final rule that establishes the GUARD Model. We also welcome comment on the processes and timing that would be necessary to operationalize a change to the set of reference countries that would minimize impacts on the model test. For example, to allow time for model operations and manufacturer activities to adjust, it may be necessary or prudent to establish a specified period when CMS would review available CIA World Factbook data for a calendar year and a minimum amount of time between CMS' identification that a country no longer meets the criteria for inclusion in the set of reference countries and when the set of reference countries would be revised. We also welcome comment on the potential benefits and drawbacks of setting a threshold for removal at 2 consecutive years and whether a different length of time would be sufficient to justify a change to the set of reference countries.

F. Proposed Submission of International Drug Net Pricing Data

In this Section of this proposed rule, we describe the process for submission of international drug net pricing data that manufacturers may choose to exercise for GUARD Model drugs. CMS is proposing at § 514.310(a) that, subject to certain conditions, manufacturers of GUARD Model drugs would have the option to voluntarily submit to CMS, the international drug net pricing data that corresponds with a manufacturer's GUARD Model drug, which could then be used to determine the GUARD Model updated international benchmark for that specific GUARD Model drug, as described in section IV.G. of this proposed rule. The international drug net pricing data would need to correspond to net pricing information for a GUARD Model drug's set of international analogs, as defined in section IV.E. of this proposed rule.

At § 514.310(b), CMS proposes to assess each data ''submission,'' which we define at § 514.5 to mean manufacturer international drug net pricing data voluntarily submitted to CMS to consider for use for the performance year for which it was submitted. In other words, each submission is only used by CMS for the specific corresponding performance year, and any subsequent performance year would need a separate submission. CMS proposes at § 514.310(b) that a submission is determined to be an applicable submission if it fulfils the data requirements which include verification of the submission for completeness and validity by CMS. As such, CMS defines at § 514.5 that ''applicable submission'' means a voluntary manufacturer submission that CMS determines fulfils the data requirements, which include verification of the submission for completeness and validity, and therefore is suitable for determination of the GUARD Model updated international benchmark per § 514.410(d). Only submissions determined to be applicable by CMS are suitable for determination of the GUARD Model updated international benchmark, as explained in section IV.G. of this proposed rule.

1. Proposed Voluntary Submission of International Drug Net Pricing Data

Under the GUARD Model, if a manufacturer elects to submit international drug net pricing data for a GUARD Model drug, CMS proposes that the manufacturer would be required to execute a data agreement at least 90 calendar days prior to submission. The ''data agreement'' would establish terms, conditions, and requirements, including data completeness and validity requirements; compliance responsibilities; CMS confidentiality obligations; and other ongoing requirements. In § 514.310(b), CMS proposes a one-year data agreement duration aligned with annual submission cycles. Manufacturers may make a submission for one or more GUARD Model drugs. For each GUARD Model drug, the submission would include the set of international analogs with sales in the reference countries identified in § 514.220(d) that occur during the performance year for which the submission applies.

CMS proposes that manufacturers who elect the option to submit international drug net pricing data for a GUARD Model drug must include data that corresponds to the same timeframe as the performance year for which it will be used to determine the GUARD Model updated international benchmark. Submission of the data must occur within 180 calendar days of the end of the performance year. For example, for the first performance year ending on December 31, 2027, CMS must receive manufacturer net pricing data by June 29, 2028, for it to be considered for the GUARD Model updated international benchmark determination, if deemed applicable, and this submission must include data for the entire first performance year (January 1, 2027 to December 31, 2027). This would mean manufacturers would have to establish a data agreement by March 31, 2028, at the latest.

CMS recognizes that 180 calendar days after the end of the performance year would mean that the published list of Part D rebatable drugs would only account for nine months of said performance year. This is due to the different timelines between the Part D Inflation Rebate Program (an applicable period begins in October and lasts 12 months) and the GUARD Model (a performance year beings in January and lasts 12 months). However, CMS believes that manufacturers are able to identify whether a drug is a Part D inflation rebatable drug and a GUARD Model drug by applying the inclusion and exclusion criteria. Therefore, CMS believes the 180 calendar days are sufficient for manufacturers to know with reasonable certainty if their drug is a Part D rebatable drug and whether it meets criteria for a GUARD Model drug.

CMS considered shortening this period, specifically considering whether a submission should occur within 90 calendar days of the end of the performance year. However, CMS believes that given the data lags, providing sufficient time for manufacturers to process data is necessary. Therefore, a longer period is preferable. CMS also considered an even longer period than the current proposal, specifically considering whether a submission should occur within 10 calendar quarters after the end of the performance year to allow for time for the list of Part D rebatable drugs to be published. However, this would extend

the time for rebate payment calculations, invoicing, reconciliation, and due dates of payments and reconciliation amounts, if a manufacturer chooses to submit international drug net pricing data. One potential way of doing this would be using the GUARD Model default international benchmark for the GUARD Model drug up until the time when the manufacturer submits international drug net pricing data, if they choose to do so. Assuming the submission is deemed an applicable submission by CMS, the payment amount would be updated and reconciled based on the GUARD Model updated international benchmark. However, this approach would be more complex and potentially create unpredictability for both CMS and manufacturers. CMS believes that manufacturers are able to identify GUARD Model drugs by applying the criteria under the Part D Inflation Rebate Program and the GUARD Model as proposed at § 514.120; therefore, we do not believe these alternative approaches are preferable. CMS welcomes comments on this proposal and the alternatives considered.

Upon submission of the data, CMS proposes to conduct a verification review to determine whether the submission meets the submission requirements as proposed in § 514.310(b), which is necessary for CMS to determine whether the submission represents an applicable submission for use in determining the GUARD Model updated international benchmark. We describe the verification review process in more detail later in this Section of this proposed rule.

For CMS to determine that the submission is an applicable submission, CMS proposes in § 514.310(c) and (d) that the data must include all the basic data elements required by CMS for the set of international analogs that corresponds to a GUARD Model drug, as described later in this Section of the proposed rule, as well as all the net pricing data elements required under one of the two options manufacturers can select to submit net pricing data, in addition to all other requirements. CMS proposes at § 514.310(g) that if, for any of the basic or net pricing data elements, third-party individuals and organizations were relied upon to gather, analyze, or submit the data, the manufacturer must note its reliance on a third party with respect to each of the type of activities (gather, analyze, or submit the data) engaged in by the third party, and the third-party individual or organization identified.

In addition, CMS proposes in § 514.310(b) that the submission is verified for completeness, which includes the executed data agreement; attestation (as described later in this Section of this proposed rule); submission using the proper portal in the manner and form requested by CMS; and all basic data elements and net pricing data elements. CMS also proposes that the submission is verified for validity as part of the verification review process, and to do so, CMS may utilize all available existing data sources and information to assess the extent to which the submission reflects international drug net pricing in the reference countries. Additionally, CMS may choose to request additional supporting information and/or data before completing the assessment of validity of the submission and finalizing review. We describe this process in more detail later in this Section of this proposed rule.

2. Basic Data Requirements

The basic data requirements, as proposed at § 514.310(c), consist of data elements that manufacturers would be required to submit in order for CMS to corroborate that the set of international analogs which are included in the submission are aligned with the GUARD Model drug. Identification of international analogs based on alignment of the international analog's identifying characteristics with the GUARD Model drug's characteristics should be consistent with the alignment approach to identify the set of international analogs proposed at § 514.410(c). CMS would issue supplementary guidance with more information.

CMS proposes that these data elements would be required for the set of international analogs that correspond to a GUARD Model drug. This means that if, for a GUARD Model drug, there are multiple reference countries that sell some or all the international products that are part of the set of international analogs, the manufacturer submission should include the basic data elements for all the international products sold in each reference country. That is, the basic data requirements necessitate submitting the data elements separately for each reference country; and within each reference country, the data submission must include all the international products that are part of the set of international analogs that are sold in the reference country. This is necessary to allow CMS to verify, by reference country the international products sold that are part of the set of international analogs for the GUARD Model drug.

The required basic data elements are the GUARD Model drug brand name, nonproprietary name, and NDC–9; and then for every reference country where some or all of the international products that are part of the set of international analogs for the GUARD Model drug are sold during the submission performance year, a list of every international product sold in that reference country. In other words, there must be a list for every reference country where at least one international product of the set of international analogs are sold. This list of international products (that are part of the set of international analogs for the GUARD Model drug) must have the following details for each international product:

- Scientific name and active ingredient(s).
- Brand name(s) (all variations if there are multiple in the reference country) and nonproprietary name.
- Names of manufacturers, marketers, distributors, licensees, or other entities responsible for selling the international product in the reference country.
- International regulatory approval status.[160]
- Route of administration and dosage form as they are expressed in the reference country and in equivalent terms to what is expressed in the NDC directory for the GUARD Model drug.
- Dosage strength and dosing unit as they are expressed in the reference country and in NCPDP equivalent units according to the GUARD Model drug's NCPDP unit.
- All package forms and sizes available.

Refer to Table B4 for an illustrative example of the basic data elements.

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[160] As defined at proposed § 514.300 ''international regulatory approval status'' means any information relevant and sufficient for CMS to determine whether each international product's approval or licensing status according to the reference country's regulatory framework would make it an international generic, international biosimilar biological product, or neither. Individual countries differ in the regulatory processes and standards governing approval of drugs and biological products.Use of international drug pricing information in the proposed GUARD Model should not be interpreted to connote FDA approval or to otherwise describe any scientific or regulatory relationship between U.S.-approved or licensed and non-U.S.-approved or licensed products.

TABLE B4: ILLUSTRATIVE EXAMPLE OF BASIC DATA ELEMENTS

Basic Data Elements are:
(1) GUARD Model drug elements for identification: brand name, nonproprietary name, and NDC-9.
(2) For every reference country where at least one international product of the GUARD Model drug's set of international analog drugs are sold during the submission performance year, a list of international products sold in that reference country must have the following details for each international product:

Example Country A:									
Intl. Product*	**Scientific Name and Active Ingredient(s)**	**Brand Name(s) and Nonproprietary Name ****	**Manufacturer(s), Marketer(s), Licensee(s), and Other Entities**	**Intl. Regulatory Approval Status**	**Route of Admin. and Dosage Form**	**Dosage Strength**	**Dosing Unit**	**NCPDP Equivalent**	**Package(s)*****
Product 1									
Product 2									
Product …									
Product n									

Notes: Intl. stands for international; Ref. Country stands for reference country; Admin. stands for administration; NDC stands for National Drug Code; NCPDP stands for National Council for Prescription Drug Program, as defined at § 514.5. Route of admin., dosage form, dosage strength, dosing unit, and NCPDP equivalent would match the GUARD Model drug's NDC-9.
*All international products sold in Ref. Country A.
**For example, brand name, non-proprietary name.
***That is, all package forms and sizes.

CMS recognizes that manufacturers may not have this data readily available in the manner and form required for submission. CMS will issue

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supplementary guidance with information regarding the definitions of the data elements, the manner and form in which they must be submitted, guidelines to facilitate identification of the international products that are part of the set of international analogs for the corresponding GUARD Model drug, guidelines on currency conversion, reasonable assumptions that may be necessary for any of the data elements, instructions for the submission process, and any other relevant topic related to the voluntary submission of international drug net pricing data.

CMS will review the basic data elements reported in each submission to determine if the appropriate set of international analogs for the GUARD Model drug have been submitted. CMS may use existing data sources of international drug pricing data, such as IQVIA MIDAS or POLI data, as well as publicly available information on the drugs sold in reference countries, to determine if the full set of international analogs that are sold in the reference countries have been submitted for a GUARD Model drug. The full set of international analogs includes all international products sold in each of the reference countries whose identifying characteristics (active ingredient, route of administration, dosage form, and strength) are in alignment with the GUARD Model drug's identifying characteristics. If the full set of international analogs are not reported for the GUARD Model drug, CMS proposes that the submission is not acceptable and thus it would not be an applicable submission, unless additional information is provided and CMS approves the use of the data. Specifically, CMS recognizes that given the requirement that international products be aligned according to all their identifying characteristics with the GUARD Model drug, it is possible that manufacturers would need flexibility in reporting for various reasons. For example, data processing and lags in compiling information (given the number of reference countries involved and the level of granularity at which the data must be submitted—NDC–9 level) and administrative lags in receiving data on manufacturer discounts and rebates (or lags associated with coordinating with third-parties that may be involved in the sales of the international products that are part of the GUARD Model drug's set of international analogs) may all pose challenges for submission of the international net pricing data at the NDC–9 level. Thus, CMS proposes at § 514.310(f) that manufacturers who cannot provide the full set of international analogs for all reference countries where they are sold provide a detailed explanation of why this is not possible. CMS will consider this information as part of the verification review process.

CMS also proposes at § 514.310(b) that during the verification process CMS may choose to request additional supporting information from manufacturers before completing its assessment of a submission's validity. In this situation, the manufacturer would be required to respond to CMS within 15 days; and if responses are acceptable to CMS, CMS will confirm the validity of the submission and proceed to use the subset of international products for which the manufacturer has submitted data, as long as it meets all other requirements, to represent the set of international analogs and thus be used to determine the GUARD Model updated international benchmark.

CMS considered the possibility of accepting a submission without explanation even if the full set of international analogs are not included in the submission and using the data that is submitted along with existing international drug pricing information to calculate an updated international benchmark. However, we decided against this approach because of concerns about combining different data sources and whether it would be logical to do so with some adjustments. We seek feedback on this potential option.

CMS also considered providing manufacturers the set of international analogs for which they must submit the international net pricing data. However, we believe that manufacturers have this information and it would not be burdensome to identify the set of international analogs that are sold in the reference countries. CMS also considered not accepting, even with appropriate explanation, any submission that does not include the full set of international analogs for the GUARD Model drug. However, we decided against this because we believe there may be legitimate reasons for a manufacturer to be unable to submit this information for certain drugs, particularly because CMS is requesting data at a granular level—the NDC–9 level—which is necessary because Part D drugs are identified by NDC–9 and the Part D Inflation Rebate Program is based on the same. CMS recognizes that this level of granularity may result in exceptional situations and circumstances where the data for a particular NDC–9 is not yet available. Therefore, under our proposed policy, CMS allows for manufacturers to share an explanation that CMS will assess for acceptability. CMS seeks feedback on our proposed policy as well as the alternatives presented, including whether CMS should provide the set of international analogs for which data should be submitted for each corresponding GUARD Model drug.

CMS recognizes the complexities inherent in international pharmaceutical markets, including variations in dosage strengths, formulations, and routes of administration; packaging differences; and diverse relationships between U.S. and international entities responsible for product marketing and distribution. For these reasons, we also considered only requesting this data for the set of international analogs that correspond to a GUARD Model drug that are sold directly by the manufacturer and not by any other subsidiary or company in the reference countries. We also considered an option where manufacturers would only submit the data for the set of international analogs that they directly sell in the reference countries. However, we believe that manufacturers have relationships with subsidiaries, wholesalers, and other businesses involved in selling the set of international analogs in the reference countries and can obtain the data that is requested under this option. CMS welcomes feedback on our policy and the alternatives presented.

CMS seeks comments on whether the proposed voluntary framework, which includes basic required data elements to ensure alignment of GUARD Model drugs and international products, adequately addresses these market complexities. CMS also seeks comments on whether additional basic data elements should be required or if any of the proposed elements present significant data collection, analysis, or submission challenges.

3. Options for Submission of Net Pricing Data Elements

CMS proposes in § 514.310(d) that manufacturers who elect to submit international drug net pricing data must submit all of the data elements required for one of the two options described later in this Section of this proposed rule, in addition to the basic data elements that are presented in this Section of this proposed rule. Manufacturers would select which option to follow. For each of the two options, manufacturers must report data elements for the international products that comprise the set of international analogs that are sold in the set of reference countries that correspond to the GUARD Model drug and which they

have included in the basic data elements.

a. Streamlined Option

Under this option, manufacturers would be required to report a set of data elements at the net price level, reference country level, and at an across-country level. Beginning with the ''net price level'', CMS proposes at § 514.300 this to mean, with respect to sales of international products, all sales of an international product in a reference country at the same price and price concession, where ''price concession,'' also defined at § 514.300, means any discounts, rebates, or other concessions offered by the manufacturer that lowers the amount paid for purchase of an international product in a reference country. Thus, a single international product may have multiple net price levels in a reference country as it may be sold at different prices to different purchasers and each purchaser may receive different concessions from the manufacturer. However, if an international product is sold at the same price to multiple purchasers and each of them receives the same concession, then it has only one net price level.

The three data elements that CMS proposes at § 514.310(d) must be reported at the net price level are gross sales amount, net sales amount, and volume in NCPDP units. ''Gross sales amount,'' defined at § 514.300, means the amount of money paid, inclusive of any price concessions, for the purchase of an international product in a reference country. In contrast, ''net sales amount,'' defined at § 514.300, means the amount of money paid, exclusive of any price concessions, for the purchase of an international product in a reference country. The net sales amount is not a list price (for example, the equivalent of WAC in the United States); rather, it is based on the net price of the international products sold in the reference countries.

Both gross and net sales amounts must be reported in local country currency and in U.S. dollars (details on the exchange rate for currency conversion are discussed later in this Section of this proposed rule). Both of these values for an international product at the net price level are expected to correspond to each other, and will have a corresponding volume of the international product that was purchased. When reporting the volume, it must be expressed in NCPDP units or converted into NCPDP units that correspond to the GUARD Model drug's NCPDP unit.

Under our proposal, CMS would expect the manufacturer to obtain every sale that is made directly to health care entities, distributors, wholesalers, or other international purchasers and aggregate those that share a price and concession amount, resulting in sales by the net price level. We considered the option of only requesting sales that manufacturers have readily available and not all sales made for the set of international analogs. However, we believe that manufacturers do have access to all sales made for the set of international analogs that correspond to a GUARD Model drug. CMS does allow for some flexibility, however, because we recognize that there may be sales that a manufacturer may not be able to provide for a variety of reasons (for example, delays in payments of price concessions, licensing agreements for third party production of products, and parallel importing arrangements). We describe an approach for how to approach this in extenuating circumstances in our verification of review process that is described later in this Section of this proposed rule.

We also considered, instead of sales, requesting manufacturer revenue. However, given that the purpose of the submission is to determine the GUARD Model updated international benchmark for a GUARD Model drug, we believe sales are the appropriate measure to request. We seek feedback on this proposal of requesting sales instead of another measure and seek comment on whether and to what extent manufacturers can submit all sales.

In Table B6, an example of the voluntary submission by the manufacturer of ''GUARD Model drug I'' is shown and a description of the data used is found in Table B5. This fictitious GUARD Model drug I has international products in three reference countries. In reference country A, it has two international products; in reference country B, it has four; and in reference country C, it has 3. For reference country A, international product one has five net price levels (sold at five price-price concession combinations); thus, the applicable submission includes gross and net sales amounts and volume in NCPDP units for each of the five levels. Also in reference country A, international product two has three net price levels; thus, the applicable submission includes three gross and net sales amounts with the corresponding volumes. It is possible that there were multiple sales of international analog one for each of those net price levels, but as the sales were at the same price and price concession, the applicable submission includes these aggregated at the net price level.

The four data elements that CMS proposes at § 514.310(d) for reporting at the reference country level are the average net-to-gross ratio, the exchange rate for currency conversion, the country-level average price, and the GDP (PPP) adjuster which will be further described later in this Section of this proposed rule.

The ''average net-to-gross ratio'' means for a reference country, the total net sales for international products that are part of a GUARD Model drug's set of international analogs in a reference country divided by the corresponding total gross sales for the same international products. This means that there is one average net-to-gross ratio for each GUARD Model drug per reference country. An example of how the average net-to-gross ratio is calculated is shown in Table B6, where for Reference Country A, the sum of all net sales amounts (including both international analogs) is divided by the sum of all gross sales amounts (including both international analogs) resulting in the average net-to-gross ratio of 0.55.

The ''exchange rate for currency conversion,'' defined at § 514.5, means the conversion rate used to convert from the currency of each reference country to U.S. dollars for data corresponding to the submission's performance year. In other words, the rate would correspond to the calendar year during which the sale of international products occurred. CMS proposes at § 514.310(e) that the exchange rate that should be applied would be from the World Bank Atlas,[161] and correspond to the submission's corresponding performance year. This exchange would be applied to all data elements requiring currency conversion in the submission.

CMS considered allowing for different possible data sources for the exchange rate for currency conversion, for instance, the International Monetary Fund exchange rates data,[162] the Federal Reserve Bank foreign exchange rates,[163]

[161] The World Bank. (n.d.). *The World Bank Atlas Method: Detailed Methodology. https://datahelpdesk.worldbank.org/knowledgebase/articles/378832-the-world-bank-atlas-method-detailed-methodology* (Accessed: 10 December 2025).

[162] International Monetary Fund. (n.d.). *IMF Data Explorer: Exchange Rate Data (4.0.1). https://data.imf.org/en/Data-Explorer?datasetUrn=IMF.STA:ER(4.0.1)* (Accessed: 10 December 2025).

[163] Annual: Board of Governors of the Federal Reserve System. (2025). *Foreign Exchange Rates—G.5A Annual. https://www.federalreserve.gov/releases/g5a/current/* (Accessed: 10 December 2025). Weekly: Board of Governors of the Federal Reserve System. (2025). *Foreign Exchange Rates—H.10 Weekly. https://www.federalreserve.gov/releases/h10/current/#* (Accessed: 10 December 2025).

and exchange rates from country-specific sources, however CMS believes that because the rates would be applied across an entire calendar year, it is important for the data source to provide consistency in reporting and methods. The World Bank Atlas provides this by considering not just an annual rate, but also taking into account the 2 preceding years, which adjusts for the difference between the rate of inflation in the country and international inflation, thereby mitigating short-term effects of inflation.[164] We solicit feedback on the data sources considered and others that should be considered for currency conversion; the methods that can be used; the challenges that might arise; and any other pertinent information related to this topic. We are also seeking feedback on whether CMS should provide the exchange rates that are used in the calculations.

The next data element reported at the country-level is the country-level net price. CMS proposes at § 514.300 that ''country-level net price'' means a weighted average net price, that excludes price concessions, for all international products sold in a reference country that are part of a GUARD Model drug's set of international analogs during a submission's corresponding performance year, where the weights are the corresponding volumes of international products sold, expressed as a per unit price, and where the units are the GUARD Model drug's NCPDP units. To express the country-level average net price in U.S. dollars, the exchange rate for currency conversion (the rate according to § 514.310(e)) is utilized. Using again the example of reference country A from Table B6, each of the net sales amounts for both international products contribute to the average according to how much volume was sold. The net sales amounts are converted from local currency to U.S. dollars using the exchange rate of 0.8 (this is calculated dividing the net sales amount by the rate). This results in an average price for one NCPDP unit of GUARD Model drug I in reference country A, which in this example would be $187.

The final country-level data element required to be reported under this option is the ''GDP (PPP) adjuster,'' which CMS proposes at § 514.5, to define as, for a reference country, the U.S. GDP (PPP) per capita divided by the reference country's GDP (PPP) per capita rounded to the third decimal place. The GDP (PPP) per capita for the reference country is the most recent estimate of GDP (PPP) per capita for that reference country available in the CIA World Factbook at the end of the corresponding performance year. The reference country's GDP (PPP) per capita and U.S. GDP (PPP) per capita must be for the same calendar year. CMS proposes the GDP (PPP) adjuster would have a lower bound of 1.000, thus if the resulting GDP (PPP) adjuster is lower than 1.000, it is set to 1.000.

CMS proposes a lower bound of 1.000 for the GDP (PPP) adjuster because CMS believes that the adjuster should not decrease a country-level average price for a drug. Setting this lower bound will ensure that an adjustment is not made that would result in an adjusted country-level average price being lower than the unadjusted country-level average price. CMS believes that the GDP (PPP) adjuster's purpose is to adjust for countries' economic resources when they are higher than those of the United States, and the lower bound proposal aims to achieves this. To exemplify this, Country X has a higher GDP (PPP) per capita than the United States, such that its GDP (PPP) adjuster without a lower bound would be 0.500 and an unadjusted country-level average price for an international product part of a GUARD Model drug's set of international analogs of $100. Without the proposed lower bound, the adjusted price would be $50, but with the proposed lower bound the adjusted price would remain $100. CMS considered not having a lower bound for the GDP (PPP) adjuster to allow for adjustments when a reference country has a higher GDP (PPP) per capita than the United States. CMS seeks feedback on this policy.

The single data element reported at an across-country level is the across-country average net price. At § 514.5, CMS proposes ''across-country average net price'' to mean the weighted average net price (excluding price concessions) for all international products sold across all reference countries that are part of GUARD Model drug's set of international analogs during a submission's corresponding performance year, where the weights are the corresponding volumes of the international product sold in NCPDP units, each price is adjusted using the reference country specific GDP (PPP) adjuster, converted into U.S. dollars using the exchange rate for currency conversion as described at § 514.310(e), and expressed as a per unit price, where the units are the GUARD Model drug's NCPDP units. An example of the across country average net price is shown in Table B6. Note that there is one value across all three reference countries. Each net sales amount for all international products in every reference country contributes to this average according to the volume sold. Each of the 29 net sales amounts are converted to U.S. dollars using the appropriate exchange rate (0.8 for the net sales amount for reference country A, 10 for the 14 net sales amount for reference country B, and 0.86 for the 7 net sales amount for reference country C) and adjusted by the reference country's GDP (PPP) adjuster (1.000 for reference country A, 1.300 for reference country B, and 1.500 for reference country C). This results in an average price of GUARD Model drug I of $182.761. This means that for GUARD Model drug I, the average price in all reference countries where it is sold is $182.761, which accounts for how much quantity is sold, the country's currency, and its GDP (PPP).

We seek feedback on the data elements included in this option.

b. Limited Option

Under this approach, manufacturers would be required to submit a very limited set of data elements that are aggregated at country-level and one data element at the across-country level. CMS proposes at § 514.310(d), that the country level data elements that would be submitted under the limited option are the average net-to-gross ratio, the exchange rate for currency conversion, the country-level average price, and the GDP (PPP) adjuster; all these elements are the same as described for the streamlined option. The one across-country level data element that CMS proposes at § 514.310(d) to be submitted under the limited option is the across-country average net price and it is also the same as described for the streamlined option. Additionally, manufacturers would be required to submit several other data elements under the limited option: the *total* gross sales amount, *total* net sales amount, and *total* volume in NCPDP units, which we describe next.

For all the international products that are part of the set of international analogs corresponding to a GUARD Model drug, for each reference country, CMS would require submission of the *total* gross sales amount, which can be computed by summing all gross sales amounts for the international products part of the GUARD Model drug's international analogs in the reference country's currency and in U.S. dollars (using the exchange rate for currency

[164] The World Bank. (n.d.). *The World Bank Atlas Method: Detailed Methodology. https://datahelpdesk.worldbank.org/knowledgebase/articles/378832-the-world-bank-atlas-method-detailed-methodology* (Accessed: 10 December 2025).

conversion); *total* net sales amount, which can be computed by summing all net sales amounts for the international products part of the GUARD Model drug's international analogs in the reference country's currency and in U.S. dollars (using the exchange rate for currency conversion); and the corresponding *total* sales volume in NCPDP units corresponding to the GUARD Model drug's NCPDP unit.

We seek feedback on the data elements included in this option.

c. Additional Considerations for Both Options

CMS would require information on how the data elements were compiled and computed, any reasonable assumptions that were made during this process, and any other pertinent information that CMS should consider in its verification process for the data. CMS proposes that if there are sales that the manufacturer has not been able to include, the manufacturer submit an explanation and CMS will consider this as part of the verification review. If the explanation is acceptable, CMS may consider the submission an applicable submission if it meets all other criteria. CMS considered not allowing this flexibility but given that the data is at a granular level (NDC–9), we believe that this flexibility is necessary. CMS will include in guidance more information on how to calculate these values and the reasonable assumptions manufacturers can make in this process under this option.

CMS recognizes that manufacturers may need to allocate gross and net sales amounts to the international products part of the set of international analogs to provide the data elements required under each of the options presented previously. CMS proposes at § 514.310(b) that any allocation and calculations be done in a manner consistent with the generally acceptable accounting principles (GAAP), international financial reporting standards (IFRS), or other internationally recognized accounting approaches.[165] We solicit feedback on whether there are other accounting approaches that CMS should consider. CMS will provide further guidance on reasonable assumptions that manufacturers may make in the calculation of these data elements.

Though both options require the same types of data, they differ in granularity of data submitted and CMS' ability to verify the data reported. In the streamlined option, CMS would require reporting of gross sales amount, net sales amount, and volume for each net price level. In the limited option, CMS would require reporting of less granular data with gross sales amount, net sales amount and volume reported across all net price levels. CMS developed the limited option to allow manufacturers to report detailed manufacturer net pricing data but without having to disaggregate at the net price level.

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[165] Ross, S. (2025). *GAAP vs. IFRS: What's the Difference?* Investopedia. *https://www.investopedia.com/ask/answers/011315/what-difference-between-gaap-and-ifrs.asp* (Accessed: 10 December 2025).

TABLE B5: ILLUSTRATIVE TABLE OF DATA ELEMENTS REQUIRED UNDER THE STREAMLINED AND LIMITED OPTIONS

Ref. Country	Gross Sales Amount	Net Sales Amount	Volume (NCPDP units)	Average Net-to-Gross Ratio	Exchange Rate	Country-Level Average Net Price	GDP (PPP) Adjuster	Across Country Average Net Price (Potential Updated IB)
Streamlined Option								
A	Gross Sales A1*	Net Sales A1*	Volume A1*	Ratio A	Rate A	Volume-weighted Average Net Price for Country A	Adjuster A	Volume-weighted Average GDP (PPP)-Adjusted Net Price
	Gross Sales A2*	Net Sales A2*	Volume A2*					
	Gross Sales A3*	Net Sales A3*	Volume A3*					
B	Gross Sales B1*	Net Sales B1*	Volume B1*	Ratio B	Rate B	Volume-weighted Average Net Price for Country B	Adjuster B	
	Gross Sales B2*	Net Sales B2*	Volume B2*					
C	Gross Sales C1*	Net Sales C1*	Volume C1*	Ratio C	Rate C	Volume-weighted Average Net Price for Country C	Adjuster C	
	Gross Sales C2*	Net Sales C2*	Volume C2*					
	Gross Sales C3*	Net Sales C3*	Volume C3*					
	Gross Sales C4*	Net Sales C4*	Volume C4*					
D	Gross Sales D1*	Net Sales D1*	Volume D1*	Ratio D	Rate D	Volume-weighted Average Net Price for Country D	Adjuster D	
	Gross Sales D2*	Net Sales D2*	Volume D2*					
Limited Option								
A	Total Gross Sales A	Total Net Sales A	Total Volume A	Ratio A	Rate A	Volume-weighted Average Net Price for Country A	Adjuster A	Volume-weighted Average GDP (PPP)-Adjusted Net Price
B	Total Gross Sales B	Total Net Sales B	Total Volume B	Ratio B	Rate B	Volume-weighted Average Net Price for Country B	Adjuster B	
C	Total Gross Sales C	Total Net Sales C	Total Volume C	Ratio C	Rate C	Volume-weighted Average Net Price for Country C	Adjuster C	
D	Total Gross Sales D	Total Net Sales D	Total Volume D	Ratio D	Rate D	Volume-weighted Average Net Price for Country D	Adjuster D	

Notes: Ref. Country stands for reference country, as defined at § 514.5; NCPDP stands for National Council for Prescription Drug Program, as defined at § 514.5; GDP (PPP) stands for gross domestic product based on purchasing power parity, as defined at § 514.5; Updated IB stands for updated international benchmark. *Gross and net sales and volume amounts for the streamlined option are reported at the net price level which means, with respect to sales of international products, sales at the same price and price concession. This means that the gross and net sales and volume are aggregated together as long as they correspond to a sale with the same price and price concession regardless of the purchaser identity.

TABLE B6: TABLE SHOWING DATA ELEMENTS REQUIRED UNDER THE STREAMLINED AND LIMITED OPTIONS FOR ILLUSTRATIVE GUARD MODEL DRUG "I"

Ref. Cty.	Int. Prod.	Net Price Level	Gross Sales Amt. (LC)	Net Sales Amt. (LC)	Vol. (NCPDP units)*	Ave. Net-to-Gross Ratio	Exch. Rate	Cty.-Level Ave. Net Price	GDP (PPP) Adjuster	Across-Cty. Ave. Net Price
Streamlined Option										
A	1	1	100	65	5	0.549	0.800	87.002	1.000	182.761
		2	460	350	20					
		3	367	270	15					
		4	80	30	10					
		5	204	48	15					
	2	1	321	132	14					
		2	245	89	6					
		3	123	60	23					
B	1	1	540	340	89	0.614	10.000	38.101	1.300	
		2	345	140	90					
		3	76	70	35					
		4	345	260	72					
		5	222	90	34					
	2	1	678	540	90					
		2	856	345	104					
		3	1020	589	302					
		4	345	140	120					
	3	1	567	300	270					
		2	908	650	309					
	4	1	345	301	190					
		2	284	187	102					
		3	401	302	201					
C	1	1	207	130	40	0.580	0.860	533.031	1.500	
		2	196	89	36					
	2	1	467	123	60					
	3	1	178	90	40					
		2	376	201	32					
		3	999	777	222					
		4	111	60	3					
Limited Option										
A	1	1	1,900	1,044	108	0.549	0.800	187.002	1.000	182.761
		2								
		3								
		4								
		5								
	2	1								
		2								
		3								
B	1	1	5,5404	3,354	1,688	0.614	10.000	38.101	1.300	
		2								
		3								
		4								
		5								
	2	1								
		2								
		3								
		4								
	3	1								
		2								
	4	1								
		2								
		3								

C	1	1	2,534	1,470	433	0.580	0.860	533.031	1.500	
		2								
	2	1								
	3	1								
		2								
		3								
		4								

Notes: Ref. Cty. stands for reference country; Int. Prod. stands for international product; Vol. stands for volume; Amt. stands for amount; Ave. stands for average; Adj. stands for adjusted; LC stands for local currency; Exch. Rate stands for Exchange Rate for Currency Conversion; NCPDP stands for National Council for Prescription Drug Program; GDP (PPP) stands for gross domestic product based on purchasing power parity. *The volumes in this example are in NCPDP units that correspond to GUARD Model drug I's NCPDP unit. In this illustrative example, for GUARD Model I the set of international analogs is composed of two international products sold in Country A, four sold in B, and three sold in C. Gross and net sales and volume amounts for the streamlined option are reported at the net price level which means, with respect to sales of international products, sales at the same price and price concession. This means that the gross and net sales and volume are aggregated together as long as they correspond to a sale with the same price and price concession regardless of purchaser identity. For the limited option the net price levels are shown but reporting is at a country level hence there is only one gross and net sales and volume amount for each country. The country-level average net price is a weighted average where the weights are the corresponding volume to each price contributing to the average. The across-country average net price is a weighted average where the weights are the corresponding volume to each price contributing to the average and where each price has been multiplied by the appropriate country's GDP (PPP) adjuster.

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4. Verification of the Submission

CMS proposes to assess each submission for validity as part of the verification process. For both options, CMS will use existing available information, including, for example U.S. Securities and Exchange Commission (SEC) filings, existing international drug pricing data from vendors, as described in section IV.E. of this proposed rule, reference countries central bank data, health ministry or other national registries and formularies, and other publicly available information to determine whether the values reported for the data elements fall within plausible and reasonable ranges. Some examples of publicly available data that could serve for the verification process are the Schedule of Pharmaceutical Benefits of the Australian Government's Pharmaceutical Benefits Scheme [166] and the United Kingdom's National Health Service Medicines A to Z [167] and Electronic Drug Tariff data.[168]

As part of the verification process, CMS proposes § 514.310(b) to conduct some or all of the following checks: cross reference check against existing international data for the set of international analogs; check for internal consistency; conduct cross-validation using external and public data; conduct technical data quality checks; and carry out any other appropriate checks for verification. CMS proposes to follow a resolution process if errors are identified, which is described later in this Section of this proposed rule.

To cross reference against existing international data for the set of international analogs for which data are submitted, CMS may compare the reported country-level average net prices and across-country average net price to existing data sources that contain gross prices. This will allow CMS to assess whether the reported data are consistent with existing data. For example, if a net price reported by a manufacturer is greater than the publicly available gross prices reported in existing international data sources, CMS may request further information. CMS believes that if this happens, it may be caused by data entry or unit error; misclassification of the price that is reported (for example, the net price estimate may actually reflect an intermediate price and not a net price); timing mismatch (for example, the net price estimate may reflect a different timeframe than the GUARD Model performance year for which it is submitted); inclusion or omission of an international product in the set of international analogs that is not aligned with the GUARD Model drug (for example, including international products with a dosage form of single-use when the GUARD Model drug is a multi-dose vial or including international products with an oral dosage form—for instance a tablet—and a strength of 5 mg when the GUARD Model drug has an inhaled dosage form and a strength of 5 mg); other errors; or legitimate reasons that require further context. In addition, because some of the reference countries use international reference pricing, we may also compare the reported data against the existing list prices or gross prices in other countries that use international reference prices. This would allow CMS to assess whether the data values submitted are within a reasonable range. If there are questions, CMS may reach out to the manufacturer for an explanation and make a determination based on the explanation.

In addition, CMS may, as part of the verification process and as proposed in § 514.310(b), check for internal consistency, which means that CMS would examine the full set of data submitted along with the explanation of how the data was collected or calculated, compare with publicly available existing data, and make a determination about whether the values are logically consistent. For example, as part of this approach, CMS would conduct net-to-gross ratio checks and use existing data and research to determine whether the values reported are within reasonable ranges. Under this

[166] Australian Department of Health, Disability and Ageing, Pharmaceutical Benefits Scheme. (n.d.). *A–Z Medicine Listing. https://www.pbs.gov.au/browse/medicine-listing* (Accessed: 10 December 2025).

[167] United Kingdom National Health Service. (n.d.). *Medicines A to Z. https://www.nhs.uk/medicines/* (Accessed: 10 December 2025).

[168] United Kingdom National Health Service Business Services Authority. (n.d.). *Drug tariff: Part VIIIA—Basic prices of drugs product list. https://www.drugtariff.nhsbsa.nhs.uk/#/00899627-DC/DC00899396/Part%20VIIIA%20-%20Basic%20Prices%20of%20Drugs%20Product%20List* (Accessed: 10 December 2025).

approach, CMS may compare net-to-gross ratios of a given GUARD Model drug with information from the reference countries about the net price of the drug. For instance, in the United Kingdom, the voluntary scheme for branded medicines pricing, access, and growth (VPAG) requires pharmaceutical companies to pay the National Health Services of the United Kingdom, a percentage of the sales of branded medicines. The percentage for 2025 was 22.9 percent and for 2026 it will be decreased to 14.5 percent.[169] So, for the United Kingdom, CMS would not expect country-level average net-to-gross discounts and rebates to be less than 0.15. CMS seeks comment as to whether a net-to-gross ratio tolerance should be considered or if a specific tolerance level should be defined.

In addition, CMS may consider temporal logic in assessing the validity of the data reported. For example, any changes in net price should track market events. CMS may examine historical publicly available data to determine whether the data submitted is reasonable. CMS encourages manufacturers to submit historical net price data, but CMS decided against making this a requirement due to the burden it might impose on manufacturers. CMS seeks feedback on whether this should be a required data element.

CMS may also conduct technical data quality checks. This includes but is not limited to verification that the data reported are in consistent units; the time period aligns with the GUARD Model performance year for which it is submitted; any sales-weighting is done appropriately; the data is submitted in the correct currency; and that any rounding and scaling is applied consistently and according to guidance.

CMS may also conduct cross-validation using external and public data. This means that CMS may check the data submitted against market data or any other relevant public data, including but not limited to financial filings in the United States as well as in reference countries. CMS may also review how the manufacturer has described the aggregation and weighting process for the set of international analogs that correspond to a GUARD Model drug for which the data was submitted. If there are concerns with the logic of how the data was aggregated, how the sales were allocated, or any other methodological concern, CMS may reach out to the manufacturer with questions. If the manufacturer is able to provide an explanation that is reasonable as assessed by CMS, CMS may consider the submission an applicable submission.

To facilitate the validation process, CMS recommends that manufacturers provide details for how they calculated the data elements for their selected option and any reasonable assumptions they made in the calculations. As part of the validity assessment, CMS may reach out to manufacturers with questions or request more information. CMS proposes at § 514.310(b) that manufacturers must respond to any questions related to the verification review in 15 calendar days. If a manufacturer does not respond, CMS will consider the submission to be unacceptable.

5. Alternatives Considered for the Submission Options

CMS considered offering a more comprehensive option for manufacturers to submit the international net pricing data. Under this option, in addition to the data elements noted in the previous options, manufacturers would have been required to submit more granular information. Specifically, in addition to submitting net sales amount at the net price level, manufacturers would be required to submit the corresponding price concessions at the net price level. However, we decided not to offer this option due to concerns around burden and challenges that manufacturers may experience in submitting data elements that are more detailed than the proposed options.

CMS also considered offering an option that allows manufacturers to submit, for the entire set of international analogs that correspond to a GUARD Model drug, only total gross revenue, total net revenue, and total volume across all reference countries. However, we decided against including this option in the proposal because CMS' ability to perform any verification would be limited.

We also considered whether, instead of manufacturers, CMS should calculate the country-level average net price and across-country average net price. We decided against this policy because we believe that the burden related to doing the calculations is minimal. In addition, we considered whether to require the manufacturer to also identify the lowest net price (and the reference country with this price) among the set of reference countries for the set of international analogs that correspond to a GUARD Model drug. However, as this information is already part of the submission, we did not believe it was necessary. We seek feedback on these policies.

In offering the two options noted previously, CMS balanced multiple policy priorities, including administrative burden for manufacturers and CMS; the need for complete and valid data submissions; and potential concerns that may arise from disclosing detailed international drug pricing information. CMS recognizes that manufacturers may encounter challenges in submission of the voluntary net pricing data for a number of reasons, including, for example, due to the way contracts are structured (for example, timing or the bundle of drugs included in sales contracts); the relationships that manufacturers may have with subsidiaries that sell drugs in the reference countries; and for other reasons. CMS seeks feedback on the types of relationships and arrangements manufacturers within U.S. have with the distributors, purchasers or other entities involved in the supply chain of the international analogs that correspond to a GUARD Model drug in the set of reference countries that may pose a challenge for manufacturers to compile and collect these data elements. We also seek feedback on other challenges that manufacturers may face in compiling and calculating these data elements and suggestions to address these challenges. CMS also seeks comments on whether there are specific data reporting issues CMS should consider, including existing mechanisms that could reduce data reporting and collection burden. We also seek comments on the voluntary framework and the proposed options, including the alternative options considered, to report net pricing information for international analogs that correspond to the GUARD Model drugs.

6. Attestation and Submission

CMS proposes that submitted data must comply with data requirements as proposed at § 514.310(b). Each submission must include an attestation by an authorized representative where they certify the completeness and validity of the data submission on behalf of the manufacturer and any third-party entities relied upon for gathering, analyzing, or submitting the manufacturer net pricing data, as proposed at § 514.310(g)(2). At § 514.300, CMS proposes to define ''authorized representative'' as an individual, designated by a manufacturer, as responsible for

[169] United Kingdom Department of Health and Social Care, & Ahmed, Z. (2025). *Innovative medicines supported as rebate rate falls by a third.* GOV.UK. *https://www.gov.uk/government/news/innovative-medicines-supported-as-rebate-rate-falls-by-a-third* (Accessed: 10 December 2025).

submitting international drug net pricing data, and who is also responsible for managing all communications related to the submission on behalf of the manufacturer. Authorized representatives must provide their contact information and attest that the submission is accurate and complete to the best of the manufacturer's knowledge, the submission is prepared in full compliance with all the requirements of § 514.310(b), and submitted with proper authority on behalf of the manufacturer. If a submission does not include the attestation as described, it would not be considered complete.

At § 514.310(h), CMS proposes to maintain confidentiality of information submitted under this section to the extent permitted by law and in accordance with applicable privacy and security requirements. CMS proposes that the data submission and attestation process would occur through the CMS Health Plan and Management System (HPMS), which is currently used for the Manufacturer Discount Program and the Drug Price Negotiation Program reporting, or another existing CMS data system that would be adapted for this purpose at § 514.310(i). We would adapt the existing functionality that has been used for the Part D Inflation Rebate Program, the Medicare Drug Price Negotiation Program, or other existing CMS program to the extent feasible. Leveraging existing technology and systems will facilitate executing the data agreements and attestations, creating data layouts for the various data submission pathways, and ensure stakeholder confidence that the data will be safely transmitted and securely stored. Further, using existing infrastructure also provides established safeguards comparable to other government price reporting mechanisms.

CMS recognizes the market-sensitive nature of international pricing data and proposes to maintain confidentiality to the extent allowable under law. CMS seeks comments on additional privacy safeguards CMS should consider for international pricing data submissions.

7. Timing, Corrections, and Resubmissions

As discussed previously, CMS proposes at § 514.310(b) that if the manufacturer is electing to submit international drug net pricing information, the data submission must occur within 180 calendar days after the end of a performance year and the data that is contained within the submission must correspond to the performance year for which the data may be used to determine the GUARD Model updated international benchmark. Recognizing potential challenges in international pricing data compilation, CMS is proposing to allow corrections and restatements of applicable submissions within 15 calendar days of the submission deadline. Following the previous example of the first performance year ending on December 31, 2027, where the manufacturers have to submit by June 29, 2028, at the latest, revisions are due July 14, 2028, at the latest. CMS may also request corrections or amendments, requiring eligible entity response within 15 calendar days of the request. CMS seeks comments on the sufficiency and appropriateness of proposed timelines.

In developing this policy, CMS also considered alternatives such as a longer timeline for submission of international drug net pricing information as manufacturers may need additional time for reconciliation of pricing data after the end of the calendar year. CMS understands that this process may vary widely by manufacturer and by reference country. As such, CMS seeks comments on whether the proposed timeline could create challenges for manufacturers submitting pricing data and how such challenges could be mitigated.

G. Determination of the GUARD Model Applicable International Benchmark

In this Section of this proposed rule, CMS describes the proposed approach to determine the GUARD Model applicable international benchmark that would be used to generate the GUARD Model rebate payment and test the alternative rebate calculation approach, as described in Section IV.H. of this proposed rule. In § 514.5, CMS proposes that the ''GUARD Model applicable international benchmark'' means, for each GUARD Model drug, the greater of the GUARD Model default international benchmark and, if available, the GUARD Model updated international benchmark; and for which an applicable adjustment factor has been applied.

We propose at § 514.5 that for each GUARD Model drug, the ''GUARD Model default international benchmark'' (also known as Method I) means for each GUARD Model drug, the lowest price in a set of country-level average prices calculated, using the steps proposed at § 514.410(c), for each reference country identified at § 514.220(d), where international drug pricing data is available from selected data sources per § 514.210 for at least one reference country and at least one reference country-level average price can be calculated. If the country-level average price is a weighted-average, the weights are the corresponding volume for a price expressed in the terms of the NCPDP unit corresponding to the GUARD Model drug. In other words, the GUARD Model default international benchmark would be the lowest among a set of country-level average prices which are either volume-weighted or not, depending on data availability, and are adjusted by the reference country's specific GDP (PPP) adjuster, per the steps proposed at § 514.410(c).

As mentioned previously, the other possible benchmark is the ''GUARD Model updated international benchmark'' (also referred to as Method II) which is defined at § 514.5 to mean, for each GUARD Model drug, the across-country average net price, which is a volume-weighted average across all reference countries, identified at § 514.220(d), where an international product that is part of the set of international analogs is sold, and includes GDP (PPP) adjustments; the across-country average net price is part of an applicable submission of international drug net pricing data by manufacturers according to § 514.310. Thus, it is an average net price across all international products that are part of the set of international analogs for a GUARD Model drug and all reference countries where these international products are sold for which data is available, weighted by volume in NCPDP units, expressed as the price for one, and adjusted by the reference country's specific GDP (PPP) adjuster.

1. Calculation of the GUARD Model Default International Benchmark

CMS proposes to calculate for every GUARD Model drug, a GUARD Model default international benchmark, in advance of determining the GUARD Model rebate amount for the first performance year. If after the first performance year, CMS identifies a new GUARD Model drug for any of the 4 subsequent performance years, then CMS would calculate a GUARD Model default international benchmark for the new GUARD Model drug, as described in this Section of this proposed rule, prior to the GUARD Model rebate payment calculation, as described in section IV.H. of this proposed rule, but not for any of the GUARD Model drugs which already have a GUARD Model default international benchmark for the previous performance year.

By proposing at § 514.410(c) that once a GUARD Model default international benchmark is established, it is not changed, the possibility of having no international drug pricing data for one

or a number of GUARD Model drugs during a subsequent performance year, while others continue to have data, would be minimized. While CMS recognizes that there can be varying reasons for data discontinuity, if the GUARD Model drug continues to be sold during the GUARD Model performance period, CMS seeks to mitigate the possibility that lack of data for subsequent performance years is due to manufacturers' limiting availability of international drug pricing data.

In addition, by not changing the GUARD Model default international benchmark, any changes to gross prices in reference countries that do not necessarily represent increases in net prices—for example, due to accompanying increases to price concessions—would not impact the GUARD Model test, mitigating the possibility of price manipulation in reference countries.

For the same reasons, CMS believes that GUARD Model drugs that first qualify as such after the first performance year should be subject to the same process; thus, determination of their GUARD Model default international benchmark would take place prior to GUARD Model rebate payment determination for the earliest subsequent performance year when they qualify as GUARD Model drugs and then not change for the remainder of the GUARD Model performance period.

a. Identifying the Set of International Analogs

For calculation of the GUARD Model default international benchmark, CMS proposes in § 514.410(c) to use the selected data source of international drug pricing data to identify data for the set of international analogs that align with each GUARD Model drug. This involves identifying international products whose identifying characteristics align, as determined by CMS, with those of the GUARD Model drug. The identifying characteristics are active ingredient(s), route of administration, dosage form, and strength. The alignment of the characteristics would be achieved using the standardized method for differentiating products across these dimensions intrinsic to the data source (or sources) selected for use according to § 514.210(b).

To facilitate this identification, CMS would make adjustments as necessary, for example, by measurement unit conversion factors, so that the international products for a given GUARD Model drug are consistent with one another and with the GUARD Model drug's NCPDP unit. These adjustments would not affect CMS' determination that the set of international analogs—composed of the international products with adjustments if needed—are aligned with the GUARD Model drug. CMS will use all available information to ensure that adjustments are appropriate. Examples of information sources are FDA sources, such as approved product labels, the *Drugs@FDA* regulatory approval database, the Purple Book and Orange Book, and the NDC Directory, the National Library of Medicine's RxNorm database, and the selected data source(s) documentation.

A more detailed description of the identification process follows here. To begin, CMS would identify from the selected data source(s), all of the international products whose identifying characteristics (active ingredient(s), route of administration, dosage form, and strength) are aligned with the GUARD Model drug, without any adjustments.

Next, for international products where their identifying characteristics do not exactly align with the GUARD Model drug's characteristics, standard adjustments that do not materially change the drug's characteristics would be applied. These include, for example, applying measurement unit conversion factors, removing prefixed or suffixes from active ingredient names, matching scientific names to active ingredient(s), and checking for idiosyncratic differences in spelling or formatting. For example, as an illustrative case, this means that if a data source has the chemical name (2S)-2-amino-3-(3,4-dihydroxyphenyl)propanoic acid, this would be equivalent and aligned to the active ingredient, levodopa. Any potential international products that, after these standard adjustments, are aligned across all their identifying characteristics to the GUARD Model drug, would be considered satisfactorily aligned.

For any international products that, after the standard adjustments, are still not aligned across all identifying characteristics of a GUARD Model drug, CMS would conduct further review. Specifically, CMS would determine whether any differences in identifying characteristics can be considered insignificant because, for example, they are attributable to the selected data source(s) internal record keeping or reference country specific considerations.

An example of a difference between product characteristics that CMS would consider equivalent related to a data source's internal record keeping is where a drug has the dosage form characteristic described as a disposable vial in some countries but in others, the dosage form is a single-dose vial. Disposable vials are single-dose vials (which are not multi-dose vials). In this case, CMS would determine that the potential international analogs with both dosage forms, disposable vial and single-dose vial, are aligned with the GUARD Model drug described at the NDC–9 level as having a single-dose vial dosage form. As another example, CMS could determine that, for a GUARD Model drug with an extended release oral solid formulation, all international products sharing the same active general form (extended release oral solids) with dosage strengths measured on the same basis (for example, active ingredient mass per unit) as the GUARD Model drug could qualify as international analogs, even if the data source used by CMS further differentiates between different subcategories of extended release oral solids (such as tablets and capsules).

An example of country-specific considerations that CMS would take into account relates to the names of active ingredients. Although not a GUARD Model drug, in the U.S. and Japan, acetaminophen is an active ingredient, while in most other countries, instead of being called acetaminophen, it is referred to as paracetamol. In this case, CMS would consider acetaminophen and paracetamol aligned for the active ingredient characteristic.

Next, for any GUARD Model drug that is still not aligned with international products across all identifying characteristics (after the standard adjustments and review for non-significant differences), CMS would conduct further review. CMS proposes to further examine international products where the remaining misalignment is only in strength (this means the GUARD Model drug and the international products align in terms of active ingredient, route of administration, and dosage form) for cases when there is no other international product already aligned for a GUARD Model drug in a reference country. In other words, for reference countries where the GUARD Model drug's set of international analogs has at least one fully aligned international product, strength-misaligned international products would not be considered. However, for reference countries where the GUARD Model drug's set of international analogs has no fully aligned international products, strength-misaligned international products will be further considered depending on the number of strength-

misaligned international products available.

If there is only one strength-misaligned international product within a reference country, then it would be included in the set of international analogs for the GUARD Model drug and be used in determining the GUARD Model default international benchmark.

If there is more than one strength misaligned-international analog product for a given reference country, CMS would find the relative difference in terms of strength between the two closest (in absolute terms) international analog product strengths to the GUARD Model drug's strength and compare it to the relative difference in prices for those same two strength-misaligned international products, unless the higher strength international product has a lower or equal price to that of the lower strength international product, in which case both international products are included in the set of international analogs. For example, if the GUARD Model drug's strength is 12 mg, and there are two strength-misaligned international analog products with strengths of 10 mg and 20 mg, their relative strength difference would be (20 mg-10 mg)/10 mg or 100 percent. If the prices for those same two strength-misaligned international products were $2.00 per NCPDP unit for the 20 mg strength and $1.25 per NCPDP unit for the 10 mg strength, their relative price difference would be ($2.00–$1.25)/$1.25 or 60 percent. If instead the prices of those same two strength-misaligned international products were reversed, meaning the price of the 20 mg strength was $1.25 and the price of the 10 mg strength was $2.00, then the price of the larger strength international product is lower than that of the lower strength international product and therefore both the 10 and 20 mg strength international products would be included in the set of international analogs and the comparison between relative differences of strengths and prices would not be considered.

In cases where the comparison of the relative difference in strengths to the relative difference in prices is considered, there are two potential options:

- If the relative price difference is equal to or greater than half of the relative strength difference within a reference country, then CMS would include in the set of international analogs, the international product whose strength is closest in magnitude to the strength of the GUARD Model drug (in that reference country, and in absolute terms, with ties defaulting to the lower-strength international product). For the above 10 mg and 20 mg example for an arbitrary reference country and a GUARD Model drug with a strength of 12 mg, this means that the 10 mg international product would be included in the set of international analogs for the GUARD Model drug (because 10 mg is closer to 12 mg in absolute terms than 20 mg).
- If the relative price difference is less than half of the relative strength difference, then both of the strength-misaligned international products with the closest strengths in absolute terms to the GUARD Model drug would be included in the set of international analogs for the GUARD Model drug. In the example noted previously, if the strength-misaligned international product with a strength of 20 mg has a starting price of $1.50 instead of $2.00, then the relative price difference is 20 percent, which is less than 50 percent. In this case, both the 10 mg and 20 mg international products would be included in the set of international analogs with their prices as observed in the data source and be part of the calculation of the GUARD Model default international benchmark.

Last, CMS may determine that potential international products are aligned with a GUARD Model drug and therefore would be included in the set of international analogs based on other factors, as long as they do not materially differ from the GUARD Model drug and if necessary, CMS would make methodologically appropriate adjustments for such inclusions. For example, for a strength-misaligned GUARD Model drug with more than one active ingredient, if there are combination products with the same set of active ingredients but different configurations of dosage strength in other countries, CMS could determine that the international products are sufficiently aligned with the GUARD Model drug.

Any potential international products that are still not aligned with a GUARD Model drug with respect to its identifying characteristics after the process described previously, would not be included in the set of international analogs used for calculation of the GUARD Model default international benchmark. CMS believes that, using the identification process described previously, we will be able to identify sets of international analogs for each GUARD Model drug to the extent to which the existing data sources of international drug pricing data, selected according to § 514.210(c), include such international analogs for the reference countries, identified in § 514.220(d). Under the proposed approach, CMS would identify international analogs that are aligned with each GUARD Model drug, accounting for country-specific or data source idiosyncratic differences. CMS seeks comment on the alignment process, the strength-misalignment strategy for cases with no other international products in the set of international analogs, and on other adjustments that could be considered.

b. Exclusion of International Products From the Set of International Analogs

For each GUARD Model drug, once we have identified a set of international analogs that are aligned to the GUARD Model drug, CMS proposes at § 514.410(c)(3)(i) to exclude any international products identified in the selected data source as being an international generic or international biosimilar biological product according to the reference country's regulatory framework. This means that if the international product has sales in multiple reference countries, the data for the reference countries where it is classified in the data source as an international generic or an international biosimilar biological product based on the own-country's regulatory system would be excluded. The data for the reference countries where they are not classified as such would be retained.

By excluding international generics and international biosimilar biological products among international products, CMS aims to keep the differences between the GUARD Model drugs—which do not include any generics or biosimilar biological products—and their set of international analogs as limited as possible to just the country of sale and price. CMS believes that this is reasonable because it means there are no generics or biosimilar biological products among either the GUARD Model drugs or the corresponding set of international analogs.

We considered the option of including international products in the set of international analogs even if they are categorized as international generics and international biosimilar biological products, according to a reference country's regulatory framework. However, CMS believes that given the exclusion of sole-source generics and all biosimilar biological products from the GUARD Model, doing the same among international products results in appropriately matching GUARD Model drugs to their corresponding international products. We seek feedback on this approach.

CMS proposes at § 514.410(c)(3)(i) to exclude an international product from being part of the set of international analogs for a GUARD Model drug if in

the selected data source, its pricing information (price, sales, or volume) aggregated for the entire period observed has a value of zero or less than zero. Exclusion of these international products is necessary because they would not contribute to the calculation of the GUARD Model default international benchmark. We expect that this exclusion would affect very few international products given the data selection requirements from section IV.E. of this proposed rule.

CMS considered excluding an international analog in a reference country where the amount of sales dollars or the number of units sold for the entire 12-month period for that reference country was under a specific threshold. CMS believes that it is not necessary to apply exclusions based on total annual sales or units sold amounts in a reference country because small magnitudes of sales or units sold are valid data points; in the interest of improving precision of the GUARD Model default international benchmark, CMS believes this data should be utilized.

c. Other Considerations for the Sets of International Analogs

Data for the set of international analogs for all reference countries where it is sold for each GUARD Model drug, to the extent that the data is available in the selected data source(s), must be expressed in the GUARD Model drug's unit—the minimum possible dosing unit in a NCPDP standard. To achieve this, CMS would convert the international analog volume data from the selected data source's dosing unit to the corresponding NCPDP standard dosing unit. For example, assume that for the selected period in reference country Y, 100 units of an international analog A were sold. In the selected data source, the unit for international analog A is described as milliliter; the dosage form describes a syringe; and the pack size describes a two-ml syringe. As for the GUARD Model drug's unit, it is an each, which corresponds to 2-ml syringes. Thus, a conversion is needed. In this case, 50 units of international analog A were sold in reference country Y, in terms of NCPDP units.

Additionally, sales and prices would be expressed in U.S. dollars. Since data for the set of international analogs for each GUARD Model drug is across one or more reference countries, it is possible that the selected data source expresses prices and sales amounts in U.S. dollars, local currency, or some other standard currency. Using the selected data source's exchange rates for currency conversion, all prices and sales amounts would be converted to U.S. dollars.

d. Process To Calculate GUARD Model Default International Benchmark

For each GUARD Model drug, CMS proposes at § 514.410(c)(iii) the steps to calculate a country-level average price for each reference country where international products part of the set of international analogs for a GUARD Model drug are sold, and among this set of country-level average prices, the lowest would be the GUARD Model default international benchmark. The calculation of the country-level average prices would use data for a GUARD Model drug's set of international analogs which includes international products for each reference country for the selected 12-month period per § 514.210; these data would be identified as outlined in § 514.410(c)(3)(i), converted (if necessary) to be in the appropriate GUARD Model drug's NCPDP unit, and converted (if necessary) into U.S. dollars.

The set of country-level average prices is composed either of average prices or volume-weighted average prices and each price of the set is a unitary price. If volume data is available, weights would be used to obtain the volume-weighted average, where the weights are in terms of volume as measured in NCPDP units; if volume data is not available then simply average prices would be calculated.

If volume data is available, the steps CMS proposes for calculating the country-level average price for a reference country, per § 514.410(c)(3)(iii), are as follows:

- First, each price (in U.S. dollars) for an international analog in a reference country will be multiplied by its corresponding volume (in NCPCP units corresponding with the GUARD Model drug unit) to obtain a weighted-price. If instead of a price, the selected data source provides sales amounts, then each sales amount (in U.S. dollars and for NCPDP units) is the weighted-price. The weighted-price is multiplied by the GDP (PPP) adjuster as defined at § 514.5.
- Second, CMS will calculate the reference country total weighted-price by adding up the weighted-prices from the first step, and the reference country total volume by adding up the volumes in NCPDP units.
- Third, CMS will divide total weighted-price and total volume from step two, obtaining the reference country's volume-weighted average price for one NCPDP unit of the international analog.

This process is repeated for each reference country, resulting in a set of country-level average prices from which the lowest in absolute terms is selected as the GUARD Model default international benchmark for the GUARD Model drug.

If volume data is not available—that is, the selected data source only has price data—then, CMS proposes to calculate the average price for a reference country at § 514.410(c)(3)(iii) by first ensuring all prices for a reference country are converted, if necessary, into the GUARD Model drug NCPDP unit, then expressed in terms of a unitary price (the price for one NCPDP unit), and multiplied by the GDP (PPP) adjuster as defined at § 514.5. Next, all these prices are added together and divided by the number of prices available resulting in a reference country's average price for one NCPDP unit. This process is repeated for each reference country, resulting in a set of country-level average prices from which the lowest in absolute terms is selected as the GUARD Model default international benchmark for the GUARD Model drug.

CMS considered excluding from the set of country-level average prices, those prices that are less than 5 or 10 percent of the GUARD Model drug's ''performance year Medicare net price'' which, as described in section IV.H.2. of this proposed rule and defined at § 514.5, is a per unit net price for the GUARD Model drug during the performance year, expressed in terms of NCPDP units calculated according to § 514.510(b) using the WAC, manufacturer direct and indirect remuneration (DIR), discounts from the Manufacturer Discount Program, and quantity dispensed across all PDE records associated with the GUARD Model drug during a performance year. As an example, if a GUARD Model drug's performance year Medicare net price is $120 and the set of country-level average prices that resulted from the international products included in the set of international analogs is $20, $10, and $5. The exclusion of country-level average prices that are less than 5 percent of the performance year Medicare net price would mean that prices less than $6 would be excluded, therefore only the $20 and $10 prices would remain in the set to be used in calculating the GUARD Model default international benchmark. The exclusion of volume-weighted average prices that are less than 10 percent of the performance year Medicare net price would mean that prices less than $12 would be excluded, therefore only the $20 price would remain in the set to be

used in the calculation of the GUARD Model default international benchmark. However, CMS believes that including all available data increases accuracy and precision so we have not proposed this approach.

CMS also considered using an across country average instead of the lowest country average and using averages without volume-weighting for calculating the GUARD Model default international benchmark. However, an across country average does not represent an actual price paid for a GUARD Model drug in the reference countries, and using averages without volume-weighting, when volume is available, does not best reflect the typical price in a country because the amount a price should influence a country's average should correspond to how much of that country's sales volume is sold at that price.

In summary, the GUARD Model default international benchmark is the lowest (reference) country-level average price in U.S. dollars across international products included in a GUARD Model drug's set of international analogs sold in that reference country. It is calculated using international drug pricing data from selected data sources, excluding any international generics or international biosimilar biological products given the reference country's regulatory framework.

The GUARD Model default international benchmark is calculated for all GUARD Model drugs after the first performance year when they are included—and prior to that performance year's GUARD Model rebate payment determination. Once a GUARD Model default international benchmark has been calculated, it will serve as the GUARD Model default international benchmark for the remainder of the GUARD Model performance period. We welcome comment on this proposal and the alternatives presented.

2. Identification of the GUARD Model Updated International Benchmark

CMS proposes to determine, for every GUARD Model drug with an applicable submission of international drug net pricing data, a GUARD Model updated international benchmark (also referred to as Method II) in advance of the GUARD Model rebate payment determination, for every performance year for which an applicable submission is received, as described in section IV.F. of this proposed rule.

In the case where a GUARD Model drug has a GUARD Model updated international benchmark for a performance year, but for the next performance year, CMS does not receive an applicable submission—for the next performance year and any subsequent performance years where there is no applicable submission, CMS proposes to utilize the default international benchmark. This is because for there to be a GUARD Model updated international benchmark for a performance year, there must be a corresponding applicable submission covering the dates for that performance year. Thus, for any subsequent performance year without an applicable submission, regardless of whether at any point previously in the GUARD Model performance period there was an applicable submission, CMS proposes that there would be no GUARD Model updated international benchmark.

By proposing that the GUARD Model updated international benchmark be limited to the performance year for which the applicable submission is received, CMS believes the most recent net price data should be used and that there would be no concerns regarding availability of net pricing data should a manufacturer choose to submit it. Manufacturer submitted data would therefore be for the same period as the one CMS would use to obtain the performance year Medicare net price, as discussed in section IV.H.2.a. of this proposed rule, which would be used to calculate the GUARD Model rebate amount for that performance year. CMS considered but decided against, using a GUARD Model updated international benchmark from a previous performance year—meaning it would have been determined from manufacturer submitted data for a previous performance year—because, given the voluntary nature of the data submission, the main focus is on ensuring the data is the most reflective of the specific performance year to which it corresponds. CMS seeks feedback on this approach.

Additionally, CMS believes that since the GUARD Model test would only determine a GUARD Model updated international benchmark if there is an applicable submission and otherwise would use the GUARD Model default international benchmark, it would encourage manufacturers to voluntarily submit data, which increases transparency.

CMS proposes in § 514.410(d) that the GUARD Model updated international benchmark would be the across-country average net price data element part of the applicable submission. This average is across the reference countries where international products that are part of the set of international analogs are sold in each of the reference countries; it is volume-weighted using the volume—units in NCPDP equivalent; and GDP (PPP)-adjusted to account for country-level differences. CMS would obtain this average from the manufacturer's submission, if it is deemed applicable. The use of an across-country average net price for the GUARD Model updated international benchmark instead of the lowest country average as in the GUARD Model default international benchmark is due to the differing nature of the prices. For the GUARD Model default international benchmark, the set of prices are derived from the selected data source are likely to be ex-manufacturer prices—prices paid to the manufacturer by wholesalers and other distributers—but this is not guaranteed; they could potentially represent prices based on a distribution channel, or another variation, as described in section IV.E. of this proposed rule. Given the increased likelihood that prices are consistent within country but not necessarily across countries (due to using the best available data, which could still potentially be derived from different sources) and the nature of the prices (for example, depending on the time period and reference country), CMS believes it is preferable to select a country price and not average across countries when using the existing international data source. For the GUARD Model updated international benchmark, the net pricing data is reported by the manufacturer who is able to observe actual net prices, so we believe it is acceptable to use an average. We seek feedback on this approach.

3. Adjustment of the Applicable International Benchmark

In § 514.410(b), CMS proposes to determine the ''GUARD Model applicable international benchmark'' for each GUARD Model drug by identifying the greater of between the default international benchmark and the updated international benchmark and then applying an applicable adjustment factor. We propose at § 514.410(e), that when the GUARD Model applicable international benchmark is based on the GUARD Model default international benchmark, the applicable adjustment factor is 102 percent; if it is based on the GUARD Model updated international benchmark, the applicable adjustment factor is 105 percent. CMS also proposes the GUARD Model default international benchmark and the corresponding applicable adjustment factor would be used when there is no GUARD Model updated international benchmark for a performance year. Table B7 provides an illustrative example of how CMS would determine the GUARD Model applicable

international benchmark for a fictious GUARD Model drug during the performance period.

CMS believes that a 2 percent adjustment for the GUARD Model default international benchmark accounts for potential differences between the U.S. market and markets in the set of reference countries for which international drug pricing information is available. Although the proposed calculation for the GUARD Model default international benchmark price includes adjustments for economic and purchasing power differences, further adjustment for some potential remaining differences by applying a minimal adjustment could be warranted. Therefore, we propose a 2 percent increase in the GUARD Model default international benchmark amount to account for potential differences between the U.S. market and markets in the reference countries that would not be addressed otherwise, meaning that the GUARD Model default international benchmark would represent 102 percent of the original value after adjustment. We believe a 2 percent adjustment is appropriate because the GUARD Model default international benchmark is already based on the lowest country-level average price among the set of reference countries.

CMS also believes a 5 percent adjustment for the GUARD Model updated international benchmark accounts for potential differences between the U.S. market and markets in the set of reference countries for which international drug pricing information is available. Although the proposed calculation for the GUARD Model updated international benchmark price includes adjustments for economic and purchasing power differences, further adjustment for some potential remaining differences by applying a minimal adjustment could be warranted. In addition, such an adjustment, if it is greater than the adjustment for the GUARD Model default international benchmark could incentivize manufacturer submission of international net pricing data. Therefore, we propose a 5 percent increase in the GUARD Model updated international benchmark amount to account for potential differences between the U.S. market and markets in the reference countries that would not be addressed otherwise; this means that the GUARD Model updated international benchmark would represent 105 percent of the original value after adjustment. This would also maintain an incentive for manufacturers to submit the voluntary international net pricing data.

We considered different adjustment factors however, we believe an adjustment factor of 2 percent for the GUARD Model default international benchmark and an adjustment factor of 5 percent for the GUARD Model updated international benchmark is appropriate given the other types of adjustments across the reference countries (for example, GDP (PPP) adjustments). We welcome comments on our proposal for the applicable adjustment factor that may help advance the aims of the model test.

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TABLE B7: ILLUSTRATIVE DETERMINATION OF GUARD MODEL APPLICABLE INTERNATIONAL BENCHMARKS FOR THE GUARD MODEL PERFORMANCE PERIOD

GUARD Model Drug	Intl. Pricing Data that Allows for Calculation of Default Intl. Benchmark	Calculation of the Default Intl. Benchmark	Voluntary Manufacturer Submission	Applicable Submission that Allows for Determination of the Updated Intl. Benchmark	Applicable Intl. Benchmark
PY 1					
1	No	No	No	N/A	None
2	Yes	Yes	No	No	Default intl. benchmark
3	Yes	Yes	Yes	Yes	Greater of default and updated intl. benchmark
PY 2					
1	Yes	Yes	No	No	Default intl. benchmark
2	N/A	No, use PY1	No	No	Default intl. benchmark
3	N/A	No, use PY1	Yes	Yes	Greater of default and updated intl. benchmark
PY 3					
1	N/A	No, use PY2	No	No	Default intl. benchmark
2	N/A	No, use PY1	Yes	No	Default intl. benchmark
3	N/A	No, use PY1	Yes	Yes	Greater of default and updated intl. benchmark
4	Yes	Yes	No	No	Default intl. benchmark
PY 4					
1	N/A	No, use PY2	No	No	Default intl. benchmark
2	N/A	No, use PY1	No	No	Default intl. benchmark
3	N/A	No, use PY1	Yes	Yes	Greater of default and updated intl. benchmark
4	N/A	No, use PY1	No	No	Default intl. benchmark
PY 5					
1	N/A	No, use PY2	No	No	Default intl. benchmark
2	N/A	No, use PY1	No	No	Default intl. benchmark
3	N/A	No, use PY1	Yes	Yes	Greater of default and updated intl. benchmark
4	N/A	No, use PY1	No	No	Default intl. benchmark
5	Yes	Yes	Yes	Yes	Greater of default and updated intl. benchmark

Notes: PY stands for performance year, as defined at § 514.5; Intl. Benchmark stands for International Benchmark; N/A stands for not applicable.

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4. Alternatives Considered

CMS considered an alternate process for identifying the set of international analogs from the selected data source of international drug pricing data. The process proposed in § 514.410(c)(3)(i) is to identify international products whose identifying characteristics align each GUARD Model drug both without any adjustments and with standard adjustments that do not change the drug's characteristics and that have non-significant differences. For any GUARD Model drugs for which there is no international product aligned but there is at least one strength-misaligned international product, CMS proposes in § 514.410(c)(3)(i), a process to consider drug pricing information for the strength-misaligned product(s) for the GUARD Model drug. An alternate process that CMS considered is to apply the process to consider drug pricing information for the strength-misaligned product(s) to all GUARD Model drugs, and not only to those that have no aligned international products. This would result in an increased number of international products contributing to the drug pricing information used to calculate the GUARD Model default international benchmark.

CMS also considered changes to the identification process in relation to which strength-misaligned product(s) would be retained. One alternative possibility that CMS considered was for cases when there is more than one strength-misaligned international product for a reference country; for such a case, records for the two strength-misaligned international products closest in strength (in absolute terms) to the GUARD Model drug's strength would be retained without any further considerations. This is different from the proposed process of comparing the relative strength difference and relative price difference to determine if one or two of the strength-misaligned international products closest in strength to the GUARD Model drug's strength would be retained.

Another possibility that CMS considered was for cases when there is more than one strength-misaligned product for a reference country and the relative difference is equal to or greater than half of the relative strength difference. In these cases, CMS has proposed to retain records for the strength-misaligned international product whose strength is closest in absolute terms to the GUARD Model drug's strength. The alternative CMS considered was to retain the same strength-misaligned international product whose strength is closest in absolute terms to the GUARD Model drug's strength but to modify its price by multiplying it by the ratio of strengths between the two strength-misaligned international products closest to the GUARD Model. CMS seeks comment on these alternative identification processes.

CMS considered a range of alternatives for identifying the GUARD Model default and updated international benchmarks. Specifically, CMS considered using the lowest country level price for the GUARD Model updated international benchmark, however, we decided against this due to concerns about the sensitivity around net price data. We seek comments on the proposed approach, and in particular, whether we should consider using the lowest country-level average net price for the GUARD Model updated international benchmark. For the GUARD Model default international benchmark, CMS considered the possibility of adjusting annually for inflation. However, it is not clear how best to do that given the differences in reference countries that exist and because each drug may have a different reference country that is used to identify the GUARD Model default international benchmark; it is also not clear if inflation adjustment should be only relative to a U.S. price or if it should consider inflation in reference countries. Therefore, we are soliciting comments on this potential policy to inflation adjust the GUARD Model default international benchmark and the best ways to implement this.

CMS also considered, for the calculation of the GUARD Model default international benchmark, not adjusting country-level average prices to account for economic differences among countries, such as GDP per capita, prior to the comparison of the available set of country-level average prices to identify the lowest country-level average price for a GUARD Model drug. We considered that perhaps there was not a need to GDP (PPP) adjust a single country-level average price for several reasons. First, the default GUARD Model default international benchmark represents an average within a country that would be expressed in U.S. dollars using the appropriate exchange rate for currency conversion. Second, while adjusting for GDP (using PPP) is valuable for selecting economically comparable countries, at the more granular level, it is limited in its ability to account for local differences in costs, taxes, tariffs, and competition.[170] Third, CMS considered that allowing the GUARD Model default international benchmark to remain unadjusted would create a benefit for manufacturers should they choose to submit net pricing information as discussed in Section IV.F. of this proposed rule. However, we decided against this because we believe that GDP (PPP) adjustment is the best practice when examining prices across countries. CMS welcomes comments on this alternative considered and other alternatives presented here, as well as our policy proposals.

Another alternative for calculation of the GUARD Model default international benchmark considered was updating said benchmark each performance year if a subsequent performance year's calculation resulted in a lower benchmark or if it changed at all. However, we decided against this to ensure that data availability did not result in some GUARD Model drug's being updated and others not.

We also considered a different approach to calculating the adjustment factor for the GUARD Model default and updated international benchmarks. In developing our proposal for the adjustment factor, we considered two options for structuring the adjustment: (1) applying a fixed adjustment (such as a percentage amount) for all GUARD Model drugs regardless of the benchmark method; or (2) applying a variable adjustment that reflects one or more characteristics of the GUARD Model drug, the alternative rebate calculations, or reference countries. Another alternative CMS considered was to delay enactment of the adjustment factor. This would mean that instead of applying the adjustment factor in performance year one, it would be applied during a subsequent performance year. We seek comment on whether the enactment of the adjustment factor should be implemented as proposed or delayed to a subsequent performance year. We also considered that no adjustment would be necessary. However, we opted to prioritize a straightforward approach that is intuitive and easy to implement. We seek feedback on whether an adjustment factor should be applied to the GUARD Model default and updated international benchmarks and the value of the adjustment factor, including any rationale for why it should be increased

[170] Pakko, M.R., and Pollard, P.S. (2003). Burgernomics—A Big Mac™ Guide to Purchasing Power Parity. *Review, 85* (Nov), 9–28. Federal Reserve Bank of St. Louis. *https://fedinprint.org/item/fedlrv/25916.*

or decreased or applied in a different way.

CMS welcomes feedback on all of the policies presented in this section of this proposed rule and the alternatives considered.

H. Determination of the GUARD Model Rebate Payment Amount

The GUARD Model would test an alternative calculation of the rebate amount described in subsection (b) of section 1860D–14B of the Act for the purpose of testing whether this reduces Medicare expenditures while preserving or enhancing quality of care; this alternative calculation would yield the ''GUARD Rebate Payment Amount.'' Under the GUARD Model, we would waive the calculation described in subsection (b) of section 1860D–14B of the Act—replacing it with the GUARD Rebate Payment Amount—in circumstances where the per unit GUARD Model rebate, as described later in this Section of this proposed rule, exceeds the per unit Part D inflation rebate amount for a GUARD Model drug in a given GUARD Model performance year.

In this Section of this proposed rule, we describe our proposal for the alternative calculation of the rebate amount described in section 1860D–14B(b) of the Act to yield the GUARD Rebate Payment amount, including the steps to calculate the performance year Medicare net price and the per unit GUARD Model rebate, as well as determining whether the per unit GUARD Model rebate exceeds the per unit Part D inflation rebate amount. To clearly identify the alternative rebate under the GUARD Model test, CMS would calculate the total GUARD Model rebate payment amount for which manufacturers would be accountable. To avoid potential duplication across activities under the Medicare Part D Drug Inflation Rebate Program, an incremental per unit GUARD Model rebate amount (calculated by comparing the per unit Part D inflation rebate amount to the per unit GUARD Model rebate) would be multiplied by the total GUARD billing units to calculate the Total Incremental GUARD Model rebate amount (as described later in this section of this proposed rule). This amount would be used to reconcile the amounts invoiced through the Medicare Part D Inflation Rebate Program against the total GUARD Model rebate payment amount.[171] This amount would be reflected in the follow-on steps for GUARD Model reporting, invoicing, and rebate payment as discussed in section IV.I. of this proposed rule. The Total Incremental GUARD Model rebate amount would be adjusted prior to these follow-on steps, when applicable, for GUARD Model drugs in shortage or when there is a severe supply chain disruption or likely shortage, as discussed in this Section of this proposed rule. We also include proposals for how we aim to account for the Manufacturer Discount Program.

The alternative calculation tested under the GUARD Model that would be used to yield the GUARD Model Rebate Amount compares a Medicare net price (that excludes manufacturer direct and indirect remuneration (DIR) and discounts paid under the Manufacturer Discount Program) for each GUARD Model drug against the GUARD Model applicable international benchmark. Comparison against a Medicare net price that is exclusive of the manufacturer DIR and Manufacturer Discount Program discount amounts ensures that the GUARD Model applicable international benchmark is compared against a price that takes into account rebates and discounts provided by manufacturers. CMS proposes this approach so that manufacturers receive ''credit'' for the rebates and discounts that they have provided to Part D plans or their PBMs and these amounts are subtracted in the calculation of the GUARD Model Rebate amount.

1. Calculation of the Total GUARD Model Rebate Drug Amount

At proposed § 514.510, CMS describes the calculation of the total GUARD Model rebate amount for a GUARD Model drug for a performance year. Specifically, CMS is proposing that the total GUARD Model rebate amount would be equal to the product of (1) the per unit GUARD Model Rebate amount for such GUARD Model drug for the performance year, and (2) the total number of units of the GUARD Model drug dispensed under Part D and covered by Part D plan sponsors for beneficiaries residing in the GUARD Model geographic areas during the performance year.

2. Calculation of the per Unit GUARD Model Drug Rebate Amount

To calculate the per unit GUARD Model rebate amount, CMS is proposing at § 514.510(b) that CMS would determine the amount by which the performance year Medicare net price for a GUARD Model drug exceeds the GUARD Model applicable international benchmark, illustrated in Figure B1. CMS proposes calculations for the performance year Medicare net price and comparison of these amounts to produce the per unit GUARD Model rebate amount.

Figure B1: Calculation of Per Unit GUARD Model Rebate Amount

a. Calculation of the Performance Year Medicare Net Price

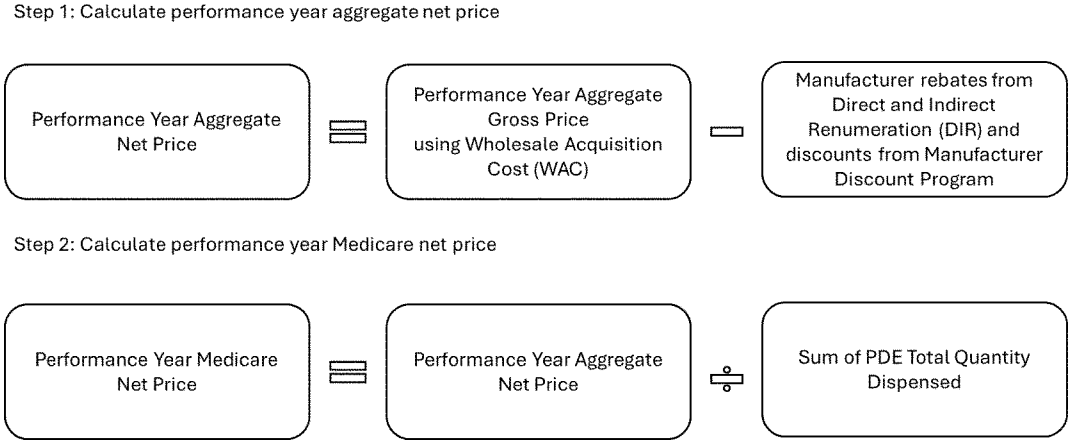
CMS is proposing that the performance year Medicare net price for a GUARD Model drug would be a per unit net price for the GUARD Model Part D rebatable drug during the performance year, expressed in terms of NCPDP units. To generate the performance year Medicare net price, CMS proposes to first calculate a performance year aggregate gross price using WAC, then subtract manufacturer rebates derived from detailed DIR [172]

[171] There are differences in timing between the GUARD Model's performance year and the Part D Drug Inflation Rebate Program's applicable period. Specifically, while the GUARD Model's performance year would be implemented on a calendar year schedule, the Part D Drug Inflation Rebate Program's applicable period is based on a fiscal year schedule. As a result, there would be Part D inflation rebate amounts from 2 fiscal years of the Part D Inflation Rebate Program that contribute to the GUARD Model's single performance year report for a GUARD Model drug. To compare the per unit Part D inflation rebate amount to the per unit GUARD Model rebate, the Part D inflation rebate amount would be weighted to produce a per unit performance year Part D inflation rebate amount as described in this section of this proposed rule.

[172] Centers for Medicare & Medicaid Services. (2025). *HPMS memos—Week 4: April 21–25*. U.S. Department of Health and Human Services. *https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-april-21-25* (Accessed: 10 December 2025).

reported by Part D plan sponsors and discount amounts provided by manufacturers via the Manufacturer Discount Program to produce a performance year aggregate net price. Finally, CMS proposes to divide the performance year aggregate net price by the sum of the total quantity dispensed across all PDE records associated with the GUARD Model drug during the performance year to yield the performance year Medicare net price. These steps are illustrated in Figure B2 and described in further detail.

Figure B2: Calculation of Performance Year Medicare Net Price for a GUARD Model Drug



CMS proposes at § 514.510(b) to use WAC as the starting point to calculate the performance year Medicare net price for the purpose of calculating the GUARD Model rebate amount. Section 1847A(c)(6)(B) of the Act defines WAC as the manufacturer's list price for the drug to wholesalers or direct purchasers in the United States as reported in wholesale price guides or other publications of drug pricing data. We believe that using WAC is appropriate for these reasons: (1) WAC is the manufacturer determined list price for the drug and the starting point for negotiations within the pharmaceutical drug supply chain market; (2) WAC does not include any discounts, rebates, or any other price concessions, which means it is an appropriate price from which to subtract manufacturer rebates, as identified in DIR, as well as discount amounts from the Manufacturer Discount Program, to calculate the performance year Medicare net price; and (3) WAC is publicly posted, which promotes transparency.

We considered using the gross covered prescription drug costs (GCPDC) reported to Medicare in PDE in lieu of WAC; however, GCPDC is based on the plan and Part D enrollee payments and does not represent the manufacturer price for a given drug. GCPDC is a beneficiary—and claim-level—spending measure and not a manufacturer pricing measure. It captures the sum of payments by plans, beneficiaries, and Medicare at the negotiated point-of-sale price, and it has no relationship with the manufacturer's list or invoice price. Manufacturer rebates are paid retrospectively, and they are not matched to individual GCPDC claims. Therefore, we do not believe it is an appropriate cost measure to use for this calculation.

CMS also considered using the AMP as the starting point to calculate the Medicare net price. AMP is the average unit price paid to the manufacturer by wholesalers for drugs distributed to retail pharmacies, and it is used as the basis for the Part D inflation rebate calculation. AMP is calculated using sales transaction data and reflects cash discounts, volume discounts, and other reductions in the actual price paid, as specified in 42 CFR 447.504(b). CMS proposes *not* to use AMP as the starting point to calculate the Medicare net price for the purpose of the GUARD Model Rebate calculation for two main reasons. First, there may be some differences in the way that AMP is calculated across manufacturers. CMS allows manufacturers to make reasonable assumptions that are consistent with statutory requirements in calculating AMP. A survey by the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) found that manufacturers reported the need for more guidance related to accounting for bona fide service fees and rebates to PBMs in the calculation of AMP, and noted that there may be differences in how manufacturers are incorporating these components into their AMP calculations.[173] Second, there are differences in how AMP is calculated for inhalation, infusion, instilled, implanted, or injectable (5i) drugs, which have a high share of units reimbursed through non-retail pharmacies. These differences would complicate the calculation of the Medicare net price (and the GUARD Rebate amount) by creating discrepancies between 5i drugs and non-5i drugs. Specifically, manufacturers with 5i drugs are required to follow an alternative methodology for AMP calculation. If 70 percent or more of the sales in units are to entities other than retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies, then a manufacturer must use the 5i methodology for the monthly AMP calculation.[174] There is also the possibility, depending on sales, that the drug may be subject to the 5i AMP methodology in 1 calendar quarter, but not subject to that methodology in the next calendar quarter. One study examined differences in AMP, Medicaid rebates, and net Medicaid costs under the standard and 5i AMP methodologies and found that AMP was 42 percent lower on average because of the differences between the 5i methodology compared to the standard methodology.[175]

[173] Office of the Inspector General. (2019). *Reasonable Assumptions in Manufacturer Reporting of AMPs and Best Prices* (OEI–12–17–00130). U.S. Department of Health and Human Services. *https://oig.hhs.gov/oei/reports/oei-12-17-00130.pdf* (Accessed: 10 December 2025).

[174] Section 1927(k)(1)(B)(i)(IV) of the Act, 42 U.S.C. 1396r–8; 42 CFR 447.504(d) and 447.507. *https://www.ssa.gov/OP_Home/ssact/title19/1927.htm* (Accessed: 10 December 2025).

[175] Dickson, S., et al. (2022). Reduction in Medicaid Rebates Paid by Pharmaceutical

Continued

For these reasons, although we believe that AMP is appropriate for the Part D inflation rebate calculation when examining year-over-year differences in manufacturer prices within the U.S., we do not believe AMP is appropriate for calculating the Medicare net price for purposes of the GUARD Model. Whereas the GUARD Model makes a point-in-time comparison of the Medicare net price to the GUARD Model applicable international benchmark, which is a single benchmark based on reference countries, the Part D inflation rebate calculation compares the same price measure over time within the U.S.

CMS also considered using National Average Drug Acquisition Cost (NADAC), which represents the prices paid by pharmacies for prescription drugs. However, because this represents a pharmacy retail price, we do not believe it is appropriate to subtract the manufacturer DIR and Manufacturer Discount Program discount amounts from this price measure. CMS seeks feedback on our approach to calculate the Medicare net price for the purpose of calculating the GUARD Model Rebate amount, including any feedback on the proposed use of WAC in lieu of AMP, GCPDC, and NADAC to calculate the Medicare net price.

(1) Performance Year Aggregate Gross Price

As proposed at § 514.510(b)(1)(i), CMS is proposing to use WAC to calculate the performance year aggregate gross price. CMS is proposing to first identify all PDE records for all NDC–11s associated with the NDC–9 of the GUARD Model drug, and with dates of service during the performance year. Second, for each of the PDE records, CMS would identify a WAC based on the NDC–11 and multiply the quantity dispensed reported on the PDE record by the identified WAC value. Third, CMS would sum all the results of the second step across all PDE records to produce the performance year aggregate gross price.

It is necessary to assign a WAC to all PDE records associated with the GUARD Model drug during the performance year because manufacturer rebates and Manufacturer Discount Program discount amounts will reflect all such PDE records. The identification of the WAC for each PDE record would involve two elements. For the first element, CMS would use third party sources to identify the WAC based on the NDC–11 for each PDE record with dates of service during the performance year. If the WAC is not available for that NDC–11, then CMS would use a WAC that is available for another NDC–11 with the same associated NDC–9, having confirmed that the WAC is expressed in a per unit amount.

The second element for the identification of the WAC for each PDE record, would involve CMS identifying the WAC in effect [176] on the date of service reported on the PDE record. If there was not an effective WAC as of the date of service for any PDE records during the performance year, CMS proposes to use the most recently effective WAC available. If the GUARD Model drug has some PDE records during the performance year for which there was an effective WAC as of the date of service, but other PDE records during the performance year for which there was not an effective WAC as of the date of service, CMS proposes to impute a WAC for the latter category of PDE records based on the available WAC that was in effect most recently before the date of service on the PDE record. If there was no WAC in effect before the date of service on the PDE record, but there was a WAC in effect after the date of service, CMS proposes that the WAC that was in effect after the date of service would be applied to that PDE record.

If after considering both elements of the identification previously described there is no WAC available for any NDC–11 associated with the NDC–9 of the GUARD Model drug, CMS will not calculate a performance year aggregate gross price or issue a GUARD Model Rebate Report for that performance year.

CMS considered whether we should use a different measure other than WAC if there is no WAC available, such as the AMP, NADAC, average wholesale price (AWP), GCPDC, or other appropriate measure. However, we believe that WAC is available for most drugs and therefore, another pricing measure is not necessary. We seek feedback on this approach and whether alternative measures such as AMP, NADAC, AWP, or GCPDC should be considered.

(2) Performance Year Aggregate Net Price

As proposed at § 514.510(b)(1)(ii), CMS would next calculate the performance year aggregate net price by subtracting manufacturer rebates derived from DIR reported by Part D sponsors and Manufacturer Discount Program discount amounts from the performance year aggregate gross price. First, for each Part D plan and each NDC–9 of a GUARD Model drug, CMS would sum the total manufacturer rebate amounts obtained from the detailed DIR report across all plans and associated NDC–11s for the GUARD Model drug for the performance year. CMS would then subtract this sum from the performance year aggregate gross price. CMS would not subtract other price concessions reflected in the DIR reports because manufacturers do not incur those amounts.

Next, CMS would calculate the total Manufacturer Discount Program discount amounts that would also be subtracted out of the performance year aggregate gross price. As described in the Revised Medicare Part D Manufacturer Discount Program Final Guidance (Manufacturer Discount Program Final Guidance), the Manufacturer Discount Program was enacted into law in section 11201 of the Inflation Reduction Act of 2022, Public Law 117–169 (IRA) and codified in sections 1860D–14C and 1860D–43 of the Act.[177] Under the Manufacturer Discount Program, participating manufacturers are required to provide discounts on their applicable drugs (defined in section 1860D–14C(g)(2) of the Act and in section 130 of the Manufacturer Discount Program Final Guidance as proposed in the Medicare Program; Contract Year 2027 Policy and Technical Changes to the Medicare Advantage Program proposed rule (90 FR 95148; November 28, 2025) [178]) when dispensed to Part D enrollees in the initial and catastrophic phases of the Part D benefit. As described in section 50 of the Manufacturer Discount Program Final Guidance, discounts are equal to 10 percent of the negotiated price of the applicable drug when dispensed to an applicable beneficiary in the initial coverage phase of the Part D benefit, and 20 percent of the negotiated price of the applicable drug when dispensed to an applicable

Manufacturers for Outpatient Infused, Injected, Implanted, Inhaled, or Instilled Drugs: The 5i Loophole. *Journal of Health Politics, Policy and Law, 47*(6), 835–851. *https://doi.org/10.1215/03616878-10041219.*

[176] The WAC in effect on a date of service is the WAC that has the closest effective date prior to the date of service and either an end date after the date or service or no end date listed.

[177] Centers for Medicare & Medicaid Services. (2024). *Revised Manufacturer Discount Program Final Guidance.* U.S. Department of Health and Human Services. *https://www.cms.gov/files/document/revised-manufacturer-discount-programfinal-guidance122024.pdf* (Accessed: 10 December 2025).

[178] Centers for Medicare & Medicaid Services. (2025). *Medicare Program; Contract Year 2027 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program* (Proposed Rule, 90 FR 54894). *https://www.federalregister.gov/documents/2025/11/28/2025-21456/medicare-program-contract-year-2027-policy-and-technical-changes-to-the-medicare-advantage-program* (Accessed: 10 December 2025).

beneficiary in the catastrophic phase of the Part D benefit. As discussed in section 50.1 of the Manufacturer Discount Program Final Guidance, the IRA establishes lower percentages for discounts during a multi-year phase-in period for certain applicable drugs of specified manufacturers dispensed to applicable beneficiaries who are eligible for a low-income subsidy (LIS) under section 1860D–14(a) of the Act and for certain applicable drugs of specified small manufacturers when dispensed to any applicable beneficiary. CMS proposes to sum the Manufacturer Discount Program discount amounts paid by a manufacturer for a GUARD Model drug during the performance year, as well as the discounts that would have been paid by a manufacturer for a GUARD Model drug if not for the specified manufacturer and specified small manufacturer phase-ins, and subtract these amounts from the performance year aggregate gross price. The resulting amount (that is, the performance year aggregate gross price, net of manufacturer rebates and Manufacturer Discount Program discount amounts) would equal the performance year aggregate net price. The reason that CMS proposes to include the discount amounts that would have been paid by a manufacturer for a GUARD Model drug if not for the specified manufacturer and specified small manufacturer phase-ins in the total amount subtracted is to allow manufacturers to continue to experience the benefit of the phase-ins, as applicable, rather than transferring liability for the full discount amounts to the GUARD Model.

(a) Calculating Manufacturer Discount Program Discount Amounts for Non-Phase-In Eligible Drugs

CMS is proposing to derive Manufacturer Discount Program discount amounts from accepted final action, non-delete PDE records for the relevant performance year. For applicable drugs that do not have a specified manufacturer or specified small manufacturer phase-in applied, CMS would aggregate the Manufacturer Discount Program discount amounts for the performance year by NDC–9 by summing the amounts in the Reported Manufacturer Discount field on the PDE Inbound file layout.[179] The Reported Manufacturer Discount amount is reported by the Part D sponsor to convey the Manufacturer Discount Program discount amounts to CMS on the PDE. Therefore, summing amounts in this field on accepted final action, non-delete PDE records for each NDC–9 not subject to phase-in would provide reliable Manufacturer Discount Program discount amounts for these manufacturers.

(b) Calculating Manufacturer Discount Program Discount Amounts for Phase-In Eligible Drugs

For PDE records of applicable drugs that do have a phase-in applied, CMS is proposing at § 514.510(b)(ii) to calculate the discount as if the phase-in had not been applicable and then aggregate the Manufacturer Discount Program discount amounts for the performance year by NDC–9 as described previously for non-phase-in eligible drugs.

CMS' proposed three-phase methodology would preserve the statutory intent to delay imposition of full Manufacturer Discount Program discount amounts for specified manufacturers or specified small manufacturers. This three-phase methodology includes: (1) identifying the phase-in eligible PDEs records;(2) determining which of the associated PDE records were adjudicated during the Initial Coverage Phase or Catastrophic Phase; and (3) calculating the 10 percent or 20 percent discount based on the benefit phase identified to derive the Manufacturer Discount Program discount amount for each NDC–9.

Specifically, CMS would identify accepted final action, non-delete PDE records where a phase-in discount was applied through use of two fields on the PDE Outbound File Layout: Applicable Discount Percentage for Specified Small Manufacturer Drugs and Applicable Discount Percentage for Specified Manufacturer Drugs Dispensed to LIS Beneficiaries.[180]

For the identified PDE records, CMS would calculate the Manufacturer Discount Program amount that would be subtracted from the Performance Year Aggregate Net Price. First, CMS would determine the drug costs that fall into the Initial Coverage and Catastrophic Phases of the Part D benefit. If the True Out-of-Pocket (TrOOP) Accumulator field included on the PDE is less than the defined standard (DS) deductible, CMS would subtract the difference between the DS deductible and the TrOOP Accumulator from the Gross Drug Cost Below the Out-of-Pocket Threshold (GDCB) amount to find the drug cost that falls in the Initial Coverage Phase. If the TrOOP Accumulator is higher than or equal to the DS deductible, then the full GDCB amount represents the drug cost that falls in the Initial Coverage Phase. The Gross Drug Cost Above the Out-of-Pocket Amount (GDCA) represents the drug cost that falls in the Catastrophic Phase. Second, CMS would calculate a discount of 10 percent for drug costs that fall in the Initial Coverage Phase and a discount of 20 percent for drug costs that fall in the Catastrophic Phase. The sum of the calculated discounts for each NDC–9 for both phases would be subtracted from the Performance Year Aggregate Net Price.

If a GUARD Model drug is not an applicable drug under the Manufacturer Discount Program, the methodology described previously to subtract Manufacturer Discount Program discount amounts from the Performance Year Aggregate Net Price would apply no differently. In other words, the Manufacturer Discount Program amount subtracted from the Performance Year Aggregate Net Price would equal zero. As discussed previously in section IV.B.2. of this proposed rule and proposed § 514.120(c)(1), CMS is proposing that generic drugs and biosimilar biological products would be excluded from the definition of GUARD Model drugs. If the proposal to exclude generic drugs and biosimilar biological products from the definition of a GUARD Model drug is finalized in a final rule establishing the GUARD Model, CMS believes that all remaining GUARD Model drugs would be applicable drugs.

(c) Converting the Performance Year Aggregate Net Price to a Per Unit Price

To generate the performance year Medicare net price, CMS is proposing at § 514.510(b)(1)(iii) to convert the performance year aggregate net price for a GUARD Model drug into a per unit price by dividing the performance year aggregate net price by the total quantity dispensed of the GUARD Model drug during the performance year. First, CMS would sum the amounts reported in the quantity dispensed field across all PDE records identified at proposed § 514.510(b)(1)(i) and described previously. CMS would then divide the performance year aggregate net price by

[179] Centers for Medicare & Medicaid Services. (2025). *PDE Outbound File Layout Effective 01/01/2025*. U.S. Department of Health and Human Services. *https://www.csscoperations.com/internet/csscw3.nsf/DIDC/YINH9MCVGW~Prescription%20Drug%20Program%20(Part%20D)~File%20and%20Report%20Layouts* (Accessed: 10 December 2025).

[180] Centers for Medicare & Medicaid Services. (2025). *PDE Outbound File Layout Effective 01/01/2025*. U.S. Department of Health and Human Services. *https://www.csscoperations.com/internet/csscw3.nsf/DIDC/YINH9MCVGW~Prescription%20Drug%20Program%20(Part%20D)~File%20and%20Report%20Layouts* (Accessed: 10 December 2025).

this sum to produce the performance year Medicare net price.

b. Comparing the Performance Year Medicare Net Price to the Applicable International Benchmark To Identify the Per Unit GUARD Model Rebate Amount

To calculate the per unit GUARD Model rebate amount, CMS would compare the performance year Medicare net price to the applicable international benchmark. Specifically, CMS is proposing at § 514.510(b) that the per unit GUARD Model rebate amount would equal the difference between the performance year Medicare net price and the applicable international benchmark. As proposed at § 514.510(b)(2), in cases where CMS determines that the applicable international benchmark price is not available for the GUARD Model drug, a per unit GUARD Model rebate amount for the performance year will not be assessed, and the total GUARD Model rebate amount would be invoiced as zero dollars in the GUARD Model Rebate Report.

3. Determination of the Per Unit and Total Incremental GUARD Model Rebate Amounts

As described in section IV.H.1. of this proposed rule, CMS is proposing that the total GUARD Model rebate amount would be equal to the product of: (1) the per unit GUARD Model rebate amount for such GUARD Model drug for the performance year; and (2) the total number of units of the GUARD Model drug dispensed under Part D and covered by Part D plan sponsors for GUARD Model beneficiaries in the GUARD Model geographic areas during the performance year.

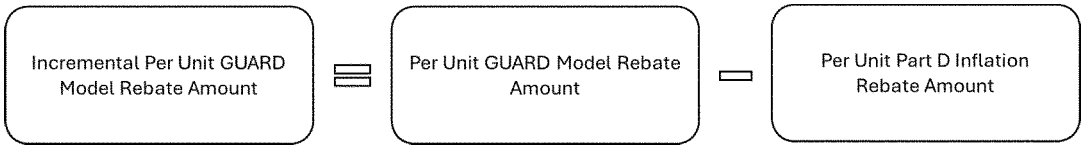
Under the circumstance in which CMS would waive the rebate amount described in section 1860D–14B(b) of the Act (that is, when the per unit GUARD Model rebate exceeds the performance year per unit Part D inflation rebate amount, as described in more detail later in this Section of this proposed rule) and instead apply the GUARD Model rebate amount, the GUARD Model rebate amount would be invoiced to the manufacturer in two stages. First, CMS would invoice the Part D inflation rebate amounts described in section 1860D–14B(b) of the Act through the Medicare Part D Inflation Rebate Program. Second, CMS would reconcile the amounts invoiced through the Medicare Part D Inflation Rebate Program against the GUARD Model rebate amount via an additional invoice that is specific to the GUARD Model. This invoicing process would occur three times, as described in greater detail later in this Section of this proposed rule: the GUARD Model Rebate Report, the GUARD Model First Reconciliation Rebate Report, and the GUARD Model Second Reconciliation Rebate Report.

The amount that would be reflected in the GUARD Model-specific invoice, used to reconcile the amounts invoiced through the Medicare Part D Inflation Rebate Program against the GUARD Model rebate amount, would be the Total Incremental GUARD Model rebate amount. The Total Incremental GUARD Model rebate amount would be equal to the product of the incremental per unit GUARD rebate amount as described later in this Section of this proposed rule and proposed at § 514.510(c)(1) and the total units dispensed during the performance year for the GUARD Model drug to GUARD Model beneficiaries, as described later in this Section of this proposed rule and determined under proposed § 514.510(d).

a. Calculation of the Incremental Per Unit GUARD Model Rebate Amount

As proposed at § 514.510(c)(1) and illustrated in Figure B3, CMS would compare the per unit GUARD Model rebate amount determined at proposed § 514.510(b) to the per unit Part D inflation rebate amount as defined at 42 CFR 428.202(a). For line extensions as defined at proposed § 514.500, CMS would compare the per unit GUARD Model rebate amount to the greater of the per unit Part D rebate inflation amount determined under § 428.202(a) for such line extension drug or the alternative line extension per unit Part D inflation rebate amount, equal to the product of the amounts determined under § 428.204(c)(1) and (2). The GUARD Model would waive the rebate amount described in subsection (b) of section 1860D–14B of the Act when the per unit GUARD Model rebate exceeds the per unit Part D rebate inflation amount.

Figure B3: Calculation of Incremental Guard Model Rebate Amount



To make this comparison, CMS is proposing a few adjustments to the per unit Part D inflation rebate amount to account for differences in the GUARD Model and Part D inflation rebate reporting cycles and in the unit type used by each. While the per unit GUARD Model rebate amount is calculated on a calendar year basis, the per unit Part D inflation rebate amount is calculated on a fiscal year basis. As such, CMS is proposing at § 514.500 to calculate the performance year per unit Part D inflation rebate amount by computing the weighted sum of the per unit Part D inflation rebate amount for the first applicable period that overlaps with the first three quarters of the performance year and the per unit Part D inflation rebate amount for the second applicable period that overlaps with the last quarter of same performance year. CMS would weigh each per unit Part D inflation rebate amount according to the number of months of overlap between the respective applicable period and the performance year. If a GUARD Model drug is a Part D rebatable drug only during the months in which one of the applicable periods overlaps with the performance year, but not the months in which the other applicable period overlaps with the performance year, the performance year per unit Part D inflation rebate amount would equal the per unit Part D inflation rebate amount for the applicable period in which the drug was a Part D rebatable drug during the months that overlap with the performance year.

Units reported on PDE are industry standard NCPDP defined values of each, milliliter and grams. In contrast, manufacturers can report the AMP unit for their drugs in the Medicaid Drug Programs systems with 10 different unit types (that is, each, capsule, tablet, suppository, transdermal patch, injectable antihemophilic factor, millicurie, microcurie, gram, and milliliter). Therefore, the per unit Part D inflation rebate amount is expressed in per-AMP unit terms and the per unit

GUARD rebate is expressed in per-NCPDP unit terms.

Once these adjustments have been made, CMS proposes to calculate the incremental per unit GUARD Model rebate amount. If the per unit GUARD Model rebate amount is greater than the performance year per unit Part D inflation rebate amount, the incremental per unit GUARD Model rebate amount is equal to the difference. If the per unit GUARD Model rebate amount is less than or equal to the performance year per unit Part D inflation rebate amount, the incremental per unit GUARD Model rebate amount is zero and so CMS would not waive the rebate amount described in section 1860D–14B(b) of the Act. In instances where the performance year per unit Part D inflation rebate amount is equal to zero, the incremental per unit GUARD Model rebate amount will equal the per unit GUARD Model rebate amount.

b. Calculation of the Total Incremental GUARD Model Rebate Amount

As described previously, CMS is proposing that the Total Incremental GUARD Model rebate amount would represent the amount to be paid by a manufacturer for a GUARD Model drug via the GUARD Model invoicing process for the performance year. To reconcile the amount already invoiced under the Medicare Part D Inflation Rebate Program against the total GUARD Model rebate amount, CMS is proposing at § 514.510(c)(2) that the Total Incremental GUARD Model rebate amount would be equal to the incremental per unit GUARD Model rebate amount described previously and determined under proposed § 514.510(c)(1), multiplied by the total units dispensed during the performance year for the GUARD Part D rebatable model drug for GUARD Model beneficiaries, as described later in this Section of this proposed rule and determined under proposed § 514.510(d). CMS is further proposing at § 514.510(c)(2) that the Total Incremental GUARD Model rebate amount would be subject to adjustment based on any reductions in accordance with § 514.520 or any reconciliations in accordance with subpart G.

4. Determination of the Total Units Dispensed

CMS would determine the total units dispensed during the performance year for the GUARD Model drug, less any applicable exclusions. First, as proposed at § 514.510(d)(1), CMS would calculate the total number of units dispensed consistent with the methodology used in the Part D Drug Inflation Rebate Program and set forth at § 428.203. The total number of units would reflect units associated with the months of the performance year in which the GUARD Model drug meets the definition of a Part D rebatable drug (as defined at § 428.20) as set forth at § 428.203(b)(1). CMS proposes to exclude units of each dosage form and strength of a GUARD Model drug for which the manufacturer provides a discount under the program under section 340B of the PHS Act, as described in section 1860D–14B(b)(1)(B) of the Act and set forth at § 428.203(b)(2). CMS also proposes to exclude units associated with compounded drugs as set forth at § 428.101(b)(1). To test an alternative calculation for the Part D inflation rebate calculation in the GUARD Model beneficiary population, CMS is also proposing at § 514.510(d)(2) to remove units for PDE records that are not associated with a GUARD Model beneficiary, as that term is defined at proposed § 514.5 and identified at proposed § 514.130(a).

5. Reducing the Total Incremental GUARD Model Rebate Amount for Drugs in Shortage and/or When There is a Severe Supply Chain Disruption or Likely Shortage

Under section 1860D–14B(b)(1)(C)(i) of the Act as codified in § 428.301, CMS will reduce the total Part D inflation rebate amount determined under § 428.201(a), if any is owed, for a Part D rebatable drug that is currently in ''shortage'', as set forth in § 428.300, at any point during the applicable period. CMS proposes at § 514.520(a) to reduce the Total Incremental GUARD Model rebate amount using a modification of the formula specified in § 428.301(b)(1). Specifically, to closely align with the Part D Drug Inflation Rebate Program, for each applicable period that overlaps with the performance year, we propose to use the applicable percent reduction and percentage of time the drug was currently in shortage during the applicable period, weighted according to the number of quarters of overlap between the applicable period and performance year. In proposed § 514.520(a)(2), we propose that the reduced Total Incremental GUARD Model rebate amount would equal:

For GUARD Model drugs that were Part D rebatable drugs during both applicable periods that overlap with the performance year, the sum of:

- The Total Incremental GUARD Model rebate amount *multiplied by* 0.75 *multiplied by* (1 *minus* (the applicable percent reduction determined under § 428.301(b)(2) for the applicable period that overlaps with the first three quarters of the performance year *multiplied by* the percentage of time the GUARD Model drug was currently in shortage during the first three quarters of the performance year determined by CMS pursuant to § 428.301(b)(3))); and
- The Total Incremental GUARD Model rebate amount *multiplied by* 0.25 *multiplied by* (1 *minus* (the applicable percent reduction determined under § 428.301(b)(2) for the applicable period that overlaps with the last quarter of the performance year *multiplied by* the percentage of time GUARD Model drug was currently in shortage during the last quarter of the performance year determined by CMS pursuant to § 428.301(b)(3))).

Our proposed calculation:

$$R_M = \{G * 0.75 [1-(P_1 * S_1)]\} + \{G * 0.25 [1-(P_2 * S_2)]\},$$

where—

- R_M = reduced Total Incremental GUARD Model rebate amount for GUARD Model Part D rebatable drugs that were Part D rebatable drugs during both applicable periods that overlap with the performance year;
- G = Total Incremental GUARD Model rebate amount;
- P_1 = the applicable percent reduction determined under § 428.301(b)(2) for the applicable period that overlaps with the first three quarters of the performance year;
- S_1 = the percentage of time the GUARD Model drug was currently in shortage during the first three quarters of the performance year determined by CMS under § 428.301(b)(3);
- P_2 = the applicable percent reduction determined under § 428.301(b)(2) for the applicable period that overlaps with the last quarter of the performance year; and
- S_2 = the percentage of time GUARD Model drug was currently in shortage during the last quarter of the performance year determined by CMS pursuant to § 428.301(b)(3).

For GUARD Model drugs that were Part D rebatable drugs during only one of the applicable periods that overlap with the performance year, the Total Incremental GUARD Model rebate amount *multiplied by* (1 *minus* (the applicable percent reduction determined under § 428.301(b)(2) for the applicable period that overlaps with the performance year and during which the GUARD Model drug was a Part D rebatable drug *multiplied by* the percentage of time the GUARD Model drug was currently in shortage during that applicable period determined by CMS under § 428.301(b)(3))).

Our proposed calculation:

$$R_S = G * [1-(P_3 * S_3)],$$

where—

- R_S = reduced Total Incremental GUARD Model rebate amount for GUARD Model

drugs that were Part D rebatable drugs during only one of the applicable periods that overlap with the performance year;
- G = Total Incremental GUARD Model rebate amount;
- P_3 = the applicable percent reduction determined under § 428.301(b)(2) for the applicable period that overlaps with the performance year and during which the GUARD Model drug was a Part D rebatable drug;
- S_3 = the percentage of time the GUARD Model drug was currently in shortage during that applicable period determined by CMS under § 428.301(b)(3).

As an alternative to our proposed approach, we considered whether, for purposes of the GUARD Model, the applicable percent reduction should be greater than or less than the applicable percentage reduction specified in § 428.301(b)(2). To maintain consistency with the Part D Drug Inflation Rebate Program and avoid creating different manufacturer incentives for addressing shortages and supply chain disruptions, CMS is proposing to apply, for purposes of the GUARD Model, the same applicable percentage reduction as used under the Part D Drug Inflation Rebate Program.

Pursuant to section 1860D–14B(b)(1)(C)(ii) of the Act as codified in § 428.302, CMS will reduce the total Part D inflation rebate amount determined under § 428.201(a), if any is owed, for a generic Part D rebatable drug or biosimilar biological product when CMS determines there is a severe supply chain disruption during the applicable period such as that caused by a natural disaster or other unique or unexpected event. As discussed in Section IV.B.2. of this proposed rule and proposed § 514.120(c)(1), CMS is proposing that generic drugs and biosimilar biological products would be excluded from the definition of GUARD Model drugs. In the event that the proposal to exclude generic drugs and biosimilar biological products from the definition of a GUARD Model drug is not finalized in a final rule establishing the GUARD Model, CMS is proposing that for any GUARD Model drug that is a generic or biosimilar biological products as described at § 428.300, CMS would reduce the Total Incremental GUARD Model rebate amount, if any, when there is a severe supply chain disruption during the performance year in the same manner as specified in § 428.302, including the limitation on rebate reductions in § 428.302(b)(4).

Accordingly, because a manufacturer already submits to CMS a rebate reduction request for a Part D rebatable drug pursuant to § 428.302(c), a manufacturer would not be required to submit to CMS a separate rebate reduction request for purposes of reducing the Total Incremental GUARD Model rebate amount. Specifically, CMS is proposing to codify in § 514.520(b) that, if CMS reduces the total Part D inflation rebate amount determined under § 428.302(a), if any is owed, for a generic Part D rebatable drug or biosimilar biological product that is a GUARD Model drug for an applicable period that overlaps with the performance year, CMS would reduce the Total Incremental GUARD Model rebate amount determined pursuant to § 514.510(c)(2), if any is owed, using a weighted average of the same percentage reduction that CMS applied under § 428.302 for each applicable period that overlaps with the performance year, weighted by the number of quarters of overlap between each applicable period and the performance year, as described in the first equation in this section of this proposed rule. For a GUARD Model drug that was a Part D rebatable drug during only one of the applicable periods that overlaps with the performance year, CMS would not use a weighted average and would instead simply reduce the Total Incremental GUARD Model rebate amount by the same percentage reduction that CMS applied under § 428.302 for the applicable period that overlaps with the performance year and during which the GUARD Model drug was a Part D rebatable drug, as described in the second equation in this Section of this proposed rule.

Under section 1860D–14B(b)(1)(C)(iii) of the Act as codified in § 428.303, CMS will reduce the total Part D inflation rebate amount determined under § 428.201, if any is owed, for a generic Part D rebatable drug when CMS determines that the generic Part D rebatable drug is likely to be in shortage, as set forth in § 428.300. As noted previously, CMS is proposing that generic drugs would be excluded from the definition of GUARD Model drugs. In the event that the proposal to exclude generic drugs from the definition of a GUARD Model drug is not finalized in a final rule establishing the GUARD Model, CMS is proposing that for any GUARD Model drug that is a generic drug as described at § 428.300, CMS would reduce the Total Incremental GUARD Model rebate amount, if any, when CMS determines that the generic GUARD Model drug is likely be in shortage in the same manner as specified in § 428.303, including the limitation on rebate reductions in § 428.303(b)(4). Accordingly, because a manufacturer already submits to CMS a rebate reduction request for a Part D rebatable drug pursuant to § 428.303(c), a manufacturer would not be required to submit to CMS a separate rebate reduction request for purposes of reducing the Total Incremental GUARD Model rebate amount. Specifically, CMS is proposing to codify in § 514.520(c) that, if CMS reduces the total Part D inflation rebate amount determined under § 428.201(a), if any is owed, for a generic Part D rebatable drug that is a GUARD Model drug for an applicable period that overlaps with the performance year, CMS would reduce the Total Incremental GUARD Model rebate amount determined pursuant to § 514.510(c)(2), if any is owed, using a weighted average of the same percentage reduction that CMS applied under § 428.303 for each applicable period that overlaps with the performance year, weighted by the number of quarters of overlap between each applicable period and the performance year, as described in the first equation in this Section of this proposed rule. For a GUARD Model drug that was a Part D rebatable drug during only one of the applicable periods that overlaps with the performance year, CMS would not use a weighted average and would instead simply reduce the Total Incremental GUARD Model rebate amount by the same percentage reduction that CMS applied under § 428.303 for the applicable period that overlaps with the performance year and during which the GUARD Model drug was a Part D rebatable drug, as described in the second equation in this Section of this proposed rule.

CMS seeks comment on the proposal for reduction of the GUARD Model rebate amount for GUARD Model drugs in shortage, when there is a severe supply chain disruption, or that are likely to be in shortage.

6. Alternatives Considered

As explained in section IV.H.2.b. of this proposed rule, CMS is proposing at § 514.510(b)(1) to calculate the performance year Medicare net price for a GUARD Model drug by subtracting manufacturer rebates and Manufacturer Discount Program discount amounts from a performance year aggregate gross price and converting the result to a per unit price by dividing by the total quantity dispensed of the GUARD Model drug. CMS is proposing at § 514.510(b)(1)(i) to use WAC to calculate the performance year aggregate gross price but considered alternative data sources. Specifically, CMS considered using GCPDC, AMP, or NADAC to calculate the performance year aggregate gross price. We refer readers to section IV.H.2.b. of this

proposed rule for further details on these alternatives considered and CMS' rationale for not using these alternatives.

I. Reports of Rebate Amounts, Reconciliation, Suggestion of Error, and Payments

In alignment with the Part D Inflation Rebate Program Rebate Report process described in 42 CFR 428.400 through 428.405, CMS proposes at § 514.610 to send a GUARD Model Rebate Report to each manufacturer of a GUARD Model drug with the following information for each performance year: (1) the total GUARD Model rebate amount; (2) the per unit GUARD Model rebate amount; (3) the performance year per unit Part D inflation rebate amount; (4) the incremental per unit GUARD Model rebate amount as calculated in § 514.510(c)(1) for each GUARD Model drug; (5) the total units dispensed during the performance year for the GUARD Model drug; and (6) the Total Incremental GUARD Model rebate amount for each GUARD Model drug as calculated in § 514.510(c)(2). Because a portion of the total GUARD Model Rebate amount will already have been invoiced via the Rebate Report through the Medicare Part D Inflation Rebate Program, the Total Incremental GUARD Model rebate amount will be the amount invoiced through the GUARD Model Rebate Report. The manufacturer of a GUARD Model drug must pay the Total Incremental GUARD Model rebate amount for each GUARD Model drug no later than 30 calendar days after the receipt of the GUARD Model Rebate Report.

Specifically, CMS proposes to send a Preliminary GUARD Model Rebate Report followed by a GUARD Model Rebate Report, as described in proposed § 514.610(b), to all manufacturers of a GUARD Model drug, even if the amount due is $0; all GUARD Model rebate amounts would be subject to reconciliation as proposed in § 514.610(d). CMS does not intend to send notice to manufacturers for drugs that are not considered GUARD Model drugs pursuant to proposed § 514.120.

To address the completeness and accuracy of the GUARD Model rebate amount, CMS proposes to conduct regular reconciliations at 2 points in time to determine whether the Total Incremental GUARD Model rebate amount must be adjusted due to updated claims and other reported data used in the calculation of such Total Incremental GUARD Model rebate amount (specified in proposed § 514.510(c)(2): (1) within 12 months after the issuance of the GUARD Model Rebate Report; and (2) within 36 months after the issuance of the GUARD Model Rebate Report. The reporting process for each reconciliation would be the same process described for the original GUARD Model Rebate Report, with payment due for any outstanding rebate amount 30 calendar days after receipt of a reconciled GUARD Model Rebate Report with a reconciled Total Incremental GUARD Model rebate amount, as proposed in § 514.640(a)(1). In addition to regular reconciliations, CMS proposes a process to conduct reconciliations of the Total Incremental GUARD Model rebate amount as needed to correct agency error and when CMS determines that the information used by CMS to calculate a GUARD Model rebate amount was inaccurate due to manufacturer misreporting.

1. Definitions

In proposed § 514.600, CMS proposes to define the following term applicable to subpart G (§ 514.600 through 514.650): ''Date of receipt'' is the calendar day following the day on which a report of a Total Incremental GUARD Model rebate amount (as set forth in § 514.510(c)(2)) is made available to the manufacturer of a GUARD Model drug by CMS.

For example, if CMS issues a GUARD Model Rebate Report through the method and process described in proposed § 514.630 on July 1, 2029, then July 2, 2029, will be the date of receipt and day 1 of the 30-calendar day payment period.

2. Reports of Rebate Amounts and Suggestion of Error

Consistent with the process specified in 42 CFR 428.401, 428.403, and 428.405 involving preliminary and final reports for the Medicare Part D Inflation Rebate Program, CMS proposes to codify a multistep process to provide a manufacturer as defined in proposed §§ 514.610 and 514.620 with the GUARD Model rebate information described at proposed § 514.610(b)(2). CMS believes adopting the process described for the Medicare Part D Inflation Rebate Program will provide manufacturers participating in the GUARD Model with a familiar and consistent process for paying a GUARD Model rebate amount due, thereby minimizing the potential burden on participating manufacturers. Further, adopting the process described at 42 CFR 428.401, 428.403, and 428.405 provides CMS with sufficient operational time to acquire the relevant information specified in the proposed part 514; sufficient operational time to calculate the GUARD Model rebate amount and the Total Incremental GUARD Model rebate amount specified in subparts F and G of the proposed part 514; and sufficient operational time to ensure the accuracy of the Total Incremental GUARD Model rebate amount through reconciliation.

As discussed further in this section of this proposed rule and at proposed § 514.610, CMS proposes to use an initial Preliminary GUARD Model Rebate Report (see proposed § 514.610(b)) and a subsequent GUARD Model Rebate Report (see proposed § 514.610(c)), with an opportunity for manufacturers to identify certain mathematical errors (see proposed § 514.620) and two regular reconciliations of the Total Incremental GUARD Model rebate amount to account for updates to claims and other reported data within 12 months and 36 months after the GUARD Model Rebate Report is issued (see proposed § 514.610(d)).

a. Identifying the Manufacturer Responsible for Paying the GUARD Model Rebate

As proposed in § 514.5, CMS proposes that, for the purposes of the GUARD Model, ''manufacturer'' will have the same meaning as defined for purposes of the Medicare Part D Inflation Rebate Program in section 1927(k)(5) of the Act and 42 CFR 428.20 thereby identifying the manufacturer that is responsible for paying a rebate using the same approach used for reporting AMP data. The reason for identifying the responsible manufacturer that is responsible for paying a rebate using the same approach as the Medicare Part D Inflation Rebate Program is to ensure that the manufacturer responsible for Part D inflation rebate amounts for a given Part D rebatable drug in geographies not included under the GUARD Model will be the same manufacturer responsible for GUARD Model rebate amounts in the geographies included under the GUARD Model. This approach would also ensure that the manufacturer responsible for a GUARD Model rebate amount is invoiced for the entire amount, since a portion of the amount will be invoiced under the Medicare Part D Inflation Rebate Program.

3. GUARD Model Rebate Reports

CMS proposes in proposed § 514.610 that the multi-step reporting process for providing GUARD Model rebate information to a manufacturer would include: (1) an initial report, which CMS proposes to entitle the Preliminary GUARD Model Rebate Report in proposed § 514.610(b); and (2) a second report, which CMS proposes to entitle

the GUARD Model Rebate Report in proposed § 514.610(c). The GUARD Model Rebate Report would serve as the invoice for the Total Incremental GUARD Model rebate amount due, if any, for each product determined to be a GUARD Model drug for the performance year, as specified in proposed § 514.610(c)(2). Manufacturers of GUARD Model drugs would receive a GUARD Model Rebate Report for their GUARD Model drugs even if the amount due is $0. CMS proposes at § 514.610(d) two regular reconciliations of the rebate amount to occur within 12 months and 36 months after issuance of the GUARD Model Rebate Report specified in proposed § 514.610(c), which would include any restatements that have occurred in the drug pricing data and claims billing data reported to CMS and used in the GUARD Model rebate calculation specified in subpart F of this part.

As the first step in the reporting process, as proposed in § 514.610(b) and consistent with the Part D Inflation Rebate Program, CMS would provide each manufacturer of a GUARD Model drug with the preliminary Total Incremental GUARD Model rebate amount through a Preliminary GUARD Model Rebate Report at least 1 month prior to the issuance of the GUARD Model Rebate Report specified in proposed § 514.610(c) for a performance year.

By structuring the GUARD Model Rebate Report process to include a Preliminary GUARD Model Rebate Report, CMS is able to provide manufacturers with an opportunity to review the Preliminary GUARD Model Rebate Report before the Total Incremental GUARD Model rebate amount is invoiced via the GUARD Model Rebate Report. CMS believes the Preliminary GUARD Model Rebate Report will facilitate manufacturer understanding of the GUARD Model Rebate Report and believes it would be beneficial for manufacturers to review the report for mathematical errors that could be corrected before invoicing via the GUARD Model Rebate Report. Further, a Preliminary GUARD Model Rebate Report would provide additional notice to manufacturers regarding whether they may owe a Total Incremental GUARD Model rebate amount.

As the second step in the reporting process, CMS proposes in § 514.610(c) to provide the Total Incremental GUARD Model rebate amount to the manufacturer through the GUARD Model Rebate Report not later than 22 months after the end of each performance year. As proposed in § 514.610(c)(1), the GUARD Model Rebate Report would include the same data elements as the Preliminary GUARD Model Rebate Report (specified in proposed § 514.610(b)(2)(i) through (xii)) and include any recalculations based on CMS acceptance of a manufacturer's Suggestion of Error from proposed § 514.620, or any CMS-determined recalculations from proposed § 514.610(d)(2), if applicable. CMS proposes that manufacturers must pay the Total Incremental GUARD Model rebate amount within 30 calendar days from the date of receipt of the GUARD Model Rebate Report as proposed in § 514.640(a)(1). We considered whether ''day 1'' of the 30-calendar day payment deadline should begin on the date of receipt of the GUARD Model Rebate Report, as defined at proposed § 514.600, or the calendar day following the date of receipt. We believe defining the date of receipt as day 1 of the 30-calendar day payment deadline is acceptable. We seek feedback on our proposed policies. For example, if the GUARD Model Rebate Report is provided on August 1, 2029, then August 2, 2029, would be the date of receipt and therefore day 1 of the 30-calendar day payment period; payment would be due no later than 11:59 p.m. PT on August 31, 2029.

a. GUARD Model Rebate Report Information

To facilitate manufacturer understanding of the Preliminary GUARD Model Rebate Report, CMS is proposing in § 514.610(b)(2)(i) through (xii) that the Preliminary GUARD Model Rebate Report would include the following information: information related to the Part D inflation rebate amount for quarters corresponding to the relevant performance year; the NDC(s) for the GUARD Model drug as defined under proposed § 514.120(a); the total number of units covered under Part D for the GUARD Model drug for the performance year as determined under proposed § 514.510(d) (which would remove units acquired through the 340B Program, units for PDE records associated with beneficiaries outside of the Model geographic areas, units associated with compounded drugs, and units dispensed when the drug does not meet the criteria for a GUARD Model drug as outlined in proposed § 514.120); the GUARD Model applicable international benchmark as described in proposed § 514.410(a); the performance year Medicare net price as identified in proposed § 514.510(b)(1); the total GUARD Model rebate amount as determined in proposed § 514.510(a); the per unit GUARD Model rebate amount for the GUARD Model drug for the performance year as determined in proposed § 514.510(b); the performance year per unit Part D inflation rebate amount in proposed § 514.500; the incremental per unit GUARD Model rebate amount as determined under proposed § 514.510(c)(1); any applied reductions as described in proposed § 514.520; the total Part D inflation rebate amount as described in § 428.201(a); and the Total Incremental GUARD Model rebate amount due as specified in proposed § 514.510(c)(2).

When determining what information should be included on GUARD Model Rebate Reports, CMS considered which data elements are necessary to review the Preliminary GUARD Model Rebate Report for error, as described in this Section of this proposed rule, and how to ensure proprietary information is protected. The elements listed previously provide sufficient information for a manufacturer to review the Preliminary GUARD Model Rebate Report for mathematical error, while protecting proprietary information, and these elements are operationally feasible for CMS to provide within the proposed reporting timelines described in Table B8. CMS considered whether the GUARD Model applicable international benchmark should not be included in the GUARD Model Rebate Reports due to the possibility that its data source of origin is proprietary and there may be other possible limitations. CMS welcomes comments on this inclusion, and that of the other elements.

b. Suggestion of Error

In proposed § 514.620, CMS proposes a process in which a manufacturer may suggest to CMS that the manufacturer believes the Preliminary GUARD Model Rebate Report includes a mathematical error within 10 calendar days after the date of receipt of the Preliminary GUARD Model Rebate Report. For example, if the Preliminary GUARD Model Rebate Report is provided on June 1, 2029, then June 2, 2029, would be the date of receipt and also day 1 of the 10 calendar day period to submit a Suggestion of Error; the Suggestion of Error would be due at 11:59 p.m. PT on June 11, 2029, in this example. This suggestion of error period is in alignment with the same process for reports issued under the Part D Inflation Rebate Program as described in § 428.403. As with the Part D Inflation Rebate Program, CMS believes a 10-calendar day period is sufficient when considering the volume of the data to be provided to manufacturers, the narrow scope of items that may be identified as

a Suggestion of Error, and the operational time necessary for CMS to provide a GUARD Model Rebate Report. As such, CMS proposes a Suggestion of Error period of 10 calendar days in § 514.620(c).

The Suggestion of Error process would be limited to mathematical steps involved in determining the total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount as specified in proposed § 514.510(c)(2). Additionally, in accordance with the restriction on administrative and judicial review as described in section 1860D–14B(f) of the Act, CMS is not providing an administrative dispute resolution process. CMS intends to consider all in-scope submissions under the Suggestion of Error process (for example, suggestions regarding a mathematical error) as described in proposed § 514.620(a). CMS does not intend to review suggestions of error that are out-of-scope or submissions for a GUARD Model drug with a Total Incremental GUARD Model rebate amount due of $0.

Table B8 summarizes the proposed GUARD Model Rebate Report milestones and deadlines.

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TABLE B8: PROPOSED GUARD MODEL REBATE REPORT MILESTONES AND DEADLINES

Milestone	Timing/Deadline*
Preliminary GUARD Model Rebate Report sent to Manufacturers	Not later than 20 months after the end of the performance year
Manufacturer Reviews	Manufacturer Suggestion of Error must be submitted to CMS not later than 10 calendar days following receipt of the Preliminary GUARD Model Rebate Report
GUARD Model Rebate Report sent to Manufacturers	Not later than 22 months after the end of the performance year
Manufacturer GUARD Model Rebate Amount Due (if applicable)	Not later than 30 calendar days after receipt of the GUARD Model Rebate Report
First Reconciliation Preliminary GUARD Model Rebate Report sent to Manufacturers	Not later than 11 months after the receipt of the GUARD Model Rebate Report
Manufacturer Reviews	Manufacturer Suggestion of Error must be submitted to CMS not later than 10 calendar days following receipt of the First Reconciliation Preliminary GUARD Model Rebate Report
First Reconciliation GUARD Model Rebate Report sent to Manufacturers	Not later than 12 months after the receipt of the GUARD Model Rebate Report
Manufacturer Reconciled Rebate Amount Due (if any)	Not later than 30 calendar days after receipt of the First Reconciliation GUARD Model Rebate Report
Second Reconciliation Preliminary Rebate Report sent to Manufacturers	Not later than 35 months after the receipt of the GUARD Model Rebate Report
Manufacturer Reviews	Manufacturer Suggestion of Error should be submitted to CMS not later than 10 calendar days following receipt of the Second Reconciliation Preliminary GUARD Model Rebate Report
Second Reconciliation GUARD Model Rebate Report sent to Manufacturers	Not later than 36 months after the receipt of the GUARD Model Rebate Report
Manufacturer Reconciled GUARD Model Rebate Amount Due (if any)	Not later than 30 calendar days after receipt of the Second Reconciliation GUARD Model Rebate Report

Notes: *The months referred to in these timelines represent calendar months. This means, for example, that if a Performance Year ends December 31, 2027, the Preliminary GUARD Model Rebate Report could be issued up until August 31, 2029.

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c. Timing

As discussed previously and in proposed § 514.1(c), the GUARD Model would begin January 1, 2027, with a 5-year performance period and 5 performance years aligning with calendar years 2027 through 2031, and 7 payment years. To calculate the GUARD Model rebate as described in proposed § 514.510(c)(2), CMS will require WAC data, quarterly Manufacturer Discount Program data, DIR data, and data from the Medicare Part D Inflation Rebate Program. Table B9 illustrates when data for performance year 1 (calendar year 2027) will be available for each of these inputs to calculate the Total Incremental GUARD Model rebate for the Preliminary GUARD Model Rebate Report.

TABLE B9: GUARD Model Performance Year 1 Data Availability

Data Required	PY 1/CY 2027 Data Available
Manufacturer Discount Program	September 2028
DIR	September 2028
Medicare Part D Inflation Rebate Program	June 2029
WAC	Immediately

Notes: PY stands for performance year, as defined at § 514.5. CY stands for calendar year. DIR stands for detailed direct and indirect remuneration, § 514.5. WAC stands for Wholesale Acquisition Cost, § 514.5.

As a result of the data lag described previously, the Preliminary GUARD Model Rebate Report for performance year 1 would be sent to manufacturers no later than August 2029 and would follow the process and cadence described at proposed § 514.610 and this section of this proposed rule. As described in proposed § 514.610(c), the GUARD Model Rebate Report cycle would occur annually thereafter until a Preliminary GUARD Model Rebate Report, GUARD Model Rebate Report, and the associated reconciled GUARD Model Rebate Report has been issued for every performance year of the performance period. As such, claims processing, data collection, invoicing, payment of GUARD Model rebates, and reconciliation would continue into CY 2036. Table B10 summarizes this proposed timeline. CMS understands the reconciliation activities for some performance years extend beyond the end of the GUARD Model payment period but we believe the reconciliation activities pose minimal burden to manufacturers. Examples of reconciliation activities that could take place after the end of the GUARD Model payment period are responses to reconciliation reports, suggestion of errors, and payment of any reconciled rebate amounts due or owed.

TABLE B10: PROPOSED TIMELINE FOR GUARD MODEL REBATE REPORTS AND RECONCILIATION FOR EACH PERFORMANCE YEAR

Performance Year (Calendar Year)	Initial GUARD Model Rebate Report	First Reconciliation	Second Reconciliation
1 (CY 2027)	CY 2029	CY 2030	CY 2032
2 (CY 2028)	CY 2030	CY 2031	CY 2033
3 (CY 2029)	CY 2031	CY 2032	CY 2034
4 (CY 2030)	CY 2032	CY 2033	CY 2035
5 (CY 2031)	CY 2033	CY 2034	CY 2036

Note: CY stands for calendar year.

d. Payment Submission

At proposed § 514.630 CMS describes a proposed standard method and process to issue GUARD Model Rebate Reports and accept manufacturer GUARD Model rebate payments using the online portal used for the same purpose in the Medicare Part D Inflation Rebate Program. This portal is called the Manufacturer Payment Portal (MPP). CMS has already onboarded many manufacturers to the secure, online portal that is facilitated by a CMS-contracted Third-Party Administrator (TPA) where reports and suggestions of calculation error for the Inflation Rebate Program are posted. CMS believes it will be less burdensome for manufacturers to use the existing secure, online portal rather than accessing a new portal for the purposes of receiving GUARD Model Rebate Reports, submitting suggestions of error, and making payments. CMS may consider the option of using a different data system for payment submission, including adapting a system that currently exists.

If this rule is finalized, CMS intends to provide future technical instructions to manufacturers of GUARD Model drugs regarding how to access GUARD Model Rebate Reports and how to receive notifications alerting the manufacturer when such information is available. CMS also intends to issue reminder notices to manufacturers regarding the due date of payments. Per the definition of manufacturer in proposed § 514.5, CMS notes that the manufacturer that may access GUARD Model Rebate Reports and make applicable payments is the manufacturer responsible for paying a GUARD Model rebate, and, as stated previously, CMS proposes to identify the manufacturer that is responsible for paying a GUARD Model rebate using the same approach used for reporting AMP data.

J. Reconciliation of a Rebate Amount

CMS considered the need to establish a standardized method and process to determine appropriate adjustments to the Total Incremental GUARD Model rebate amount for a GUARD Model drug for each performance year to account for revisions to Manufacturer Discount Program, DIR, WAC, and Medicare Part D Inflation Rebate Program data as well as options for recalculation based on CMS identifying an agency error or manufacturer misreporting. As such, CMS is proposing policies for reconciliation, including with respect to enforcement of payment of any reconciled GUARD Model rebate amount, consistent with the statutory framework for the Part D Inflation Rebate Program and the express authority in sections 1102 and 1871 of the Act to adopt regulations for the proper administration of the Medicare Program.

As proposed at § 514.610(d), CMS believes that it is necessary and

appropriate for CMS to recalculate the GUARD Model rebate amount for each performance year at regular intervals to include updated information about key data elements included in the calculation of the GUARD Model rebate amount. These data elements as set forth in proposed § 514.610(d)(1)(i)(A) through (H) include: total units as specified at § 514.510(d); the total GUARD Model rebate amount specified at § 514.510(a); the per unit GUARD Model rebate amount specified at § 514.510(b); the incremental per unit GUARD Model rebate amount as calculated at § 514.510(c)(1); and the Total Incremental GUARD Model rebate amount as calculated at § 514.510(c)(2). Updating these calculation inputs at regular reconciliation intervals will result in a GUARD Model rebate amount that more fully reflects the majority of shifts in the underlying data following additional time for claims run-out, which refers to the maturation of PDE records in CMS' internal PDE database. Because the information extracted represents the PDE records' status in CMS' internal PDE database at that moment in time, additional run-out may yield different information, either because more PDE records with dispensing dates during the applicable period were finalized and added to the database or because the status of the existing PDE records changed. CMS refers to ''X months of runout'' as the period between the end of the applicable period and the date when CMS accesses information about the PDE records; for example, ''3 months of runout'' means that PDE records are accessed for PDE records with dispensing dates during a performance year 3 months after the end of such performance year. Conducting a reconciliation of the Total Incremental GUARD Model rebate amount with additional claims runout will improve the accuracy of the Total Incremental GUARD Model rebate amount. Additionally, reconciliation of payment amounts is consistent with the approach to the calculation of the payment amounts in other CMS programs (such as the Manufacturer Discount Program) that provide for a reconciliation period.

CMS notes that the reconciliation of the Total Incremental GUARD Model rebate amount, whether during a reconciliation proposed at § 514.610(d)(1) or a discretionary reconciliation proposed at § 514.610(d)(2) discussed further later in this Section of this proposed rule, will not create a separately payable and distinct Total Incremental GUARD Model rebate amount. Rather, reconciliation updates the prior Total Incremental GUARD Model rebate amount owed to CMS, if any, by a manufacturer of a GUARD Model drug so that the Total Incremental GUARD Model rebate amount ultimately accounts for shifts in the underlying data following additional time for claims runout after the GUARD Model Rebate Report is issued as well as subsequently identified data integrity issues, if applicable, to reflect a more precise calculation of the Total Incremental GUARD Model rebate amount. This reconciliation approach aligns with the reconciliation process described in 42 CFR 428.401(d). Moreover, because the reconciled Total Incremental GUARD Model rebate amount is an adjustment of the prior Total Incremental GUARD Model rebate amount, CMS proposes at § 514.610(d)(1)(i)(G) for a report of a reconciled Total Incremental GUARD Model rebate amount to also identify the difference between the Total Incremental GUARD Model rebate amount due as specified on the GUARD Model Rebate Report set forth in proposed § 514.610(b)(2)(xii) and the reconciled Total Incremental GUARD Model rebate amount. CMS would only collect the net Total Incremental GUARD Model rebate amount due, if any, upon reconciliation to prevent any duplicate payments. CMS also proposes to refund any overpayment made by a manufacturer, as determined during reconciliation, as discussed in proposed § 514.640(b).

As CMS noted in the CY 2025 Physician Fee Schedule (89 FR 97710) for the Inflation Rebate Program, CMS evaluated several options to reconcile the inflation rebate amount for Part D rebatable drugs to account for revised information. This informed the current proposal to establish two regular reconciliations at regular intervals to reconcile the Total Incremental GUARD Model rebate amount to account for revised information. As in the Part D Inflation Rebate Program, CMS considerations for the GUARD Model included the length of time needed to capture relevant changes to data inputs for recalculation and manufacturer burden. Specifically, CMS considered the average time span needed to ensure submission of the majority of Part D plan unit revisions specified in section 1860D–14B(b)(6) of the Act and proposed § 514.510(d), and the average time span needed for the submission of data from Manufacturer Discount Program, DIR, and the Medicare Part D Inflation Rebate Program. CMS believes a longer period of claims runout (at least 12 and 36 months of runout time under the proposed approach) would ensure that CMS more fully accounts for capturing of revised units. Further, the first reconciliation would include at least 13 months of claims runout for the performance year and would be issued within 12 months after the GUARD Model Rebate Report for the same performance year. The second reconciliation would include at least 37 months of claims runout for the performance year and would be issued 36 months after the GUARD Model Rebate Report for the same performance year.

The first reconciliation, issued 12 months after the GUARD Model Rebate Report, would provide sufficient time to capture the majority of updates to the data specified in proposed § 514.610(d)(1)(i)(A) through (H). The second reconciliation, to be issued 36 months after the GUARD Model Rebate Report, is sufficient to capture the remainder of the updates to the data specified in proposed § 514.610(d)(1)(i)(A) through (H) while also closing out the calculation of the Total Incremental GUARD Model rebate amount for a performance year within a reasonable time period after the GUARD Model Rebate Report is issued (except for the circumstances in proposed § 514.610(d)(2) regarding CMS' identification of mathematical errors or manufacturer misreporting).

Further, in considering whether consistency across CMS programs is critical, CMS believes that consideration for the completeness of data, as discussed previously, should be prioritized over consistency across program timelines. That is, when examining timelines from other CMS programs that collect data contributing to calculation of the Total Incremental GUARD Model rebate amount, CMS prioritized completeness and accuracy of the data elements contributing to the calculation of the Total Incremental GUARD Model rebate amount rather than prioritizing consistency among the data collection and reconciliation timelines themselves. To ensure an accurate Total Incremental GUARD Model rebate amount, CMS proposes to update additional calculation inputs as described in proposed § 514.610(d)(1)(i)(A) through (H). CMS believes that a restatement of each data element included in proposed § 514.610(d)(1) to reconcile the Total Incremental GUARD Model rebate amount provided in the GUARD Model Rebate Report in proposed § 514.610(c)(1) is appropriate to capture an updated Total Incremental GUARD Model rebate amount and is in line with

other CMS programs that provide for a reconciliation period. While some data points may not change, CMS would review the data to determine if there are any updates and use the updated data in the reconciliation to provide a reconciled Total Incremental GUARD Model rebate amount to the manufacturer. CMS notes that the applicable international benchmark will not be updated during reconciliation.

Based on these considerations, similar to the multistep process for the GUARD Model Rebate Report proposed in § 514.610(b) and (c), CMS proposes a multistep process to provide each manufacturer of a GUARD Model drug with a reconciled Total Incremental GUARD Model rebate amount on a regular basis. At both the 12-month reconciliation point and the 36-month reconciliation point, CMS proposes a reconciliation process that would include: (1) a preliminary reconciliation of the total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount, which CMS would provide to manufacturers of GUARD Model drugs as proposed in § 514.610(d)(1)(i); and (2) a reconciled total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount, which CMS would provide to manufacturers of a GUARD Model drug as proposed in § 514.610(d)(1)(ii). CMS also proposes to apply the Suggestion of Error process specified in proposed § 514.620 to each preliminary reconciliation.

1. Regular Reconciliation

First, as specified in proposed § 514.610(d)(1) and similar to the Preliminary GUARD Model Rebate Report process proposed in § 514.610(b) and (c), for each reconciliation CMS proposes to provide the manufacturer with information about the preliminary reconciliation of the total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount within 60 calendar days prior to the issuance of the reconciled total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount (see proposed § 514.610(d)(1)(i)) to each manufacturer of a GUARD Model drug for a performance year. CMS proposes in § 514.610(d)(1)(i)(A) through (H) that the preliminary reconciliation would include, at a minimum, the same information outlined for the GUARD Model Rebate Report and the following updated information, if applicable: updated total number of units, including updates submitted by a PDP or MA–PD plan sponsor and updates to 340B units and units excluded as specified in proposed § 514.510(d); the total GUARD Model rebate amount if any inputs are restated within the reconciliation run-out period as specified in proposed § 514.510(a); the per unit GUARD Model rebate amount if any inputs are restated within the reconciliation run-out period as specified in proposed § 514.510(b); the incremental per unit GUARD Model Rebate Amount as specified in proposed § 514.510(c)(1), using the most recent per unit Part D inflation rebate amount for the performance year (if any inputs are restated within the reconciliation runout period); WAC for the performance year; the reconciled Total Incremental GUARD Model rebate amount as set forth in proposed § 514.610(c)(2); and the difference between the Total Incremental GUARD Model rebate amount due as specified on the GUARD Model Rebate Report and the reconciled Total Incremental GUARD Model rebate amount as set forth in proposed § 514.610(d)(1)(i)(G).

Second, CMS proposes in § 514.610(d)(1)(ii) to provide a reconciled Total Incremental GUARD Model rebate amount to the manufacturer within 12 months and 36 months after the GUARD Model Rebate Report was issued for each performance year. As proposed in § 514.610(d)(1)(i)(A) through (H), the information in the report for a reconciled total GUARD Model rebate amount would include the same data elements as provided to the manufacturer of a GUARD Model drug in the report detailing a preliminary reconciliation of a total GUARD Model rebate amount and would include any recalculations based on CMS acceptance of a manufacturer's Suggestion of Error from proposed § 514.620. A reconciliation of the Total Incremental GUARD Model rebate amount may result in an increase, decrease, or no change to the total GUARD Model rebate amount or Total Incremental GUARD Model rebate amount, compared to the GUARD Model Rebate Report for a performance year or a previous reconciliation in the case of reconciliation conducted 36 months after issuance of the GUARD Model Rebate Report (see proposed § 514.610(d)(3)).

2. Suggestion of Error

Similar to the Suggestion of Error process described in section IV.I.3. of this proposed rule, CMS proposes in § 514.620(c) a process by which the manufacturer of a GUARD Model rebatable drug may submit a Suggestion of Error within 10 calendar days after the date of receipt of the information about the preliminary reconciliation of the total GUARD Model rebate amount. CMS proposes that a manufacturer may suggest to CMS that the manufacturer believes the difference between the preliminary reconciliation of the total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount contains a mathematical error. CMS believes a 10-calendar day period is sufficient due to the same considerations of data volume, the narrow set of in-scope items for review, and the operational time necessary for CMS to publish the reconciled total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount.

3. Reconciliation Due to Error or Misreporting

CMS considered options for establishing circumstances where a recalculation of the total GUARD Model rebate amount or Total Incremental GUARD Model rebate amount may be appropriate for a performance year after issuing the GUARD Model Rebate Report and/or a reconciled total GUARD Model rebate amount or Total Incremental GUARD Model rebate amount based on CMS identifying an error or CMS determining that the information used by CMS to calculate a total GUARD Model rebate amount or Total Incremental GUARD Model rebate amount was inaccurate due to false reporting or similar fault by the manufacturer. CMS also considered potential time limits for revisions and whether certain circumstances, such as instances of false reporting, should be exempt from such time limits.

Based on these considerations, CMS believes that, to capture an accurate total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount, and consistent with reconciliations of data submitted to CMS that provide for revisions when necessary due to errors, including mathematical errors, and manufacturer misreporting, certain circumstances merit reconciliation of the total, GUARD Model rebate amount and/or Total Incremental GUARD Model rebate amount separate from the 12-month and 36-month reconciliations proposed at § 514.610(d)(1). Specifically, CMS proposes in § 514.610(d)(2) that CMS may reconcile a total GUARD Model rebate amount and/or a Total Incremental GUARD Model rebate amount of an issued GUARD Model Rebate Report when CMS identifies either: 1) an agency error such as a mathematical error or an error in the information specified in a GUARD Model Rebate Report as described in proposed § 514.610(c) or report of a

reconciled GUARD Model rebate amount as described in proposed § 514.610(d)(1), including reporting system or coding errors; or 2) CMS determines that information used to calculate the total GUARD Model rebate amount or Total Incremental GUARD Model rebate amount was inaccurate due to manufacturer misreporting. Examples of agency errors could include CMS incorrectly calculating the billing units per GUARD Model drug or the GUARD Model Rebate Report incorrectly displaying the Total Incremental GUARD Model rebate amount. Examples of manufacturer misreporting could include instances in which the manufacturer has made a correction to previously submitted data as well as instances in which the reporting individual or entity reporting data or information to CMS on behalf of the manufacturer knows or should know is inaccurate or misleading (for example, inaccurate manufacturer pricing or product data under section 1927(b)(3) of the Act), including information submitted by the manufacturer related to the international benchmark. This does not include standard restatements to WAC or other data outside of the standard process of issuing a reconciled Total Incremental GUARD Model rebate amount. In addition to manufacturer-initiated corrections, CMS may become aware of manufacturer misreporting based on fact finding and conclusions of enforcement authorities, for example, the HHS OIG, the CMS Center for Program Integrity, or the Department of Justice. In a situation where an error or manufacturer misreporting is identified prior to the 12- or 36-month reconciliation of the total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount proposed in § 514.510(c)(1), CMS may choose to include a correction based on the circumstances proposed in § 514.610(d)(2) concurrently with the 12- or 36-month reconciliation. When CMS reconciles data due to an instance of agency error or manufacturer misreporting, CMS proposes that the agency would limit the scope of the reconciliation to the specific information that is the basis for the reconciliation and not update or otherwise revise any other data elements in the GUARD Model Rebate Report (specified in proposed § 514.610(b)(2)(i) though (xii)) or the reconciled GUARD Model Rebate Report (specified in proposed § 514.610(d)(1)(i)(A) though (H)) unless the correction directly impacts additional data fields. For example, updates to WAC effective dates may not change the performance year Medicare net price if the new effective WAC for a date of service matches the WAC that CMS had imputed for that date of service.

In addition, because reconciling a Total Incremental GUARD Model rebate amount imposes substantial administrative burden on CMS to reprocess the total GUARD Model rebate amount and Total Incremental GUARD Model rebate amount, retest the reporting system, and reissue a reconciled GUARD Model Rebate Report, CMS proposes in § 514.610(d)(2) that it may exercise discretion not to initiate recalculation of the total GUARD Model rebate amount or Total Incremental GUARD Model rebate amount in these situations which are outside of the regular reconciliation process proposed in § 514.610(d)(1).

4. Timeframe for Reconciliation Due to Agency Error

CMS proposes that for a recalculation due to an agency error, the error must be identified within 5 years of the date of receipt of the GUARD Model Rebate Report for the performance year (see proposed § 514.610(d)(2)(i))). Identification means that CMS has knowledge of the error; CMS does not need to have completed its revision of the impacted data or determined if the revision impacts the total GUARD Model rebate amount or Total Incremental GUARD Model rebate amount within the 5-year period. CMS would timely complete these steps and determine, when reconciliation does impact the total GUARD Model rebate amount and/or Total Incremental GUARD Model rebate amount, whether the reconciliation could be included in an upcoming reconciled Total Incremental GUARD Model rebate amount for the performance year or if the reconciliation must be conducted outside of the regular reconciliation process described at proposed § 514.610(d). CMS proposes 5 years to account for the additional time of the second reconciliation that would be conducted at 36-months as proposed in § 514.610(d)(1). CMS believes that a 5-year period dating from the issuance of the GUARD Model Rebate Report allows for sufficient time to include restatements of underlying data while also placing a reasonable time limit on potential discretionary reconciliations, after which a manufacturer of a GUARD Model drug would not receive additional GUARD Model Rebate Report.

5. Timeframe for Manufacturer Misreporting

CMS proposes in § 514.610(d)(2)(ii) that for a circumstance in which a manufacturer misreports data, CMS may recalculate a rebate at any time if the information used by CMS to calculate the rebate amount was inaccurate due to manufacturer misreporting. For example, if a determination is made that a manufacturer misreported WAC, which affected the calculation of the model year Medicare net price, then CMS may recalculate the total GUARD Model rebate amount and the Total Incremental GUARD Model rebate amount owed for a GUARD Model drug. CMS requests comments on the proposals related to manufacturer misreporting.

6. Payment Deadline and Report Issuance

CMS proposes in § 514.640(a)(1) that upon receipt of a reconciled Total Incremental GUARD Model rebate amount, manufacturers must pay that reconciled Total Incremental GUARD Model rebate amount within 30 calendar days from the date of receipt of the reconciled Total Incremental GUARD Model rebate amount. A 30-calendar day payment deadline aligns with the payment period for the initial GUARD Model Rebate Report and for similar reconciliations in the Inflation Rebate Program described at 42 CFR 428.405.

As specified in proposed § 514.630(a)(1), CMS would use the same method and process for issuing GUARD Model Rebate Reports and submission of payments for reports with a reconciled Total Incremental GUARD Model rebate amount. CMS would provide notice to manufacturers for reports with a reconciled Total Incremental GUARD Model rebate amount. CMS proposes in § 514.640(b) that if a refund is owed to a manufacturer based on a reconciled Total Incremental GUARD Model rebate amount, CMS would initiate the process to issue such refund within 60 calendar days from the date of receipt of the reconciled Total Incremental GUARD Model rebate amount. CMS will issue additional information on this method and process through future program communications.

K. Enforcement of Manufacturer Payment of Rebate (§ 514.650)

Consistent with the Medicare Part D Drug Inflation Rebate Program and enabled by CMS' waiver of subsection (b) of section 1860D–14B of the Act, and as described in this Section of this

proposed rule, CMS proposes that manufacturers of a GUARD Model drug that have failed to timely pay the Total Incremental GUARD Model rebate amount as described in proposed § 514.510(c)(2) may be subject to a Civil Money Penalty (CMP). Given the importance of these rebates, CMS may impose available CMP authority under regulations at 42 CFR 428.500 of the Medicare Part D Inflation Rebate Program under section § 1860D–14B(e) of the Act to ensure timely compliance with payments. CMS proposes in § 514.650 to impose a CMP equal to 125 percent of the rebate amount described at § 514.510(c) for each GUARD Model drug for each performance year that a manufacturer fails to pay the rebate amount for each dosage form and strength for each GUARD Model drug.

Consistent with the Medicare Part D Inflation Rebate Program at Section 1860D–14B(e), and the implementing regulations at 42 CFR 428.500, the proposed § 514.650 would implement the already established procedures for imposing and collecting a CMP. The total GUARD rebate payment amount, which would replace the rebate amount described at section 1860D–14B(b) of the Act, would be invoiced in two separate parts: the rebate amount in the Medicare Part D Inflation Rebate Program's Rebate Reports plus the Total Incremental GUARD Model rebate amount in the GUARD Model Rebate Report for a GUARD Model drug.[181] Because CMS would have already imposed any potential CMP on the rebate amounts in the Medicare Part D Inflation Rebate Program's Rebate Reports, the GUARD Model would calculate any additional CMP owed as an amount equal to 125 percent of the Total Incremental GUARD Model rebate amount due or a reconciled Total Incremental GUARD Model rebate amount due for the GUARD Model drug in the relevant performance year.

Additionally, CMS proposes to rely on our general CMP authority in section 1128A of the Act, also referenced in section 1860D–14B(e) of the Act, and the implementing regulations at 42 CFR 428.500. Specifically, section 1128A(a)(8) of the Act allows a CMP to be imposed against anyone who ''knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items or services furnished under a Federal health care program.'' CMS believes that any GUARD Model manufacturer that knowingly fails to comply with the GUARD Model requirements as set forth in this regulation, could be subject to a CMP under section 1128A of the Act. Any CMP imposed against a GUARD Model manufacturer would be an amount equal to 125 percent of the Total Incremental GUARD Model rebate amount due for the drug and applicable calendar year in addition to the Medicare Part D Inflation rebate amount that is due.

CMS is proposing it may impose a CMP when a manufacturer fails to pay the GUARD Model rebate amount in full for a GUARD Model drug by the payment deadlines in proposed § 514.640(a)(1). This means a manufacturer may be subject to a CMP if the manufacturer fails to pay the Total Incremental GUARD Model rebate amount as invoiced in the GUARD Model Rebate Report or any reconciled Total Incremental GUARD Model rebate amount that is greater than the amount invoiced in the GUARD Model Rebate Report. More specifically, a manufacturer could be subject to a CMP when a manufacturer fails to pay a Total Incremental GUARD Model rebate amount due by any payment deadline proposed in § 514.640(a)(1) for: (1) a GUARD Model Rebate Report specified in proposed § 514.610(c); or (2) a reconciled Total Incremental GUARD Model rebate amount greater than the amount reflected in the GUARD Model Rebate Report specified in proposed § 514.610(d). As discussed earlier in section IV.J. of this proposed rule, CMS notes that the reconciled or corrected Total Incremental GUARD Model rebate amount is not a separately payable and distinct rebate amount. Rather, the reconciled Total Incremental GUARD Model rebate amount is an update to the Total Incremental GUARD Model rebate amount owed to CMS by a manufacturer of a GUARD Model drug.

CMPs are due at the applicable GUARD Model Rebate payment deadline, which occurs 30 calendar days after the date of receipt of a GUARD Model Rebate Report or a report of a reconciled Total Incremental GUARD Model rebate amount. CMS proposes to establish the same methodology as in 42 CFR 428.500 for determining the amount of the CMP as equal to 125 percent of the Total Incremental GUARD Model rebate amount for such drug for a performance year. This penalty would be due in addition to the Total Incremental GUARD Model rebate amount due. That is, a manufacturer would be responsible for paying the Total Incremental GUARD Model rebate amount due in addition to any CMP imposed because of late payment. CMS is proposing this approach to apply CMPs based on a violation of section 1860D–14B(a)(2) of the Act, and its regulatory enforcement mechanism at 42 CFR 428.500, which this model is adopting and cross-referencing, as described in § 514.650 for each GUARD Model drug. CMS believes that the ability to impose a CMP is necessary to ensure compliance with the GUARD Model in all circumstances where a manufacturer fails to make a rebate payment that is due for a Total Incremental GUARD Model rebate amount to CMS.

The CMP would be calculated based on the outstanding Total Incremental GUARD Model rebate amount due at the payment deadline, which is defined in proposed § 514.640(a)(1) as 30 calendar days after the date of receipt of a GUARD Model Rebate Report or a report of a reconciled Total Incremental GUARD Model rebate amount containing any Total Incremental GUARD Model rebate amount due. Once a GUARD Model CMP is imposed due to a late payment, the penalty would remain in effect through any appeal procedures even if the manufacturer pays the outstanding Total Incremental GUARD Model rebate amount after the penalty is imposed due to a missed payment deadline. Any CMP would be assessed before the next 12- or 36-month reconciliation.

As described at § 428.500, CMPs for the Medicare Part D Drug Inflation Rebate Program may be calculated at several points in time associated with missing a payment deadline for the rebate amount owed by the manufacturer. Accordingly, CMS is proposing that a CMP may be imposed after missing a payment deadline associated with any Total Incremental GUARD Model rebate amount if the Total Incremental GUARD Model rebate amount is reconciled to be greater than the amount invoiced in the GUARD Model Rebate Report. As these separate events can result in distinct and separate impositions of CMPs, this means that CMS would not modify a CMP from a prior missed payment deadline based on changes to the Total Incremental GUARD Model rebate amount due following reconciliation, including scenarios where the Total Incremental GUARD Model rebate amount is reduced following reconciliation. However, in the event

[181] There are differences in timing between the GUARD Model performance year and the Part D Inflation Rebate Program. Specifically, while the GUARD Model would be implemented on a calendar year schedule, the Part D Inflation Rebate Program is based on a fiscal year (FY) schedule. As a result, there would be inflation rebate amounts from 2 FYs of the Part D Inflation Rebate Program that contribute to the GUARD Model's single performance year report for a GUARD Model drug. The inflation rebate amounts would be weighted as described in section IV.H. of this proposed rule.

that the Total Incremental GUARD Model rebate amount due on a GUARD Model Rebate Report was not paid and a CMP was issued for violation of the payment deadline, CMS would not issue a second CMP on a reconciled Total Incremental GUARD Model rebate amount if reconciliation decreased the Total Incremental GUARD Model rebate amount stated on the GUARD Model Rebate Report. CMS believes that enforcing this requirement after each payment deadline, regardless of what Total Incremental GUARD Model rebate amount a manufacturer may or may not owe at a future payment deadline, is necessary to maintain the integrity of the model and consistency of the implementation of the model. Further, CMS is proposing this approach to ensure an enforcement approach that is operationally feasible and applied consistently in all cases.

Payment of any CMP by a GUARD Model manufacturer would be in addition to any GUARD Model rebate amount due for a GUARD Model drug. In addition, CMS is evaluating all available options to ensure manufacturers' timely compliance with their Total Incremental GUARD Model rebate payment obligations, including, without limitation, potential recovery approaches and enforcement actions. For example, CMS may refer manufacturers to the Department of Justice, Department of the Treasury, and/or the HHS OIG for further review and investigation.

As described at § 428.500(c), and also reflected in proposed § 514.650, if CMS makes a determination to impose a CMP on a manufacturer for violation of a payment deadline, CMS would send a written notice of the decision to impose a CMP that includes a description of the basis for the determination, the basis for the penalty, the amount of the penalty, the date the penalty is due, the manufacturer's right to a hearing, and information about where to file the request for a hearing. To ensure a consistent approach to civil money penalties, CMS proposes using existing appeal procedures for CMPs in § 1128A as referenced in section 1860D–14B(e) of the Act, and in 42 CFR 423, subpart T for manufacturers appealing a CMP imposed under the GUARD Model, consistent with the approach taken for the Medicare Part D Drug Inflation Rebate Program. CMS has utilized this appeals process for many years for CMP determinations affecting MA organizations and Part D sponsors. CMS therefore proposes to use this well-established legal process for CMP appeals from manufacturers that do not make inflation rebate payments by the payment deadline. CMS also proposes that the scope of appeals is limited to: (1) CMS determinations relating to whether payment of the Total Incremental GUARD Model rebate amount was made by the payment deadline; and (2) the calculation of the civil monetary penalty amount.

Section 1860D–14B(e) of the Act states that the provisions of section 1128A of the Act (except subsections (a) and (b)) apply to civil money penalties under this subpart to the same extent that they apply to a CMP or procedure section 1128A of the Act. In alignment with the procedures outlined in section 1128A of the Act, CMS proposes that collection of the CMP would follow expiration of the timeframe for requesting an appeal, which is 60 calendar days from the civil money penalty determination in cases where the manufacturer did not request an appeal. In cases where a manufacturer requests a hearing and the decision to impose the CMP is upheld, CMS would initiate collection of the CMP once the administrative decision is final, recognizing that the manufacturer still has appeal rights.

CMS proposes in that in the event that a manufacturer declares bankruptcy, as described in Title 11 of the United States Code, and as a result of the bankruptcy, fails to pay either the Total Incremental GUARD Model rebate amount owed or the total sum of CMP imposed, the government reserves the right to file a proof of claim with the bankruptcy court to recover the unpaid Total Incremental GUARD Model rebate amount and/or civil monetary penalties owed by the manufacturer.

L. Quality and Monitoring Strategy

In this section of the proposed rule, we describe the quality and monitoring strategy for the GUARD Model. The CMS Innovation Center is testing the GUARD Model to monitor and evaluate whether the alternative payment methodology proposed under the GUARD Model reduces Medicare spending while preserving or improving quality of care. The proposed quality measurement strategy is consistent with section 1115A(b)(4) of the Act, including the measurement of patient-level outcomes and patient-centeredness criteria. CMS proposes to implement robust monitoring and evaluation activities to identify any changes in quality.

1. General

The GUARD Model tests an alternative to the inflation rebate payment calculation to understand whether this leads to greater savings while preserving or enhancing quality of care. The GUARD Model does not introduce any new financial incentives tied to quality performance for manufacturers, plans, or any stakeholder in the prescription drug supply chain. However, the GUARD Model does introduce additional liabilities for manufacturers in the form of rebate payments if the Medicare net price is greater than the GUARD Model applicable international benchmark, as described in section IV.H. of this proposed rule. We do not expect these additional liabilities to reduce quality of care. It is possible that manufacturers respond to the GUARD Model by reducing their Medicare net price in an effort to reduce the GUARD Model rebate payments, or reduce their launch prices over time for new drugs likely to be included in the GUARD Model during the performance period. If manufacturers respond in these ways, it is possible there would be a series of changes throughout the pharmaceutical supply chain. For example, if manufacturers reduce the net price of a GUARD Model drug, that may result in reductions in coinsurance rates for GUARD Model drugs, which would improve affordability for Part D enrollees who take these medications. However, given that this is a test, we cannot say precisely how manufacturers will respond; therefore, it is necessary to monitor quality and evaluate certain quality measures to fully understand the impact of the Model.

Consistent with the evaluation provisions of section 1115A(b)(4) of the Act, CMS proposes utilizing quality measures to monitor and evaluate whether quality of care improves or is maintained. This includes monitoring, and if appropriate, evaluating changes in patient level outcomes that may occur as a result of the proposed alternative inflation rebate payment approach that is being tested under the GUARD Model drugs. To determine whether quality is preserved or enhanced in the GUARD Model, at § 514.720(a), CMS proposes to examine multiple domains of quality, including but not limited to utilization of care, out-of-pocket costs, access to GUARD Model drugs, changes in Part D plan premiums, and patient experience, as described later in this Section of this proposed rule. Monitoring activities would take place at least annually and as appropriate based on availability of the data discussed in this section. CMS is interested in public feedback on how to structure and monitor quality of care in the GUARD Model.

To detect possible changes in quality of care that may be associated with the

GUARD Model, CMS proposes in § 514.720(b), to examine a range of outcomes using existing data. For example, administrative claims data such as PDE data may be used to conduct historic comparisons of trends in GUARD Model drug utilization and program spending (for example, Medicare Part D total gross drug spending and total out-of-pocket spending for the GUARD Model drugs). The Part D Formulary File [182] could be used to examine prescribing patterns (including observing for any shift to compounded or other categories of drugs that are not included in the GUARD Model). We would also use existing claims-based or administrative data to examine changes in MA–PD plan and PDP monthly premiums, MA–PD plan and PDP enrollment, and other indicators of quality of care. We anticipate that monitoring activities may also include patient and/or provider survey data analytics and tracking patient complaints and appeals. Examining these and other measures will help CMS assess quality of care, which must be evaluated under section 1115A(b)(4) of the Act.

The proposed GUARD Model does not test the efficacy of pharmacy dispensed prescription drugs, but rather, it tests the impact of an alternative Part D inflation rebate calculation. Thus, CMS does not propose new monitoring of changes to drug-related adverse events. If, during the GUARD Model, the patient experience of care, quality measures, and claims-based monitoring strategies are found to be insufficient to adequately monitor and measure the quality of care that GUARD beneficiaries are receiving, CMS may specify additional measures to monitor quality.

2. Quality Measures

CMS proposes at § 514.720 to use a variety of data sources to monitor and evaluate the quality of care, including patient-level factors. For example, CMS may monitor or evaluate outcomes related to any of the following:

- Changes in Part D prescribing patterns (for example drug substitution effects, use of certain drug formulations or therapeutic alternatives over others, high-risk medication prescribing).
- Changes in enrollment of standalone PDPs or MA–PD plans that are beyond expected variation.
- Changes in drug formularies and tiering of Part D drugs in regions.
- Patient experience measures for prescription drugs (for example medication access, refills, communication with prescribers).
- Medication adherence (for example proportion of days covered).
- Changes in costs to Medicare beneficiaries (for example, monthly Part D premiums, coinsurance, copayments).
- Changes in generic drug substitution rates.

As proposed at § 514.720(b), CMS may also find it necessary to supplement these measures by surveying beneficiaries who receive Part D medications dispensed at a pharmacy to better understand their individual experiences. In such a scenario, CMS plans to utilize existing surveys such as the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey or the MCBS, whenever possible. Any new surveys would limit stakeholder burden to a minimum and utilize validated survey items.

CMS believes that examining these and other quality measures will allow us to promptly identify any unintended consequences and assess whether quality of care improves or is maintained under the GUARD Model. CMS seeks feedback on our approach to monitoring quality of care and what other data sources or measures we should consider.

M. Beneficiary Protections and Compliance Related Activities

CMS recognizes that stakeholders may have concerns about the potential changes that may occur as the GUARD Model is implemented. For example, stakeholders may have concerns over potential disruptions to Medicare Part D enrollees' access to drugs covered under Medicare Part D, including those that are GUARD Model drugs, as a result of changing financial incentives under the GUARD Model. To alleviate these concerns, CMS has considered ways to protect beneficiary access to Medicare Part D drugs during the model performance period, which we describe later in this Section of this proposed rule, along with our approach for compliance, audits and record retention, and enforcement authority and remedial action.

1. Beneficiary Protections

CMS proposes to use the Complaints Tracking Module,[183] as described in § 423.129(a), an existing reporting system maintained by CMS, to record and track complaints submitted to CMS from beneficiaries, and others. CMS would periodically, but no more than monthly, examine whether complaints submitted are related to the GUARD Model drugs. Analyses conducted of complaints submitted could notify CMS that a particular drug has become harder to source or obtain after the implementation of the GUARD Model. A reporting system such as this would allow CMS to gather information to inform potential follow-up investigations to determine if any drug access issues are occurring. Therefore, CMS proposes at § 514.710(b) to use the existing Complaints Tracking Module as described in § 423.129(a) to monitor for complaints related to the GUARD Model.

Additionally, as proposed at § 514.710(b)(2) and as stated, for all CMS Innovation Center models at § 512.150(b), CMS proposes to address as appropriate, any information related to the GUARD Model drugs that is reported through the existing Medicare hotline phone number (1–800–MEDICARE), including but not limited to requesting additional information from the submitter and conducting additional analyses to determine whether the report requires further action from CMS or other governmental entities. In addition, the Medicare hotline phone number will also be posted on the GUARD Model website along with an email address that beneficiaries or other stakeholders can use to share concerns with CMS about the GUARD Model.

To ensure full and continued compliance with existing beneficiary protections, CMS expects Part D plans to continue to fulfill all of the existing Part D requirements under 42 CFR part 423, including:

- Compliance with all enrollment and anti-discrimination requirements stated in subpart B of part 423, and in particular the following:
  - ++ Allowing enrollment of all eligible beneficiaries who choose to enroll regardless of their anticipated drug utilization or costs.
  - ++ Not restricting enrollees' pharmacy choices or taking any actions that would discourage enrollment or discriminate against beneficiaries based on their health status, prescription drug needs, or other factors indicating higher expected costs.
- Compliance with all benefits and beneficiary protections including access

[182] The Medicare Part D Formulary file is a suite of five sub-files: Formulary, Excluded Drug, Over-the-Counter Drug, Indication-based Formulary, and Part D Senior Savings (PDSS) Model that contain information on how the plan covers the prescription drugs filled (as described in the Part D Drug Event (PDE) file. Available at: *https://resdac.org/cms-data/files/part-d-formulary-file.*

[183] Centers for Medicare & Medicaid Services. (2025). *Updated Complaints Tracking Module Standard Operating Procedures.* U.S. Department of Health and Human Services. *https://ncpa.org/sites/default/files/2025-01/CTMSOP01062025.pdf* (Accessed: 10 December 2025).

to covered Part D drugs stated in Subpart C of Part 423 and in particular the following:

++ Preserving enrollees' fundamental access rights to Part D covered drugs, which would include GUARD Model drugs, from any pharmacy.

++ Disclosure and transparency requirements, specifically, providing clear, accurate, and timely information about changes in enrollees' drug coverage, cost sharing, or access to medications as well as changes to formularies or utilization management requirements.

• Compliance with beneficiary coverage determinations and appeals processes stated in Subpart M of Part 423, and, in particular, the right to request formulary exceptions, tiering exceptions, and prior authorization exceptions under existing Part D requirements and adhering to existing timeframes, processes, and standards for coverage determinations, redeterminations, reconsiderations, or Administrative Law Judge hearings.

2. Monitoring and Compliance Activities

The CMS Innovation Center has designed and tested numerous alternative payment models that each include specific payment, quality, and other policies. However, there are some general provisions that are very similar across models. The general provisions address various topics, including but not limited to monitoring and compliance, described at 42 CFR 512.150, and the requirement of model participants to cooperate in model evaluation and monitoring described at 42 CFR 512.130. We propose at § 514.730 to apply these general provisions on monitoring and compliance, based on the similar requirements that have been previously finalized in existing model tests.

In addition, as described in section IV.L. of this proposed rule and as allowed under proposed § 514.720(a), CMS intends to monitor for specific potential issues that could arise under the GUARD Model. Specifically, CMS intends to monitor for major changes in Part D enrollees' access to GUARD Model drugs, cost sharing for Part D enrollees who are taking GUARD Model drugs, and other measures, as described in section IV.L. of this proposed rule, at least annually and as appropriate based on data availability. CMS would also monitor changing list prices in the United States and the Medicare net price as part of understanding how manufacturers respond to the GUARD Model. CMS may also consider examining any changes in drug innovation, research and development; changes in launch prices of drugs; and timing of drugs coming to market in the United States. CMS also proposes to collaborate with the FDA to review shortage lists and determine whether the number of drugs or length of time on the shortage list changes over time.

Consistent with other CMS Innovation Center models, and as stated at § 512.150(b) and (c), CMS, as described previously, would conduct monitoring, and compliance activities for the GUARD Model to ensure the integrity of the GUARD Model and that the model is implemented safely and appropriately. As part of the CMS Innovation Center's assessment of the impact of new models such as the GUARD Model, we have a special interest in ensuring that model tests do not interfere with the integrity and sustainability of the Medicare program from a financial, policy, and beneficiary-rights perspective.

For these reasons, as part of the models currently being tested by the CMS Innovation Center, CMS or its designee(s) monitors model participants to assess compliance with model terms and with other applicable program laws and policies as well as to ensure that model participants are not falsifying data, increasing program costs, or taking other actions that compromise the integrity of the model or are not in the best interests of the model, the Medicare program, or Medicare beneficiaries. As stated at § 512.150(b) for all CMS Innovation Center models, GUARD Model participants would also be monitored to determine the effects of the GUARD Model on GUARD beneficiaries, pharmacies and other dispensing entities, and on the Medicare program and to facilitate real time identification and response to any potential issues.

Further, as proposed specifically for the GUARD Model at § 514.750(a) and as stated generally for all CMS Innovation Center models at § 512.160, a GUARD Model participant could be subject to the remedial actions as stated at § 512.160(b) if CMS determines that one of the violations stated at § 512.160(a) exists.

CMS also proposes at § 514.750(b), that a manufacturer of a GUARD Model drug is required to notify CMS within 15 calendar days after becoming aware that the manufacturer of the GUARD Model drug is under investigation or has been sanctioned by the federal, state, or local government, or any licensing authority (including, without limitation, the imposition of program exclusion, debarment, civil monetary penalties, corrective action plans, and revocation of Medicare billing rights).

3. Audits and Record Retention

We propose to adopt the audit, access, and record retention requirements set forth in § 512.135(a) and (b) for the GUARD Model. As stated in proposed § 514.740, which applies specifically to the GUARD Model, and as detailed in § 512.135(a), which applies to all CMS Innovation Center models, the Federal Government, including CMS, HHS, the Comptroller General, and their designees, has the right to inspect, investigate, and evaluate any documents and other evidence regarding implementation of an Innovation Center model. As stated in § 512.135(b), manufacturers of GUARD Model drugs are required to maintain and provide to the Federal government access to any documents and other evidence regarding all items set forth in § 512.135(b).

4. Enforcement Authority and Remedial Action

It is necessary for CMS to have the ability to impose remedial actions to address non-compliance with the requirements of the GUARD Model and to ensure that the GUARD Model does not interfere with the program integrity interests of the Medicare Program. As stated explicitly for all CMS Innovation Center models at § 512.150(e), nothing contained in subpart A of part 500 including the newly proposed part 514, limits or restricts the authority of the HHS OIG or any other Federal Government authority to audit, evaluate, investigate, or inspect the manufacturer of a GUARD Model drug.

Therefore, as proposed specifically for the GUARD Model at § 514.750(a), and as stated for all CMS Innovation Center Models at § 512.160, CMS may take the remedial actions stated at § 512.160(b) if CMS determines that one or more grounds for remedial action enumerated at § 512.160(a) exists. To assist CMS in its responsibility of oversight, at § 514.750(b), we propose that CMS requires the GUARD participant to notify CMS within 15 calendar days after becoming aware that the GUARD participant is subject to investigation or sanction by the federal, state, or local government, or any licensing authority.

N. Interaction and Coordination With Other Models and Programs

CMS is committed to ensuring people with Medicare continue to have access to robust and affordable prescription drug benefits. Upon reviewing potential interactions with other models and programs, we have found some

interaction between the GUARD Model and the existing programs and policies; however, we do not believe these interactions pose significant challenges, largely due to the intentional design of the GUARD Model. Namely, the GUARD Model has been designed to work with and in addition to all Part D benefit modifications pursuant to the IRA. Most of the IRA-related Part D provisions will have been implemented before the GUARD Model is implemented. Where there may be opportunities for interactions, CMS has designed the GUARD Model to avoid any serious complications for the GUARD Model test due to overlap or interactions with other models, or for the existing program or policies.

1. Approach for Overlap With CMS Innovation Center Models

Upon reviewing existing and ongoing CMS Innovation Center models, we have not identified any models that would have significant overlap or interaction with the GUARD Model at this time. We seek comments on any significant impacts on other models that the GUARD Model might have, as well as impacts on the GUARD Model by any other models. We anticipate model overlap may occur between the proposed GUARD Model and future CMS Innovation Center models or programs not yet implemented. If the proposed GUARD Model is finalized, CMS would take the GUARD Model into consideration in the development of future model designs to address potential impacts of overlap with the GUARD Model.

In summary, we are not proposing to modify or adjust any CMS Innovation Center model or CMS program or initiative with respect to model overlap with the proposed GUARD Model as we have presently not identified any significant overlap. If, in the future, CMS determines a modification or adjustment to the GUARD Model or other CMS Innovation Center model or CMS program or initiative is necessary for purposes of testing the GUARD Model, CMS would pursue such modification or adjustment at such time through the appropriate mechanisms. For example, modifications or adjustments to the GUARD Model would be pursued through notice and comment rulemaking whereas it might be appropriate for modifications or adjustments to other CMS Innovation Center models or CMS programs and initiatives to be pursued through updates to model policies and participation agreements, or program participation criteria or requirements.

2. Medicare Drug Price Negotiation Program

The Medicare Drug Price Negotiation Program, codified in sections 1191 to 1198 of the Act, gives the Secretary authority to negotiate a MFP for a specified number of certain high expenditure, single source drugs without generic or biosimilar competition with participating drug manufacturers.[184] In August 2023, CMS published the list of 10 drugs covered under Medicare Part D selected for the initial price applicability year and for which MFPs will go into effect on January 1, 2026. The second set of 15 drugs was announced in January 2025 and the MFP for these drugs is expected to go into effect in 2027.[185] The GUARD Model avoids significant interaction with the Medicare Drug Price Negotiation Program by excluding any Part D drug from being a GUARD Model drug when an MFP for that drug is in effect.

3. Part D Premium Stabilization and Part D Premium Stabilization Demonstration

As established by the IRA, codified at section 1860D–13(a)(8) of the Act, the premium stabilization provision caps the annual increase in the base beneficiary premium at 6 percent for each year from 2024 through 2029.[186] Further, the Part D Premium Stabilization Demonstration went into effect in 2025 to test an approach to stabilize the year-over-year changes in premiums for PDPs during the implementation of IRA's Part D redesign.[187]

We acknowledge that the GUARD Model may affect the Part D plan sponsor market. Therefore, we seek comments on any potential impacts on, or interactions with, the Part D plan market, particularly for standalone PDPs. CMS acknowledges that the recent IRA related changes to the Part D program, as discussed in section II. of this proposed rule, have placed pressure on the Part D plan market, which can be observed from the increase in Part D plan bids and premiums that would have occurred if the base beneficiary premium stabilization had not gone into effect. We seek comments on whether and to what extent there may be additional pressures placed on the Part D plan market due to the GUARD Model and potential solutions to avoid or mitigate such impacts. We also seek comments on any potential interactions with the market for MA–PD plans.

4. 340B Drug Discount Program

The Health Resources and Services Administration (HRSA) administers the 340B Drug Pricing Program that allows certain hospitals and other health care providers (covered entities) to obtain discounted prices on covered outpatient drugs (as defined at section 1927(k)(2) of the Act) from drug manufacturers. HRSA calculates a 340B ceiling price for each covered outpatient drug, which represents the maximum price a manufacturer can charge a covered entity for the drug that is provided to an eligible patient. Several types of hospitals as well as clinics that receive certain federal grants from the HHS may enroll in the 340B program as covered entities.[188] To coordinate with the 340B program, GUARD Model drug units associated with claims for GUARD Model drugs under the 340B program would be removed as discussed in section IV.H. of this proposed rule.

5. Part D Direct Subsidy and Reinsurance

Under section 1860D–15 of the Act, Medicare provides direct subsidy payments to Part D plan sponsors to help cover the cost of providing prescription drug benefits. The direct subsidy calculation is based on the Medicare Part D National Average Monthly Bid Amount (NAMBA).[189] Additionally, Medicare's reinsurance

[184] Congressional Research Service. (2023). *Medicare Drug Price Negotiation Under the Inflation Reduction Act: Industry Responses and Potential Effects. https://www.congress.gov/crs_external_products/R/PDF/R47872/R47872.5.pdf* (Accessed: 10 December 2025).

[185] Centers for Medicare & Medicaid Services. (2015). *HHS Announces 15 Additional Drugs Selected for Medicare Drug Price Negotiations in Continued Effort to Lower Prescription Drug Costs for Seniors.* U.S. Department of Health and Human Services. *https://www.cms.gov/newsroom/press-releases/hhs-announces-15-additional-drugs-selected-medicare-drug-price-negotiations-continued-effort-lower* (Accessed: 10 December 2025).

[186] Congressional Research Service. (2025). *Medicare Part D Premium Stabilization Demonstration. https://www.congress.gov/crs_external_products/IF/PDF/IF12889/IF12889.2.pdf* (Accessed: 10 December 2025).

[187] Centers for Medicare & Medicaid Services. (2025). *2026 Medicare Part D Bid Information and Part D Premium Stabilization Demonstration Parameters.* U.S. Department of Health and Human Services. *https://www.cms.gov/newsroom/fact-sheets/2026-medicare-part-d-bid-information-and-part-d-premium-stabilization-demonstration-parameters* (Accessed: 10 December 2025).

[188] Congressional Research Service. (2022). *Overview of the 340B Drug Discount. https://www.congress.gov/crs_external_products/IF/PDF/IF12232/IF12232.4.pdf* (Accessed: 10 December 2025).

[189] Centers for Medicare & Medicaid Services. (2025). *2026 Medicare Part D Bid Information and Part D Premium Stabilization Demonstration Parameters.* U.S. Department of Health and Human Services. *https://www.cms.gov/newsroom/fact-sheets/2026-medicare-part-d-bid-information-and-part-d-premium-stabilization-demonstration-parameters* (Accessed: 10 December 2025).

program provides additional financial protection to Part D plan sponsors by covering a portion of drug costs for brand-name drugs and biological products for enrollees who reach the catastrophic coverage phase. CMS acknowledges the need for increased stability of the Part D benefit, which has recently been transformed pursuant to the IRA.[190] The GUARD rebate calculation methodology does not directly impact the Part D program direct subsidy nor how reinsurance payments are reconciled post-coverage year. CMS solicits feedback on any relevant considerations related to the Part D program direct subsidy and reinsurance.

6. Part D Low-Income Subsidies (LIS)

Under section 1860D–14 of the Act, the LIS provides premium and cost sharing subsidies for eligible Part D enrollees with income and resources below statutory thresholds. The subsidy structure reduces beneficiary liability for premiums, deductibles, and other cost sharing consistent with the requirements of the statute and regulations.[191]

The GUARD Model is designed to coordinate with the LIS by maintaining all existing LIS eligibility criteria and benefit structures, which would allow beneficiaries to continue receiving appropriate cost sharing protections. Therefore, the GUARD Model rebate payments are structured to work alongside, not modify, existing LIS provisions.

7. Request for Comments

We seek comment on our proposed approach to address overlap between the proposed GUARD Model and other ongoing or future Innovation Center models and CMS programs, as described in this Section of this proposed rule. We also seek comment on the potential need for any specific modifications or adjustments to the proposed GUARD Model that would be necessary to support a robust model test of the model or other CMS Innovation Center models. We also seek feedback on potential impacts on the Part D market with respect to unintended changes to market competition, Part D plan benefit and network offerings, and Part D plan bids and premiums. We welcome suggestions for potential policy options that may help to address any potential challenges. We welcome comments on the potential ways the proposed GUARD Model may impact CMS programs and initiatives and the potential need for modifications or adjustments to the proposed GUARD Model that may be necessary to minimize model overlap impacts.

O. Evaluation

P. Limitations on Review

CMS would conduct an evaluation of the proposed GUARD Model, as required under section 1115A(b)(4) of the Act and as proposed at § 514.720(a). The evaluation would analyze changes in Medicare spending and quality of care attributable to the GUARD Model. The evaluation would require, as needed, the collection of representative information from manufacturers of GUARD Model drugs, Part D plans (standalone PDPs and MA–PD plans), drug purchasers, providers, and beneficiaries. The collection and analysis of this data would inform how such a model might function were it to be integrated within the Medicare program.

All CMS Innovation Center models, which would include the GUARD Model, are rigorously evaluated on their ability either to improve quality without increasing spending or reduce spending without reducing quality. In addition, we routinely evaluate data from CMS Innovation Center models for potential unintended consequences of the model that run counter to the stated objective of lowering costs without adversely affecting quality of care. The design and evaluation methods, the data collection methods, key evaluation research questions, the evaluation period and anticipated reports for the GUARD Model are outlined as follows.

1. Evaluation Methods

The evaluation methodology would deploy multiple, mixed-method strategies to identify the effect of the GUARD Model's impact on the net cost to Medicare and the quality of care for beneficiaries. The evaluation's primary outcome is net Medicare Part D drug and total spending, which would be estimated by assessing the change in net spending for beneficiaries residing in geographic areas subject to the model intervention compared to areas not subject to the model intervention.

We would also conduct additional analyses that help isolate the effect of the GUARD Model on additional outcomes of interest through, for example, an interrupted time-series which would exploit the introduction of the GUARD Model to assess how trends in ''pre'' period were disrupted to identify the model's effects; a threshold analysis that exploits the drug spending threshold to assess the model's effect on key outcomes associated with those drugs that were just above the threshold for inclusion in the model compared to those just below the threshold for exclusion from the model; and the use of alternative comparison groups that are not part of the model, such as beneficiaries who are in EGWPs or therapeutic classes of drugs excluded from the GUARD Model.

We are considering several populations of interest for the GUARD Model evaluation, such as Medicare beneficiaries who are likely to receive one of the GUARD Model drugs based on recent diagnoses and/or prior treatment or other patient populations. Population subgroup analyses would capture the model's specific impact on beneficiaries affected by the changes due to the model.

Medicare spending would be examined in terms of net Part D drug spending for GUARD Model drugs, net Part D drug spending for any Part D drugs, total Parts A and B spending, and potentially other spending measures for specific types of health care services (for example, inpatient hospital spending). Total Medicare spending to the extent available would be net of DIR.

CMS believes the proposed model may have some downstream impacts and the evaluation would examine quality to ensure it is maintained or enhanced. The evaluation of any impact of the model on quality of care would examine patient experience, drug access, and health care utilization. Patient experience would be measured through patient experience surveys and measures of patient costs, inclusive of premiums and out-of-pocket costs. Drug access would be measured by prescribing patterns and claims-based drug utilization (for example, rates of any use and duration of use) of both Part D (both GUARD Model drugs and non-GUARD drugs) and Part B drugs (particularly, for Part B drugs that can substitute for GUARD rebatable drugs). We would also examine non-drug health care utilization that may change because of the GUARD Model to estimate any downstream impacts on access to care. Examples of health care utilization include hospitalizations, emergency department visits, and condition specific utilization related to a given subgroup of beneficiaries. The impact

[190] MedPAC. (2025). *Chapter 12, The Medicare Prescription Drug Program (Part D): Status Report. www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch12_MedPAC_Report_To_Congress_SEC.pdf* (Accessed: 10 December 2025).

[191] Feyman, Y., et al. (2024) *Medicare Enrollees and the Part D Drug Benefit: Improving Financial Protection through the Low-Income Subsidy.* Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services. *https://www.ncbi.nlm.nih.gov/books/NBK611501/pdf/Bookshelf_NBK611501.pdf* (Accessed: 10 December 2025).

estimates would reflect the collective effect of the GUARD Model's changes to Medicare rebates for GUARD rebatable drugs.

CMS also proposes assessing the model's market impact by examining its effect on the broader Part D drug market and on Part D plans, including through assessing various stakeholders' responses. We also recognize that it is important to evaluate if the model resulted in any unintended consequences.

2. Data Collection Methods

We are considering multiple sources of data to evaluate the effects of GUARD. We expect to base much of our analysis on secondary data sources such as Medicare enrollment and claims data. Beneficiary level claims data would be analyzed to estimate the GUARD Model's impacts on Medicare expenditures (total and by type of drug and service). We would examine other sources of data that may include rebate or provider discount information and international pricing data.

For Part D drugs, we would analyze data on drug utilization patterns, pricing, and expenditures. We would also consider CMS evaluation contractor administered site visits, interviews or surveys with appropriate samples of providers, plans, manufacturers, wholesale drug purchasers, and beneficiaries. These qualitative methods would provide information that would help us understand better the dynamics and interactions occurring among the stakeholders in the GUARD Model that cannot be estimated using the proposed secondary data sources.

3. Key Evaluation Research Questions

Our evaluation would assess the impact of the GUARD Model on reducing Medicare net drug spending and preserving or enhancing quality of care. This would include assessments of drug pricing dynamics, Medicare expenditures, and beneficiary access to medications. For example, we would explore how net savings, if any, were related to specific aspects of the payment test, such as how the alternative benchmarks were identified, as discussed in section IV.G. of this proposed rule, and other secondary analyses. Our key evaluation questions would include, but are not limited to, the following:

- Medicare Payments. Did the model result in net savings to Medicare, and if so, how?
- Market Impact. How did manufacturer behavior change in response to the model? Is there evidence of broader changes to the pharmaceutical market, such as changes in the supply of drugs? How did Part D plans (standalone PDPs or MA–PD plans) respond, including making changes to formulary placement or premiums? How did other stakeholders such as PBMs respond to the model?
- Quality. What was the impact of the model on the patient's quality of care, including patient experience? Did beneficiaries' costs, including premiums and cost sharing or access to drugs change under the model, and if so, how? Were there changes in drug or other health service utilization patterns that can be attributed to the model?
- Unintended Consequences. Did the GUARD Model result in unintended consequences?

The GUARD Model evaluation will gather evidence to inform certification through a rigorous, evidence-based process to determine how this model would perform if expanded nationally across the Medicare program. The evaluation would provide evidence to demonstrate if the model achieved its goals during the test period. It would also assess if the results were generalizable at a national scale and financially and operationally sustainable.

4. Evaluation Period and Anticipated Reports

As proposed, the GUARD Model would have a 5-year model performance period beginning in January 2027. The evaluation period would encompass this entire model performance period, the payment test period, and a baseline period. The evaluation would continue until all reconciliation has been completed. Continued evaluation after the end of the performance period and the payment period is necessary to fully assess the impact of the GUARD Model on reducing Medicare expenditures and preserving or enhancing quality. We would evaluate the GUARD Model on a continuous basis and release public evaluation reports annually.

We recognize that interim results are subject to changing policies and issues such as sample size and market fluctuations. Hence, while CMS intends to release periodic summaries to offer useful insight during the model test, a final analysis after the end of the model would be important for synthesizing and validating results.

Section 1115A(d)(2) of the Act precludes administrative and judicial review of certain specified model decisions. These preclusions are applicable for the GUARD Model, and there is no administrative or judicial review under section 1869 or 1878 of the Act, or otherwise, of the specified model decisions. We are also proposing to adopt section 1860D–14B(f) of the Act which would preclude administrative and judicial review of specific data inputs or calculations related to the underlying GUARD Model Rebate Report and reconciliation; therefore, such data and calculations are not appealable through this process.

Q. Program Waivers

We believe it may be necessary and appropriate to waive only to the extent necessary, certain requirements of title XVIII of the Act for the testing of the GUARD Model. We propose to issue these waivers using our waiver authority under section 1115A(d)(1) of the Act. The purpose of these waivers would be to allow Medicare to test the GUARD Model described in this Section of this proposed rule, with the goal of reducing Medicare expenditures while improving or maintaining the quality of beneficiaries' care. Section 1115A(d)(1) of the Act provides authority for the Secretary to waive such requirements of title XVIII of the Act as may be necessary solely for the purposes of carrying out section 1115A of the Act with respect to testing models described in section 1115A(b) of the Act. This provision affords broad authority for the Secretary to waive statutory Medicare program requirements as necessary to carry out the provisions of section 1115A of the Act.

We welcome comments on other possible waivers under section 1115A of the Act of certain Medicare program rules beyond those specifically discussed in this proposed rule that might be necessary to test this model. We will consider the comments that are received during the public comment period and may make future proposals regarding program rule waivers during the course of the model test.

1. Waiver of the Calculation of the Rebate Amount

At § 514.800, we propose to waive program requirements that are necessary solely for the purposes of testing the GUARD Model. Specifically, we propose to waive the provisions in section 1860D–14B(b)(1) of the Act, which are the Medicare Part D inflation rebate calculation provisions, to implement the proposed alternative calculation for the rebate amount.

We believe that section 1115A of the Act is broad and grants us significant flexibility in the design and implementation of new models. Further, in section 1115A(b)(2)(A) the Act provides the Secretary with broad authority to test innovative payment and service delivery models. We believe

this supports our proposed implementation of the GUARD Model test that incorporates drug pricing information from economically comparable countries to reduce Medicare Part D expenditures while preserving or enhancing quality of care. Further, the Secretary has the authority under section 1115A(d)(1) of the Act to waive certain Medicare and Medicaid statutory requirements ''as may be necessary solely for purposes of carrying out this Section of this proposed rule with respect to testing models.''

We believe this proposed waiver of the Part D inflation rebate calculation provisions in section 1860D–14B(b)(1) of the Act, is necessary to implement the proposed alternative calculation for the rebate amount as described in section IV.H. of this proposed rule. The GUARD Model would test an alternative calculation of the rebate amount described in section 1860D–14B(b) of the Act; this alternative calculation would yield the GUARD Rebate Payment Amount. The GUARD Model would waive the calculation described in section 1860D–14B(b)(1) of the Act—replacing it with the GUARD Rebate Payment Amount—in circumstances where the per unit GUARD Model rebate (described later in this section) exceeds the per unit Part D inflation rebate amount for a GUARD Model drug in a given GUARD Model performance year. As such, we believe the proposed waiver of the Medicare Part D inflation rebate calculation in section 1860D–14B(b)(1) of the Act as part of the GUARD Model test is necessary to implement the proposed alternative calculation for the rebate amount.

We seek comment on our proposed waiver of section 1860D–14B(b)(1) of the Act.

2. Waiver of Timing Requirements

In proposed § 514.800, we propose to waive program requirements as necessary solely for the purposes of testing the GUARD Model. Specifically, we propose to waive section 1860D–14B(a)(1) of the Act and instead we propose the following deadlines, effective dates, and time period requirements for the GUARD Model. Section 1860D–14B(a)(1) of the Act describes the timing requirements for manufacturer rebate reports issued by CMS—this section specifies that CMS will issue these rebate reports within nine months of the applicable period; we are proposing to waive these timing requirements and establish new deadlines for the rebate reports in the GUARD Model.

First, as described in section IV.I. of this proposed rule, we propose in § 514.610(b)(1) that no later than 20 months after the end of the first performance year, CMS would, for each GUARD Model Drug, issue the Preliminary GUARD Model Rebate Report to the GUARD manufacturers; the Preliminary GUARD Model Rebate Report would include the following for such performance year: per unit GUARD Model rebate amount, applicable GUARD Model billing units, and total GUARD Model Rebate Amount. We propose at § 514.610(c) that CMS would, for each GUARD Model Drug, issue the GUARD Model Rebate Report to the GUARD manufacturers no later than 22 months after the end of each performance year. The GUARD Model Rebate Report, as is the case for all the other rebate reports, would include the following for such performance year: per unit GUARD Model rebate amount, applicable GUARD Model billing units, and total GUARD Model Rebate Amount.

We also propose in § 514.610(d)(1) that no later than 12 months after the receipt of the GUARD Model Rebate Report, CMS would, for each GUARD Model Drug, issue the First Reconciliation of the Preliminary GUARD Model Rebate Report to the GUARD manufacturers. No later than 12 months after the receipt of the GUARD Model Rebate Report, CMS would, for each GUARD Model Drug, issue the First Reconciliation of the GUARD Model Rebate Report to the GUARD manufacturers; the First Reconciliation of the GUARD Model Rebate Report would include the following for such performance year: per unit GUARD Model rebate amount, updated applicable GUARD Model billing units, and total GUARD Model Rebate Amount. Within 30 calendar days of receipt of the First Reconciliation of the GUARD Model Rebate Report, the Manufacturer Reconciled Rebate Amount would be due.

We also propose in § 514.610(d)(1)(ii) that no later than 36 months after the receipt of the GUARD Model Rebate Report, CMS would, for each GUARD Model Drug, issue the Second Reconciliation of the Preliminary GUARD Model Rebate Report to the GUARD manufacturers. No later than 36 months after the receipt of the GUARD Model Rebate Report, CMS would, for each GUARD Model Drug, issue the Second Reconciliation of the GUARD Model Rebate Report to the GUARD manufacturers. Within 30 calendar days of receipt of the Second Reconciliation of the GUARD Model Rebate Report, the Manufacturer Reconciled Rebate Amount would be due.

As described in this section of this proposed rule, we believe these waivers are necessary to implement the GUARD Model on the timeline proposed herein given various operational considerations necessary to calculate GUARD Model Rebate Amounts. We believe that by issuing these rebate reports on the schedule outlined previously instead of the schedule specified in section 1860D–14B(a)(1) of the Act, CMS would be able to both calculate the necessary information for comprehensive rebate reports as well as align with the need to provide timely information about Medicare Part D inflation rebates and GUARD Model Rebate Amounts to GUARD Manufacturers. As such, we propose waiving section 1860D–14B(a)(1) of the Act to the extent necessary to allow CMS to issue GUARD rebate reports on the schedule outlined previously.

We seek comments on our proposed waiver of section 1860D–14B(a)(1) of the Act.

R. Severability

We propose at § 514.900 that should any provision of the proposed part 514 be held invalid or unenforceable by its terms, or as applied to any person or circumstance, such provisions would be severable from the remainder of part 514 and the invalidity or unenforceability would not affect the remainder of the provisions of part 514. For example, should the proposed alternate rebate calculation payment methodology in this proposed rule be deemed invalid or unenforceable, the underlying obligation under current statute will continue.

We seek comment on our proposed severability policies.

S. Model Terminations

We propose at § 514.910(a) that the standard provisions for Innovation Center models relating to termination of an Innovation Center model by CMS as set forth at § 512.165 would apply to the GUARD Model. Consistent with these provisions, if we terminate the GUARD Model, we would provide, as required at § 512.165(b), written notice to manufacturers of GUARD Model drugs specifying the grounds for termination and the effective date of such termination or ending. We propose to state at § 514.910(b), that consistent with section 1115A(d)(2) of the Act, termination of the GUARD Model is not subject to administrative or judicial review.

We seek comments on our proposed model termination policies.

IV. Collection of Information Requirements

As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of Centers for Medicare & Medicaid Services (CMS) Innovation Center Models. As a result, the information collection requirements contained in this proposed rule need not be reviewed by the Office of Management and Budget (OMB). However, costs incurred through information collections are discussed in section IV. of this proposed rule.

V. Regulatory Impact Analysis

A. Statement of Need

As explained in section II of this proposed rule, existing research finds that the prices of drugs sold in the United States are much higher than the prices of the same drugs sold in other countries. For brand-name originator drugs,[192] U.S. prices are approximately 422 percent of prices in economically comparable countries. The disparity between U.S. drug prices and prices in other economically comparable countries may have several drivers, but a key component is the substantial difference in the way prescription drug prices are determined in the United States and other economically comparable countries. Although there is wide variation in the way drug prices are determined in economically comparable countries, in general, many countries take a more centralized approach to drug pricing and/or have greater involvement in determining prices for drugs than the United States.[193]

High prescription drug prices in the United States influence Part D spending, which have also increased over time. As discussed in Section II of this proposed rule, total Part D gross drug spending increased from $121 billion in 2014 to $276 billion in 2023, an increase of over 100 percent, as reported by the Medicare Payment Advisory Commission (MedPAC).[194] High drug costs limit access to care and treatment, which in turn, can have cascading consequences that lead to poor health for patients, increased medical spending, and potentially avoidable expenditures for Medicare beneficiaries.[195]

Within the United States, the prices of certain types of drugs have been increasing over time, as discussed in section II of this proposed rule, which impacts spending in Part D and affordability of Part D coverage for Medicare beneficiaries. Brand-name drugs and biologics, in particular, represent a large portion of Part D spending in spite of the fact that generic drugs have a higher volume of use.[196] [197] The Inflation Reduction Act of 2022 (IRA), Public Law 117–169, addresses certain high drug costs under Part D, however, the IRA provisions—specifically the Drug Price Negotiation Program—focuses on a small set of drugs and only after they are available in the market for a period of time. The current Part D Inflation Rebate Program requires manufacturers to pay a rebate for certain drugs that exceed the rate of inflation based on price changes over time within the United States. While this approach is useful for curbing post-launch increases in drug prices, the Part D Inflation Rebate Program does not address the high launch prices of drugs, which continue to increase over time and contribute to high Medicare drug spending.

Under the CMS Innovation Center's statutory authority under section 1115A of the Act, CMS proposes to address this key issue of persistent high domestic Medicare drug spending for certain drugs and biologics through the GUARD Model, which tests changes to the Part D inflation rebate provision by implementing an innovative alternative payment method for the purpose of reducing Medicare drug spending and preserving or improving quality of care for Part D enrollees.

This proposed rule is necessary to test and implement the alternative payment model that modifies the Part D inflation rebate calculation for GUARD Model drugs using international drug pricing information for the purpose of understanding whether this change results in reduced spending for Medicare and maintains or improves quality of care for Medicare Part D enrollees. Specifically, as described in section IV.F. of this proposed rule, the model would include testing more than one method for identifying a benchmark amount for the modified rebate calculation—namely, the default international benchmark (also referred to as Method I) and the updated international benchmark (also referred to as Method II). The evaluation would examine the impact of changing the Part D inflation rebate calculation for GUARD Model drugs. CMS expects that the innovative alternative rebate calculation would reduce Medicare Part D expenditures while preserving or enhancing beneficiaries' quality of care.

As detailed in section IV.A. of this proposed rule, the proposed GUARD Model would establish a 5-year performance period and a 7-year GUARD Model alternative payment test for a subset of Part D rebatable drugs that are dispensed to Medicare beneficiaries who are in the cohort and that are paid under the GUARD Model. As described in section IV.C. of this proposed rule, and subject to certain exclusions, participants would include manufacturers of proposed GUARD Model drugs. GUARD Model participants would be subject to the requirements during the GUARD Model test period, as described in section IV.C.2. of this proposed rule.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993); Executive Order 13132 ''Federalism''; Executive Order 14192, ''Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Act (impact on small rural hospitals); section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more, or adversely

[192] The 2024 ASPE repot defines brand-name originators as ''the original drugs developed and licensed or approved via 351(a) or a New Drug Application (NDA) pathway.'' The authors of the study are solely responsible for how brand-name originator drugs were defined for the study.

[193] Syversen, I.D., et al. (2024). A Comparative Analysis of International Drug Price Negotiation Frameworks: An interview study of key stakeholders. *Milbank Quarterly, 102*(4), 1004–1031. *https://doi.org/10.1111/1468-0009.12714.*

[194] MedPAC. (2025). *Health Care Spending and the Medicare Program. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf* (Accessed: 16 December 2025).

[195] Nekui, F., et al. (2021). Cost-related Medication Nonadherence and Its Risk Factors Among Medicare Beneficiaries. *Medical Care, 59*(1):13–21. *https://doi.org/10.1097/MLR.0000000000001458.*

[196] Trish, E. & Blaylock, B. (2025). *Shifting Cost-Sharing Burden to Beneficiaries in Medicare Part D.* U.S.C. Schaeffer Center White Paper Series. White Paper No. 2025–06. *https://schaeffer.usc.edu/research/cost-sharing-burden-medicare-part-d/* (Accessed: 16 December 2025).

[197] MedPAC. (2025). *Health Care Spending and the Medicare program. https://www.medpac.gov/wp-content/uploads/2025/07/July2025_MedPAC_DataBook_SEC.pdf* (Accessed: 10 December 2025).

affect in a material way a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, OMB's Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant per section 3(f)(1) of E.O. 12866. Accordingly, we have prepared a regulatory impact analysis that presents, to the best of our ability, the estimated costs and benefits associated with this rulemaking.

C. Accounting Statements and Tables

As required by OMB Circular A–4,[198] in Table C1, we have prepared an accounting statement showing the transfers associated with the provisions of this proposed rule over a 6-year period spanning fiscal years 2028 through 2033. This demonstrates that the first effects of the proposed GUARD Model that begins in January 2027 would be observed in calendar year 2028. We cannot accurately predict what will happen during the reconciliation years so only 6 years are presented. Table C1 is based on the analysis discussed in the ''Estimated Impacts of the Proposal'' Section in this RIA in this proposed rule.

As stated later in this section, we estimate that the GUARD Model would result in an overall aggregate saving of $14.1 billion in Medicare Part D net spending during the model period. In this estimate, we assume manufacturer behavior changes. When annualized over a 6-year period, we estimate that the GUARD Model would result in an overall cost savings in Medicare Part D net spending of approximately $2.2 to 2.3 billion when the effects of discount of 3 or 7 percent are taken into consideration.

TABLE C1: ACCOUNTING TABLE ($ MILLIONS)

Item	Annualized at 3%	Annualized at 7%	Period	Who is Affected
Transfers	(2,307.1)	(2,246.7)	2027-2031	The numbers represent reductions in cost to the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund arising from reduced payments of plans to manufacturers for certain prescription drugs.

D. Estimated Impacts of the Proposal

In this section of this proposed rule, we discuss the estimated overall impact of the proposed GUARD Model on Medicare spending (and specifically, the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund) and the impact on Part D enrollees; we also show that the information burden associated with these activities is negligible in comparison.

1. Estimated Impacts to Medicare

The proposed GUARD Model modifies the existing Part D inflation rebate calculation for certain Part D rebatable drugs administered to beneficiaries under Medicare Part D. For beneficiaries in model geographic areas, a performance year Medicare net price for model drugs will be compared to an international benchmark and the inflation-adjusted payment amount, with the manufacturer rebating any excess to CMS (referred to as the ''Total Incremental GUARD Model rebate amount'' as set forth at § 514.510(c)). The performance year Medicare Part D net price for GUARD is defined as the wholesale acquisition cost (WAC) minus the per unit manufacturer rebate (from direct and indirect remuneration (DIR)) and per unit manufacturer discount program payment amount. The rebates would exclude units that are currently exempt from the existing inflation rebate calculation, including units acquired through the 340B program. The proposed model would also exclude units dispensed to enrollees in employer group waiver plans (EGWPs) as beneficiaries enrolled in EGWPs are proposed to be excluded from the GUARD Model. Additionally, certain drugs may be excluded from the model based on therapeutic categories, spending thresholds, ineligibility for the inflation rebate program, or competitive status within the market.

The estimates presented in this section of this proposed rule assume that all manufacturers are included in this mandatory model. If certain manufacturers were excluded due to interactions with other CMS Innovation Center models or for any other reason, the impacts from this proposed demonstration could be significantly less than described in this analysis.

In developing our estimate of the potential GUARD Model spending impacts, we started with 2024 Part D claims data for GUARD Model drugs. The CMS Office of the Actuary (OACT) relied on the CMS Innovation Center for a list of drugs that would have been included in the model in 2024, and we estimate that GUARD Model drugs would have comprised approximately 35 percent of non-EGWP Part D gross drug spending for 2024. The model excludes drugs that are paid based on a maximum fair price (MFP) that has been negotiated through the Medicare Drug Price Negotiation Program; as new drugs are selected for the negotiation program and have a payment limit that is based on the MFP, we expect the proportion of drugs targeted by the GUARD Model will decrease over time.

We estimated which drugs would have an effective MFP during the model performance period and reduced the model rebate to account for the exclusion of these drugs from the model. OACT estimates of which drugs would be negotiated were developed independently, without input from the

[198] Office of Management and Budget. (2003). *OMB Circular A–4: Regulatory analysis. https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf* (Accessed: 10 December 2025).

Medicare Drug Rebate and Negotiation Group within CMS.

By the end of the model, we estimate that GUARD Model drugs comprise approximately 16 percent of non-EGWP Part D drug spending for 2024, which reflects the increased amount of spending expected to be subject to the Medicare Drug Price Negotiation Program over time.

The model geographic areas will be selected to comprise 25 percent of Part D beneficiaries, further reducing the drug spending targeted by the GUARD Model. The model also excludes 340B units. The Medicare Part D prescription drug event (PDE) data does not currently track whether a Part D claim is 340B; therefore, we assumed that 10 percent of Part D units were 340B based on estimates in available literature.[199]

To reflect the international benchmarks that would be used in the model, we relied on international data furnished by the CMS Innovation Center, after adjustments for gross domestic product (GDP) and purchasing power parity (PPP). On average these international benchmarks were approximately 49 percent below the estimated Medicare Part D net price if GUARD was in effect in 2024, adjusted to reflect a 2027 benefit structure. This would reflect the upper limit of potential savings as we expect that manufacturers and other stakeholders may engage in a variety of responses that may reduce the potential Federal savings of the model.

Our first anticipated manufacturer reaction is to report their international net pricing data to CMS in cases where that data shows higher prices than the GUARD Model default international benchmark (Method I). Under the GUARD Model, manufacturers would be eligible to voluntarily report international drug net pricing data, and if those prices are higher than the GUARD Model default international benchmarks, the GUARD Model updated international benchmarks (Method II) would become the GUARD Model applicable international benchmark for the GUARD Model rebate calculation for those GUARD Model drugs for which the international net pricing data is submitted. This effect would have an upward pressure on the GUARD Model applicable international benchmarks over time and would reduce the GUARD Model rebates paid by manufacturers. Manufacturers will need to overcome the difference between the prices used under the GUARD Model default international benchmarks (Method I) and the net prices submitted under the GUARD Model updated international benchmarks (Method II) to move the benchmarks higher.

Our estimate assumes that the previous manufacturer reporting would reduce the level of total GUARD Model rebates by 30 percent by the end of the model test period. This assumption is informed by the average difference between lowest reference country price and prices averaged over all reference countries (after GDP (PPP) adjustments) for GUARD Model drugs. Table C2 shows an example of how this response was measured for the pricing of a hypothetical drug.

TABLE C2: EXAMPLE OF MANUFACTURER RESPONSE FOR A HYPOTHETICAL DRUG

NDC Code	GUARD Model Default International Benchmark (Method I)	GDP (PPP) Adjusted Average of all Reference Countries
XXXXX-YYYY	$100	$130

Notes: NDC stands for national drug code; PPP stands for purchasing power parity; GDP (PPP) stands for gross domestic product based on purchasing power parity.

Manufacturers that increase international prices in response to the model will likely need time to implement changes to the international prices. Accordingly, we phased this adjustment into our analysis, beginning with a 10 percent change to 2026 international price data and reaching 30 percent in the 2029 international price data. These factors are applied at an aggregate level to the rebates calculated under the GUARD Model default international benchmarks. For example, the total GUARD rebate paid based on 2027 utilization using the default international benchmark is reduced by 10 percent in our impacts to reflect this manufacturer response. Table C3 shows the percentage adjustment by performance year:

TABLE C3: PERCENTAGE ADJUSTMENT BY PERFORMANCE YEAR

	2026	2027	2028	2029	2030	2031
Phase-in of GUARD Model Updated International Benchmark (Method II) Adjustment	-10%	-20%	-30%	-30%	-30%	-30%

We anticipate that there will be some collaboration between manufacturers and providers to incentivize the increased use of brown-bagging, where drug utilization would be shifted to the office or facility setting and would be reimbursed under the Part B benefit, allowing the manufacturer to avoid owing a GUARD Model rebate amount

[199] Dickson, S., et al. (2023). Trends in Proportion of Medicare Part D Claims Subject to 340B Discounts, 2013–2020. *JAMA Health Forum, 4*(11), e234091. *https://doi.org/10.1001/jamahealthforum.2023.4091.*

for those units. We compared current total Part D drug spending for GUARD Model drugs to comparable Healthcare Common Procedure Coding System (HCPCS) codes in the Part B program to identify drugs that have a high potential to be moved to the Part D benefit. Combined with assumptions about how much utilization would move, we estimate that this effect would further reduce the total GUARD Model rebate amounts by an additional 5 to 8 percent (dependent on year).

The GUARD Model does not make any adjustments to the Part D benefit design and GUARD rebates would not be reflected at the point of sale; so, we do not expect any induced utilization effect for GUARD Model drugs.

In addition to the manufacturer responses described previously, we considered other manufacturer reactions. Manufacturers could opt to change list prices in response to the model, but this will impact their pricing across the entire domestic market and would have unfavorable implications for inflation rebates outside of the model. Alternatively, manufacturers could increase rebates for Part D plan sponsors. This would reduce their liability for GUARD Model rebates, and perhaps enhance formulary positions for more utilization. However, these rebates would be expected both inside and outside of the model in negotiations with large plan sponsors and would be difficult to remove once the model is over. Lastly, we considered whether manufacturers could negotiate more aggressively for drugs selected for negotiation under the IRA. Because this response could be more proportional to the model, would be more flexible in response to actual GUARD impacts, and would be less obvious to stakeholders, we considered it the most likely option.

We worked under the assumption that the manufacturers will negotiate more aggressively for upcoming selected drugs in the IRA's Medicare Drug Price Negotiation Program, so that the maximum fair prices would be closer to the ceiling prices specified under the IRA than assumed absent the model. We determined how this will impact the Part D benefit. Because not all manufacturers will be able to respond for a particular years' selected drugs, and because responses may vary, we assumed that 60 percent of the incremental GUARD rebate would be offset by the change in the OACT projection of negotiated prices. This 60 percent assumption is based off similar situations OACT has encountered albeit in different rules and different contexts. Lowering this assumption to 50 percent would result in approximately 8 percent more federal savings. We invite stakeholder response on the most appropriate percentage for this.

Once the total GUARD Model rebate is estimated as a percentage of gross drug costs, we apply those percentages to the estimated gross drug costs for each relevant year to obtain the aggregate GUARD Model rebate under the baseline gross drug costs. This amount is then reduced by the projected Part D inflation rebate amount attributable to the GUARD Model geography. The result is the estimated incremental GUARD rebate by year.

We expect manufacturers to respond to the anticipated GUARD rebates beginning in the initial price applicability year 2028 negotiation cycle, moving the MFP closer to the ceiling prices defined in the IRA. Because of the timing requirements for the GUARD rebate, this means that the manufacturer response will take effect before the first expected GUARD rebate payment, which is expected to be paid in fiscal year 2029.

This change in negotiated prices flows through the Part D benefit with impacts to Part D federal cost and beneficiary cost. The results are shown in Table C4 on a fiscal year cash basis in billions.

TABLE C4: IMPACTS TO PART D FEDERAL COST ($ BILLIONS)

Fiscal Year	2028	2029	2030	2031	2032	2033	Total 2028-2033
Benefit Cost	2.9	(5.3)	(4.1)	(2.4)	(2.0)	(2.6)	(13.6)
Premium Offset	($0.0)	($0.0)	$0.2	$0.2	$0.2	$0.0	$0.6
Federal Cost	2.9	(5.3)	(4.3)	(2.6)	(2.1)	(2.7)	(14.1)

Note: All estimates presented in billions of dollars.

2. Estimated Impacts to Medicare Part D Enrollees

As mentioned previously, we do not expect the GUARD rebates to be visible to beneficiaries at the point of sale. However, the assumed change in manufacturer negotiations for the IRA's Medicare Drug Price Negotiation Program will impact beneficiaries' cost sharing due to higher point of sale prices for initial price applicability year 2028 and subsequent years. The change in manufacturer negotiations will also impact beneficiary premiums after the end of the IRA premium stabilization provisions. These impacts are shown in Table C5, on a calendar year basis in billions.

TABLE C5: IMPACTS TO MEDICARE PART D ENROLLEES ($ BILLIONS)

Calendar Year	2028	2029	2030	2031	2032	2033	Total 2028-2033
Beneficiary Cost Sharing	1.0	0.8	0.5	0.4	0.4	0.0	3.0
Beneficiary Premium	(0.0)	(0.0)	0.2	0.2	0.2	0.0	0.6
Total Beneficiary Impact	1.0	0.7	0.7	0.6	0.5	0.0	3.6

Note: All estimates presented in billions of dollars.

3. Other Potential Responses

We also considered the following responses but either determined their impact would be small or that we lacked sufficient data to properly quantify the level of impact they would have on GUARD Model rebates:

- As a change in list prices for model drugs will shift the balance between the GUARD Model rebate amount and the inflation rebate amount, there are incentives for manufacturers to raise list prices across all payers to counteract the lost revenue from the model. This reaction could create additional effects

on Medicaid or Federal Marketplace spending. The likelihood of this response increases when the spending for a given drug outside of Medicare is higher. We welcome comments on the probability and magnitude of this response to inform future analysis.

- There also exists the possibility for manufacturers to increase DIR payments to plans in exchange for more favorable formulary placement and potential increased volume. This response would reduce GUARD unit rebates, but would be difficult to align with the GUARD Model structure. We would welcome comments on the probability and magnitude of this response to inform future analysis.
- Since drugs selected for negotiation would be excluded from the model, we might expect manufacturers would try to change their pricing to become eligible for the Medicare Drug Price Negotiation Program if they see it being more favorable for their reimbursement. Given the criteria for drug selection under the Medicare Drug Price Negotiation Program, we believe it would be difficult for manufacturers to achieve this. Additionally, the model does not impact reimbursement for all Part D beneficiaries as negotiations would, so this response would require dramatic pricing differences to be favorable to manufacturers.

We seek feedback on the assumptions used for this analysis, including anticipated stakeholder reactions, to inform future analysis.

d. Collection of Information and Paperwork Cost

As discussed in section V.A. of this proposed rule, as specified at section 1115A(d)(3) of the Act, models are exempt from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 through 3521). Nevertheless, and for discussional purposes only, we briefly review the main paperwork burden of this proposed rule and show it is negligible. The main information burden arises from voluntary manufacturer-reported submission of international net pricing information. The analysis of cost is summarized in Tables C6 and C7 with line items explained afterwards. Table C7 presents an analysis of items for which we have an experience basis for quantification. Table C8 discusses other items affecting the cost of submission requirements for which CMS has no prior experience on which to base quantification. To meaningfully deal with this lack of prior experience, we assume each item will increase the total quantifiable burden by some factor; a range of factors is presented to account for our lack of precise quantification.

TABLE C6: DISCUSSION OF QUANTIFIABLE BURDEN FOR SUBMISSION

Line Identification	Period	2027	2028-2031
(1)	Number of unique manufacturers	91	91
(2)	Payments per year	1	1
(3)	Hours/Preparation	20	10
(4)	Hours/Submission	6	3
(5)=(2)*((3)+(4))	Total Hours per period per Manufacturer	26	13
(6)=(1)*(5)	Total Unadjusted Aggregate hours for full period	2366	1183
(7)	Percent applied for period	1	1
(8)=(6)*(7)	Total Aggregate hours for period	2366	1183
(9a)	Mean Wage (Administrative assistants)(43-6014)	$22.90	$22.90
(9b)	Mean Wage (Health Service managers)(11-9111)	$66.22	$66.22
(9c)	Mean Wage (Software Developers, Programmers, Testers) (15-1250)	$65.34	$65.34
(9d)	Mean Wage (Lawyers) (23-1011)	$87.86	$87.86
(9e)	Mean Wage (Pharmacists)(29-1051)	$65.97	$65.97
(9f)=2/13*((9a - (9e)) +3/13*(9a)	Average weighted hourly wage for five professions	$52.71	$52.71
(10)	Factor for Fringe Benefits/Overtime	2	2
(11)=(9)*(10)	Adjusted mean wage	$105.43	$105.43
(12)=(11)*(8)	Total Estimated Cost	$249,442	$124,721
(13)=sum of row (12) with a weight of 4 for years 2028-2031	Total Cost 5 Years	$748,326	$748,326

We next explain the various line items in sequential order.

(1): We performed analysis on manufacturers of rebatable GUARD drugs based on two sources of manufacturers, FDA data sources (National Drug Code (NDC) Directory, Orange Book, and Purple Book) and Medi-Span.[200] There were 91 unique manufacturers. Although some of these manufacturers are owned by the same parent company, we used the higher 91 figure because our goals are to show the negligibility of burden.

(2), (3), and (4): The hours required for submission are split between preparation, including reading rules, gathering data, and so forth, and actual submission. We used similar estimates of submission to CMS from a Supporting Statement of the Manufacturer Submission of Average Sales Price (ASP) for Medicare Part B Drugs and Biologicals and Supporting Regulations in 42 CFR 414.800 through 806 (CMS–10110, OMB 0938–0921) from 2023. The supporting document listed 10 hours for preparation and three hours for submission per submission. In contrast to OMB 0938–0921 which required four submissions per year, for GUARD there is only one submission per year. However, we believe that extra hours would be required for the first year, and in the absence of more reliable data we simply doubled the 10 and three.

(7): The GUARD Model performance period, for which manufacturers could choose to report international drug net pricing data, is proposed to last from January 2027 through December 2031.

(9a–9f): The $21.90 is the mean wage obtained from the Bureau of Labor Statistics website for Secretaries and Administrative Assistants, Occupational Code 43–6014, for the latest year available at this time, 2024. Note that CMS still uses mean wages even though many agencies use median wages. However, replacing the mean by the median would not change the conclusion of negligibility. 43–6014, is the same occupational title used for estimates in OMB 0938–0921. However,

[200] *Medi-Span Electronic Drug File (MED-File) v2, Medi-Span,* Wolters Kluwer, 2025, Available at *https://www.wolterskluwer.com/en/solutions/medi-span/about* (last accessed Oct. 5, 2025).

we believe that this approach (using only administrative assistants) was overly simplified. While administrative assistants are appropriate staff for the 3 hours submission, we believe the preparation would involve a team of administrative assistants, health care managers, software engineers, lawyers, and pharmacists. The mean hourly wages of these staff for 2024 are displayed along with their occupational titles and code. The wages of these five staff are combined to produce a single mean hourly wage for the team. In the absence of further data, the weights assume that all five staff work equally in the 10 hours of preparation resulting in 2 hours per staff. The administrative staff exclusively work during the three hours of submission. Thus, the weights are five-thirteenths for administrative staff and two-thirteenths for each of the other staff.

(10): Per HHS guidance,[201] CMS uses a factor of two to account for overtime and fringe benefits.

We next turn to items for which we have no basis on which to quantify. The total analysis is presented in Table C7. As noted in the table there are two non-quantifiable issues that have to be addressed.

New and Departing participants: Each year, the group of GUARD Model participants may change based on whether their drug meets the criteria for inclusion in GUARD. We have no way of estimating with accuracy whether a given manufacturer would be included or excluded in GUARD. If we assume nine new manufacturers, then bottom line estimates from Table C7 would increase 10 percent (9/91). This is a low estimate. In a worst-case scenario, the number of participants might increase as much as 50 percent corresponding to a factor of 1.5; though this is unlikely, it helps define a range of possible costs.

19 Countries: If a manufacturer were to opt to report manufacturer-submitted data, they would do so for up to 19 countries. The 10 hours preparation assumed in Table C6 provides time for each GUARD participant to address marketing, pricing, and licensing requirements. But likely, this is different for different countries. We do not have enough information to quantify this. We approach the extra time as a factor by which we increase cost. For example, assuming that half the countries require the same preparation time, we would multiply the bottom line cost burden by a factor of 9.5 (19/2). On the other hand, if charts are readily available of licensing, marketing, and pricing for each individual country, it might only require an extra 2 hours of work resulting in an increase of 1.15 (2/13). We take these as the low and high estimates and insert an intermediate estimate.

To obtain a range of adjusted bottom line estimates we multiply the factors together. For example, as just discussed previously, if half the countries require the same amount of work (resulting in a factor of 9.5) and if the number of participants increases 50 percent (resulting in a factor of 1.5) then we multiply the bottom line number from Table C6, $748,326, by 14.25 (1.5 *9.5) and obtain a high cost burden of $10.7 million, as shown in Table C7. As shown on the bottom line of Table C7, the resulting range of estimates of cost burden is between roughly $1 million and $10.5 million.

TABLE C7: ADJUSTING COST BURDEN TO ACCOUNT FOR NON-QUANTIFIABLE ISSUES

Line Identification	Issue	Low Factor	Intermediate Factor	High Factor
(1)	19 countries	1.16	5	9.5
(2)	New and departing participants to GUARD Model	1.1	1.3	1.5
(3)=(1)*(2)	Product of factors	1.276	6.5	14.25
(4) (From Table C4)	Quantifiable Burden	$748,326	$748,326	$748,326
(5)=(4)*(3)	Range of Possible Adjusted Burdens	$954,864	$4,864,117	$10,663,642

Notes: (1) The GUARD Model will involve 19 countries. For a discussion of the low and high factor or for a discussion of new and departing participants see the paragraph immediately preceding Table C5.

E. Initial Regulatory Flexibility Act Analysis

The RFA requires agencies to analyze options for regulatory relief for small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. The RFA requires that CMS analyze regulatory options for small businesses and other entities unless CMS certifies that a rule will not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the proposed rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

HHS considers a significant impact on a substantial number of small entities to be one with a three percent revenue effect on 5 percent of small entities.[202] As discussed in the preamble of this proposed rule, manufacturers that are GUARD Model participants would pay GUARD Model rebates to the Medicare Part D account in the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund. If the Medicare net price determined under proposed § 514.510(b)(1) for GUARD Model drugs exceeds a GUARD Model applicable international benchmark (as described in section IV.F. of this proposed rule), our analysis shows that the proposed rule would impact 26 percent of small entities, and the annual impact is estimated to be between 3.5 and 5

[201] Office of the Assistant Secretary for Planning and Evaluation. (2016). *Guidelines for Regulatory Impact Analysis. https://aspe.hhs.gov/sites/default/files/private/pdf/242926/HHS_RIAGuidance.pdf* (Accessed: 10 December 2025).

[202] U.S. Department of Health and Human Services. (2003). *Guidance on Proper Consideration of Small Entities in Rulemaking of the U.S. Department of Health and Human Services. https://aspe.hhs.gov/reports/proper-consideration-small-entities-rulemakings-us-dhhs* and *https://aspe.hhs.gov/sites/default/files/documents/dd6288d1b8db19ee8a1f37b3ce775003/guidance-proper-consideration-hhs-2003-rulemaking.pdf* (Accessed: 10 December 2025).

percent of the small entities' annual revenue in the United States. Given the uncertainty, CMS concludes that this proposed rule, if finalized as proposed, will have significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this proposed rule, serves as the Initial Regulatory Flexibility Analysis, as required by the RFA.

F. Description and Number of Affected Small Entities

We use the North American Industry Classification System (NAICS) to identify the industry potentially affected by the proposed rule. We also use the Small Business Administration (SBA) size standards to identify small entities,[203] as codified at 13 CFR 121.201 and explained at Title 13 part 121. The SBA considers any ''Pharmaceutical Preparation Manufacturing'' firm (NAICS code 325412) with fewer than 1,300 employees as a small business.

We use financial and employment information publicly available on annual reports published on companies' websites or submitted to the Securities and Exchange Commission (SEC) for 2024. Most companies self-identified as ''global'' and provided information separately for their global consolidated business and for the United States. We used the Internal Revenue Service's yearly average currency exchange rates for 2024 to convert revenue information into U.S. dollars when this information was provided in a foreign currency.[204]

We identified 91 unique manufacturers belonging to 69 unique parent companies that would be associated with 542 unique NDC–9 codes for GUARD Model drugs.[205] For purposes of this analysis, we consider the impact on the 69 unique parent companies. Table C8 shows that 26 percent of the affected manufacturers would be considered small based on the SBA definition. In 2024, the total company revenue in the United States for these small companies exceeded $6 billion. These companies accounted for about 0.6 percent (6,261/1,065,917) of the total U.S. revenue among all the 69 affected entities.

TABLE C8: NUMBER OF ENTITIES BY EMPLOYMENT SIZE AND REVENUE, 2024

Company Size	Total Number of Either Global or U.S. Employees*	Percent of Unique Parent Companies	Total Global Revenue ($million)	Total US Revenue ($million)
Small	1,300 or fewer	26%	$10,317	$6,261
Large	1,301 or more	74%	$1,734,565	$1,065,917
Total	-	100%	$1,744,882	$1,072,178

Notes: *There was only one company with more than 1301 global employees and less than 1,300 U.S. employees. Since the global employees exceeded 10,000 we classified this company as large.

1. Description of the Potential Impacts on Small Entities

We anticipate that payments to CMS in the form of rebate amounts would represent the largest impact to small entities. Table C9 presents the estimated, annual aggregate projected GUARD rebate amounts for small companies using the 2024 experience, adjusted for projected changes to GUARD eligibility and benchmarks by drug and by year. We categorized NDCs by the size of the parent manufacturer and summed the rebates for NDCs associated with manufacturers with 1300 or fewer employees. Our analysis estimates that for small companies, the total GUARD rebates will comprise approximately 3.6 to 5 percent of total revenue, which, by HHS standards is considered significant. We note that these estimates are based on available data which could change in the future and as such, the estimated impacts could vary. Specifically, the estimates are based on the current status of rebatable drugs and employment and revenue information using 2024 (or other available data) as of the publication of this proposed rule. Given this uncertainty, we conclude that the proposed rule, if finalized as proposed, will have a significant impact on a substantial number of small entities. We welcome comments on our conclusion, approach, assumptions, and data used to estimate these impacts.

TABLE C9: ESTIMATED IMPACT ON SMALL ENTITIES

Company Size	Total U.S. Revenue ($million)	Estimated aggregate projected GUARD Rebate Amount as Percent of Revenue for 2027 GUARD Eligible Drugs	Estimated aggregate projected GUARD Rebate Amount as Percent of Revenue for 2028 GUARD Eligible Drugs	Estimated aggregate projected GUARD Rebate Amount as Percent of Revenue for 2029 GUARD Eligible Drugs	Estimated aggregate projected GUARD Rebate Amount as Percent of Revenue for 2030 GUARD Eligible Drugs	Estimated aggregate projected GUARD Rebate Amount as Percent of Revenue for 2031 GUARD Eligible Drugs
Small	6,261	5.0%	4.6%	3.4%	3.6%	3.6%

[203] U.S. Small Business Administration. (2023). *Table of Size Standards. https://www.sba.gov/document/support-table-size-standards* (Accessed: 10 December 2025).

[204] Internal Revenue Service. (2025). *Yearly average currency exchange rates. https://www.irs.gov/individuals/international-taxpayers/yearly-average-currency-exchange-rates* (Accessed: 10 December 2025).

[205] Based on the preliminary list of Part D rebatable drugs for 2024 as of October 1, 2025.

As explained, there is significant uncertainty around the assumptions for these estimates. We welcome comments on our estimate of significantly affected small manufacturers and the magnitude of estimated effects. We also welcome comments on adjustments to the GUARD Model that could be considered while preserving the innovative alternative payment approach tested under the GUARD Model.

2. Alternatives To Minimize the Impact on Small Entities

We considered the following alternatives to minimize the impact on small entities: (1) establishing a different spending threshold; (2) establishing an exemption process; and (3) establishing different compliance dates.

- Spending threshold: CMS is excluding from the GUARD Model, GUARD Model drugs when their associated application-level total gross covered prescription drug costs are below the ''GUARD Model minimum spend threshold'' which for performance year one is proposed to be $69 million. This GUARD Model minimum spend threshold applies to all manufacturers irrespective of size. While lowering the GUARD Model minimum spend threshold increases the number of drugs that could be included in GUARD, it also increases the number of small manufacturers that could potentially be impacted. For this reason and others as discussed in section IV.B.2. of this proposed rule, CMS proposes not to select a higher threshold. Further, increasing the threshold reduces both the number of small and large manufacturers and the number of drugs in GUARD.
- Exempting small entities: As discussed in section IV.B.2. of this proposed rule, to avoid interactions with other initiatives and programs that focus on manufacturers of Medicare Part D drugs, CMS would exclude drugs when there is an active price applicability period and the price of the drug is based on a negotiated MFP. Because small and large manufacturers could potentially be eligible for this proposed exclusion, we do not believe that additional processes for exemptions are needed. CMS seeks comments on other factors or considerations regarding exemptions for small entities.
- Compliance dates: CMS also considered the flexibility of providing different compliance dates to small manufacturers. While creating significantly different compliance dates could provide more time for small manufacturers to comply, it could interfere with the statutory requirement of evaluating the model annually to determine whether the GUARD Model is reducing Medicare spending while preserving or increasing quality of care for Medicare Part D enrollees.

In summary, the purpose of the GUARD Model is to test an innovative payment model that modifies the inflation rebate calculations for GUARD Model drugs using international drug pricing information. CMS expects would reduce program expenditures for Medicare Part D while preserving or enhancing beneficiaries' quality of care. For this reason, CMS declined to propose the alternatives considered. We welcome comments on the alternatives considered as well as other factors that could be considered to mitigate the impact on small manufacturers.

G. Effects on Small Rural Hospitals

Section 1102(b) of the Act requires CMS to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

H. Unfunded Mandates Reform Act

Section 202 of the UMRA also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately $187 million. The analysis of impacts on the GUARD Model does not report an estimate of any unfunded effect on State, local, or Tribal governments, in the aggregate, or on the private sector that exceeds the $187 million threshold. However, this proposed rule, if finalized as proposed, would result in additional impacts associated with changes in behavior; these are not quantified. Therefore, the Secretary has concluded that the requirements of section 202 of the UMRA have been met for the GUARD Model. We request comments, including on the potential magnitude of this impact

I. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this proposed rule does not impose any substantial costs on State or local governments, preempt State law or have federalism implications, the requirements of Executive Order 13132 are not applicable.

J. Unleashing Prosperity Through Deregulation

E.O. 14192, titled ''Unleashing Prosperity Through Deregulation,'' was issued on January 31, 2025, and requires that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.''

VI. Response to Comments

Because of the large number of public comments we normally receive on documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on December 10, 2025.

List of Subjects for 42 CFR 514

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV, subchapter H as set forth below:

■ 1. Subchapter H is amended by adding and reserving part 513 and adding part 514 to read as follows:

SUBCHAPTER H—HEALTH CARE INFRASTRUCTURE AND MODEL PROGRAMS

PART 513 [Reserved]

PART 514—GUARD MODEL

Sec.

Subpart A—General Provisions

Authority: 42 U.S.C.1302, 1315(a), and 1395hh.

PART 514—GUARDING U.S. MEDICARE AGAINST RISING DRUG COSTS (GUARD) MODEL

Subpart A—General Provisions

§ 514.1 Basis, scope, and duration.

(a) *Basis.* This part implements the test of the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model under section 1115A(b) of the Act. Except as specifically noted in this part, the regulations under this subpart do not affect payment, coverage, program integrity, or any other requirements that otherwise apply to providers of services, suppliers, and manufacturers under this chapter.

(b) *Scope.* This part sets forth the following:

(1) GUARD Model participants.

(2) The beneficiaries included in the GUARD Model.

(3) The Part D rebatable drugs included in the GUARD Model.

(4) The methodologies for establishing the GUARD Model Rebate amount.

(5) GUARD Model rebate payment calculations.

(6) Rebate reports.

(7) Payment reconciliation.

(8) Beneficiary protections.

(c) *Duration.* The GUARD Model has a 7-year test period consisting of a 5-year performance period and a 7-year payment period. The first performance year (performance year 1) begins on January 1, 2027, and the final performance year (performance year 5) ends on December 31, 2031, unless sooner terminated in accordance with § 514.910. The first payment year begins on January 1, 2027, and the final payment year ends on December 31, 2033.

(d) *Severability.* Were any provision of this part to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, the provisions would be severable from this part and the invalidity or unenforceability would not affect the remainder thereof or any other part of this subchapter or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 514.5 Definitions.

For the purpose of this part, the following definitions are applicable unless otherwise stated:

Across-country average net price means the weighted average net price (excluding price concessions) for all international products sold across all reference countries that are part of GUARD Model drug's set of international analogs during a submission's corresponding performance year, where the weights are the corresponding volumes of the international product sold in National Council for Prescription Drug Programs (NCPDP) units, each price is adjusted using the reference country specific gross domestic product (GDP) based on purchasing power parity (GDP (PPP)) adjuster, converted into U.S. dollars using the exchange rate for currency conversion as described at § 514.310(e), and expressed as a per unit price, where the units are the GUARD Model drug's NCPDP units.

Applicable submission means a voluntary manufacturer submission that CMS determines fulfils the data requirements, which include verification of the submission for completeness and validity, and therefore is suitable for determination of the GUARD Model updated international benchmark per § 514.310(b).

AMP stands for average manufacturer price.

ANDA stands for abbreviated new drug application.

Biosimilar biological product means for the United States a marketed biological product submitted in a biologics license application (BLA) under section 351(k) of the Public Health Services Act (PHS Act).

BLA stands for biologics license application.

Country-level average price means the average or weighted-average price for all international products sold in a reference country that are part of a GUARD Model drug's set of international analogs, where, if available, the weights are the corresponding volumes of international product sold expressed in NCPDP units, and expressed as a per unit price, where the units are the GUARD Model drug's NCPDP units.

Covered Part D drug has the same meaning set forth in section 1860D–2(e) of the Act and § 423.100 of this chapter.

DIR stands for direct and indirect remuneration.

EGWP stands for Employer Group Waiver Plan.

Exchange rate for currency conversion means the conversion rate used to convert from the currency of each reference country, identified in § 514.220(d), to U.S. dollars corresponding to the submission's performance year.

FDA stands for Food and Drug Administration.

FD&C Act stands for the Food, Drug and Cosmetics Act.

GDP stands for gross domestic product.

GDP (PPP) stands for GDP based on purchasing power parity.

GDP (PPP) adjuster means for a reference country, the U.S. GDP (PPP) per capita divided by the reference country's GDP (PPP) per capita rounded to the third decimal place, where—

(1) The GDP (PPP) per capita for the reference country is the most recent estimate of GDP (PPP) per capita for that reference country available in the Central Intelligence Agency (CIA) World Factbook at the end of the corresponding performance year.

(2) The reference country's GDP (PPP) per capita and U.S. GDP (PPP) per capita must be for the same calendar year. The GDP (PPP) adjuster has a lower bound of 1.000, thus if the resulting GDP (PPP) adjuster is lower than 1.000, it is set to 1.000.

Generic means for the United States, a drug submitted in an ANDA and approved under section 505(j) of the FD&C Act.

GUARD Model applicable international benchmark means, per § 514.410(b), for each GUARD Model drug, the greater of the default international benchmark and, if available, the updated international benchmark; and for which an *applicable adjustment factor,* according to § 514.410(e), has been applied.

GUARD Model beneficiary means an individual who is enrolled in a Part D plan, either in a standalone prescription drug plan (PDP) or Medicare Advantage prescription drug (MA–PD) plan, but not in an EGWP, and who resides in a GUARD Model geographic area as determined by the beneficiary's address of record with Medicare.

GUARD Model beneficiary population means all Part D enrollees (with the exception of those who are enrolled in an EGWP) who are furnished with a GUARD Model drug as identified in Medicare Part D prescription drug event (PDE) data within the GUARD Model performance period and who reside within a GUARD Model geographic area.

GUARD Model default international benchmark, which is also referred to as the Method I benchmark, means for each GUARD Model drug, the lowest price in a set of country-level average prices calculated, using the steps proposed at § 514.410(c), for each reference country identified at § 514.220(d), where international drug pricing data is available from selected data sources per § 514.210 for at least one reference country and at least one reference country-level price can be calculated.

GUARD Model drug means, subject to the exclusions set forth in § 514.120(c) a Part D rebatable drug, as defined in 42 CFR 428.20 and determined in 42 CFR 428.101, that is a sole-source drug or sole-source biological product as defined in § 514.100, has a United States Pharmacopeia (USP) category classification that includes at least one of the USP selected categories, as defined in § 514.120(e), and is identifiable by a unique National Drug Code (NDC) 9 code for which a payment was made under Medicare Part D.

GUARD Model drug unit means, with some exceptions, as described in § 514.125(a), units dispensed based on Part D PDE records for GUARD Model drugs that are furnished to Part D enrollees who reside in GUARD Model geographic areas and are part of the GUARD Model beneficiary population.

GUARD Model geographic area means the geographic areas, defined by Zonal Improvement Plan Code Tabulation Areas (ZCTAs), selected for participation in the GUARD Model in accordance with § 514.110(d).

GUARD Model participant means a manufacturer of a GUARD Model drug that receives a Part D inflation rebate report for an applicable period that overlaps with the GUARD Model performance period.

GUARD Model payment period means the 7-year period beginning on January 1, 2027, through December 31, 2033, as specified in § 514.1(c).

GUARD Model performance period means the 5-year period beginning on January 1, 2027, through December 31, 2031, as specified in § 514.1(c).

GUARD Model updated international benchmark, which is also referred to as the Method II benchmark, means for each GUARD Model drug, the across-country average net price, which is a volume-weighted average across all reference countries, identified at § 514.220(d), where an international product that is part of the set of international analogs is sold, and includes GDP (PPP) adjustments; the across-country average net price is part of an applicable submission of international drug net pricing data by manufacturers according to § 514.310.

International biosimilar biological product means for a reference country identified in § 514.220(d), a biological product approved and licensed in a reference country under that reference country's regulatory framework under a pathway similar to section 351(k) of the PHS Act in the United States.

International generic means for a reference country identified in § 514.220(d), a drug approved and marketed in a reference country under that reference country's regulatory framework under a pathway similar to section 505(j) of the FD&C Act in the United States.

International product means a drug or biological product sold in a reference country as identified in § 514.220(d) that is aligned across its identifying characteristics with a GUARD Model drug. The identifying characteristics are specific to each GUARD Model drug (which in accordance with § 514.120(a), is identified at the NDC–9 level) and include active ingredient(s), route of administration, dosage form, and strength. Alignment across identifying characteristics, as according to § 514.410, allows for adjustments that do not materially modify the nature of the drug but account for country-specific differences such as differences due to language, units of measurement, labeling standards, or differences in dosage form or strength.

Manufacturer has the meaning set forth in section 1927(k)(5) of the Act and § 428.20 of this chapter.

MFP stands for maximum fair price.

National Drug Code (NDC) has the same meaning as the meaning set forth in § 428.20 of this chapter.

NCPDP stands for National Council for Prescription Drug Programs.

NDA stands for new drug application.

Part D rebatable drug has the meaning set forth in section 1860D–14B(g)(1) of the Act and § 428.20 of this chapter.

Payment year means a 12-month period beginning on January 1 and ending on December 31 during the GUARD Model payment period.

Performance year means a 12-month period beginning with January 1 of a year (beginning with January 1, 2027) and ending on December 31 during the GUARD Model performance period.

Performance year Medicare net price means a per unit net price for the GUARD Model drug during the performance year, expressed in terms of NCPDP units, calculated according to § 514.510(b) using the wholesale acquisition cost (WAC), manufacturer direct and indirect remuneration (DIR), discounts from the Manufacturer Discount Program, and quantity dispensed across all PDE records associated with the GUARD Model drug during a performance year.

PHS Act stands for Public Health Services Act.

Prescription drug event (PDE) data means records submitted by a Part D plan to CMS each time a beneficiary fills a prescription under Medicare Part D. A PDE record is data summarizing the final adjudication of a Part D dispensing event that is reported to CMS by the Part D sponsor using a CMS-defined file layout.

Reference country means the countries CMS identified in § 514.220(d).

Set of international analogs means for each GUARD Model drug, the set of international products sold across all reference countries identified at § 514.220(d).

Submission means manufacturer international drug net pricing data voluntarily submitted to CMS to consider for use for the performance year for which it was submitted.

Subsequent performance year means every performance year after the first. There are four, starting January 1st and ending on December 31st of 2028, 2029, 2030, and 2031.

U.S. stands for United States.

USP stands for United States Pharmacopeia.

USPS stands for the United States Postal Service.

WAC stands for Wholesale Acquisition Cost.

Subpart B—Inclusion in the GUARD Model

§ 514.100 Definitions.

For the purpose of this subpart the following definitions are applicable unless otherwise stated:

Application-level total gross covered prescription drug costs means the sum of total gross covered prescription drug costs, as defined in 42 CFR 428.100, from Medicare Part D PDE data for all rebatable Part D drugs belonging to the same FDA application.

CPI–U has the same meaning set forth in section 1927 of the Act and § 428.20 of this chapter.

Gross covered prescription drug costs have the same meaning set forth in section 1860D–2(b)(3) of the Act and § 423.308 of this chapter.

GUARD Model minimum spend threshold means—

(1) For the performance year beginning on January 1, 2027, an amount equal to $69 million;

(2) For the performance year beginning January 1, 2028, an amount equal to $69 million increased by the percentage increase in CPI–U for the 12-month period beginning January 1, 2027;

(3) For subsequent performance years, the minimum spend threshold is equal to the minimum spend threshold for the prior performance year increased by the percentage increase in the CPI–U for the 12-month period beginning with January of the previous performance year; and

(4) If the resulting amount is not a multiple of $10, CMS rounds that amount to the nearest multiple of $10.

MA–PD stands for Medicare Advantage prescription drug.

PDP stands for prescription drug plan.

Resides within the GUARD Model geographic area means the beneficiary's home address as recorded in CMS's Medicare Enrollment Database is within the GUARD Model geographic areas as determined by CMS in § 514.110(d).

Sole-source biological product means a biological product licensed by the FDA under a BLA under section 351(a) of the PHS Act, that is not the reference biological product, as defined at 42 U.S.C. 262(i)(4), for a biosimilar biological product licensed by FDA in a BLA under section 351(k) of the PHS Act. The biosimilar biological product must have the biological product as its reference product in the FDA's Purple Book and be identified as marketed in the FDA's NDC Directory.

Sole-source drug means a drug approved by the FDA under a NDA under section 505 of the FD&C Act for which there are no generic(s), as defined at § 514.5, rated as therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations''). The generic rated as therapeutically equivalent to the drug must be recognized as a therapeutic equivalent in the FDA's Orange Book and be identified as marketed in the FDA's NDC Directory.

Zonal Improvement Plan (ZIP) Code means a trademark of the USPS created to coordinate mail handling and delivery. The USPS assigns ZIP Code ranges to regional post offices, which in turn assign ZIP Codes to delivery routes.

ZIP Code Tabulation Areas (ZCTAs) means approximate area representations of USPS 5-digit ZIP Code service routes that the U.S. Census Bureau creates using whole blocks to present statistical data from censuses and surveys.

§ 514.110 GUARD Model participation.

(a) *GUARD Model participants.* The GUARD Model requires participation by all manufacturers of GUARD Model drugs that receive a Part D inflation rebate report during an applicable period that overlaps with the GUARD Model performance period.

(b) *GUARD Model participant requirements during the GUARD Model performance period and payment period.* During the GUARD Model performance period and payment period described in § 514.1(c), GUARD Model participants must do all of the following:

(1) Adhere to the GUARD Model rebate invoicing and payment instructions in subpart G of this part and as established by CMS and its contractors responsible for providing GUARD Model rebate invoices, and processing GUARD Model rebates, including without limitation to ensure appropriate and accurate GUARD Model rebate payments; and

(2) Participate in GUARD Model monitoring and evaluation activities in accordance with § 403.1110(b), including collecting and reporting of information as the Secretary determines is necessary to monitor and evaluate the GUARD Model.

(3) If electing to submit international net drug pricing data, adhere to the requirements set forth in § 514.310 and the GUARD Model data agreement.

(c) *GUARD Model participant requirements after the GUARD Model performance period and payment period conclude.* GUARD Model participants must do all of the following:

(1) Adhere to the GUARD Model rebate invoicing and payment instructions in subpart G of this part and as established by CMS and its contractors responsible for providing GUARD Model rebate reports and invoices, and processing GUARD Model rebates, including without limitation to ensure appropriate and accurate GUARD Model rebate payments.

(2) Participate in GUARD Model monitoring and evaluation activities in accordance with 42 CFR 403.1110(b), including collecting and reporting of information as the Secretary determines is necessary to monitor and evaluate the GUARD Model during the GUARD Model performance period.

(3) Continue the GUARD Model reconciliation activities as described in § 514.610.

(4) If electing to submit international net drug pricing data, adhere to the requirements set forth in § 514.310 and the GUARD Model data agreement.

(d) *Model geographic scope.*

(1) CMS will determine the geographic scope of the GUARD Model no later than 60 calendar days before the beginning of the GUARD Model performance period by selecting a simple random sample of ZCTAs that would enable a representative sample of Medicare Part D enrollees and Medicare expenditures, including Part D expenditures.

(2) ZCTAs are the geographic unit of selection.

(i) The GUARD Model geographic areas are identified by ZIP codes that are aligned with ZCTAs.

(ii) During the model performance period, if a ZIP Code that is within the GUARD Model geographic area is split or redesignated, that ZIP Code will not

get reassigned to a GUARD Model geographic area.

(iii) Beneficiaries already assigned to the GUARD Model geographic area remain assigned to the GUARD Model geographic area regardless of any subsequent changes to their Zip Code.

(iv) Newly enrolled beneficiaries in a split or redesignated ZIP Code are not assigned to a GUARD Model geographic area.

(3) The identified GUARD Model geographic areas must include approximately 25 percent of the United States, excluding U.S. territories.

(4) The identified GUARD Model geographic areas are not subject to administrative or judicial review.

§ 514.120 Identification of GUARD Model drugs.

(a) *GUARD Model drugs.* Subject to the limitations specified in paragraph (c) of this section, GUARD Model drugs include Part D rebatable drugs as defined in 42 CFR 428.20 and determined in 42 CFR 428.101, identified at the NDC–9 level—

(1) Are sole-source drugs and sole-source biological products, as defined in § 514.100, in accordance with paragraph (b) of this section; and

(2) Have a USP category classification identified according to paragraph (d) of this section that includes at least one of the USP selected categories according to paragraph (e) of this section.

(b) *Sole-source condition.* Sole-source drugs or sole-source biological products that during a performance year no longer fulfill the definition of sole-source drug or sole-source biological product proposed at § 514.100 will be subject to the GUARD Model for the period of the performance year during which the drug or biological product did fulfill the definition.

(c) *Exclusions.* All of the following are excluded from the GUARD Model:

(1) Generics and biosimilar biological products as defined in § 514.5.

(2) A drug with application-level total gross covered prescription drug costs as defined in § 514.100 below the GUARD Model minimum spend threshold as defined in § 514.100 for the corresponding performance year. If a GUARD Model drug exceeds the GUARD Model minimum spend threshold for a performance year during the GUARD Model performance period, the GUARD Model drug is no longer subject to exclusion for subsequent performance years.

(3) A drug that is a selected drug (as defined in section 1192(c) of the Act) with an MFP that is in effect.

(d) *USP category classification.* For a GUARD Model drug, its USP category classification is the category or categories identified for the GUARD Model drug in the USP Medicare Model Guidelines.

(1) At time of consideration for inclusion into the GUARD Model, the most recently published version of the USP Medicare Model Guidelines will be utilized to identify the categories.

(2) Identification is done using the GUARD Model drug's NDC–9, RxNorm Concept Unique Identifier, active ingredient(s), or FDA approved indication(s), and matching all USP categories in the USP Medicare Model Guidelines associated with the GUARD Model drug.

(3) Once a category or categories are assigned it remains the GUARD Model's drug category or categories for the entire performance period.

(e) *USP selected categories.* From the most recent USP Medicare Model Guidelines available (according to paragraph (d)(1) of this section) as follows:

(1) USP categories corresponding to Medicare Protected Classes, as defined in Chapter 6 section 30.2.5 from the Medicare Prescription Drug Benefit Manual.

(i) Any change to the definition of Medicare Protected Classes in Chapter 6 section 30.2.5 from the Medicare Prescription Drug Benefit Manual is carried over.

(ii) The current USP categories that correspond to Medicare Protected Classes are Anticonvulsants, Antidepressants, Antineoplastics, Antipsychotics, Antivirals, Bipolar Agents, and Immunological Agents.

(2) USP categories of Analgesics, Antimigraine Agents, Blood Glucose Regulators, Cardiovascular Agents, Central Nervous System Agents, Gastrointestinal Agents, Genetic or Enzyme or Protein Disorder Replacement or Modifiers or Treatment, Metabolic Bone Disease Agents, Ophthalmic Agents, and Respiratory Tract/Pulmonary Agents.

(f) *Carry over of changes to definitions.* Any changes to the definition of applicable threshold and Part D rebatable drug in 42 CFR 428.20 and the determination of Part D rebatable drugs in 42 CFR 428.101 are carried over.

§ 514.125 GUARD Model drug units.

(a) *Inclusion.* All GUARD Model drug units dispensed to GUARD Model beneficiaries who reside in GUARD Model geographic areas during the performance period, identified using Medicare Part D PDE records.

(b) *Exclusions.* CMS will exclude drug units covered under 340B.

§ 514.130 Defined population, inclusion and exclusion criteria.

(a) *Beneficiary eligibility criteria.* An individual is eligible to be a GUARD Model beneficiary if the individual meets all of the following criteria:

(1) Is enrolled in a standalone PDP or MA–PD plan under Medicare Part D that is not an EGWP;

(2) Resides within a GUARD Model geographic area, as determined by the beneficiary's address recorded in CMS's Medicare Beneficiary Database (MBD), System No. 09–70–0536; and

(3) Is not excluded from GUARD Model participation under paragraph (d) of this section.

(b) *Initial model cohort and comparison group.* Subject to the paragraph (d) of this section, approximately 30 calendar days prior to GUARD Model start, using available Medicare program administrative information as determined by CMS, CMS will identify the—

(1) Initial model cohort consisting of Medicare beneficiaries who meet the beneficiary eligibility criteria under paragraph (a) of this section for inclusion in the model at model start (as identified by CMS under § 514.1(c)) and add such beneficiaries to the model cohort.

(2) Comparison group consisting of Medicare beneficiaries enrolled in Medicare Part D who do not have an address of record within the GUARD Model geographic areas selected for inclusion in the model, and add such beneficiaries to the comparison group.

(c) *Updated cohort.* Subject to the paragraph (d) of this section, periodically (not more frequently than weekly), using available Medicare program administrative information as determined by CMS will update the model cohort.

(1) CMS will add the Medicare beneficiaries who meet all the following criteria to the model cohort:

(i) Are enrolled in a standalone PDP or MA–PD plan under Medicare Part D (but not an EGWP).

(ii) That have Medicare as their primary payer.

(iii) That have an address of record within the GUARD Model geographic areas selected for inclusion (as identified by CMS under § 514.110(c)).

(iv) That are not yet included in the model cohort.

(v) That are not also in the comparison group.

(2) Beneficiaries in the model cohort who no longer are enrolled in the standalone PDP or MA–PD plan under Medicare Part D, no longer have Medicare as their primary payer, or are enrolled in an EGWP will be removed

from the model cohort at the next update.

(d) *Exclusions.* The following individuals are excluded from being model beneficiaries.

(1) Beneficiaries who do not have Medicare as their primary payer.

(2) Beneficiaries who are not enrolled in the standalone PDP or MA–PD plan under Medicare Part D.

(3) Beneficiaries who are enrolled in an EGWP.

(e) *Review.* The identification of included GUARD Model beneficiaries and the timing of such identification, as well as the identification of the beneficiaries in the comparison group are not subject to administrative and judicial review.

Subpart C—Existing International Data Sources and Reference Countries

§ 514.210 Existing data sources of international drug pricing data.

(a) *General.* Subject to requirements in paragraph (b) of this section and selection criteria outlined in paragraph (c) of this section, CMS will select a data source of international drug pricing data for each GUARD Model drug's set of international analogs that are sold in the reference countries determined in § 514.220(d), CMS does the following prior to the GUARD Model rebate payment calculation:

(1) For the first performance year, identifies available data sources of international drug pricing data.

(2) For each subsequent performance year, identifies available data sources of international drug pricing data for any GUARD Model drug that was not a GUARD Model drug in a previous performance year or did not have a GUARD Model default international benchmark in a previous performance year.

(b) *Requirements for data sources of international drug pricing data.* Data sources, as determined by CMS, must do all the following:

(1) Utilize a standardized method for identifying drugs across countries within that data source, such as using internationally recognized scientific and nonproprietary product names.

(2) Utilize a standard method for identifying a drug's route of administration and dosage form across countries within that data source, such as using an internationally recognized nomenclature for pharmaceutical forms like the New Form Code classification.

(3) Utilize a standard method for identifying a drug's strengths across countries within that data source, and they are expressed in internationally recognized measures such as milligrams or milliliters.

(4) Utilize a standard method to identify a drug's regulatory approval pathway across countries within that data source, that at a minimum distinguishes international generics and international biosimilar biological products, as defined at § 514.5.

(5) Contain at a minimum one of the following forms of drug pricing data and utilizes a standard method across countries within that data source to record the pricing data:

(i) Coordinated sales and volume data, meaning a sales amount corresponding to a volume recorded in a standardized currency across countries within that data source, and which corresponds to actual or calculated transaction amount between a seller and a purchaser of a drug or biological product, and its corresponding volume, meaning the quantity of units—recorded in a standardized unit measure across countries within that data source—where the lowest dispensable amount is or can be converted into NCPDP units that correspond to the GUARD Model drug.

(ii) Coordinated price and volume data, meaning a price recorded in a standardized currency across countries within that data source, and which corresponds to the price for an actual or calculated transaction between a seller and a purchaser of a drug or biological product, and its corresponding volume, meaning the quantity of units—recorded in a standardized unit measure across countries within that data source—where the lowest dispensable amount is or can be converted into NCPDP units that correspond to the GUARD Model drug.

(iii) Price data, meaning a price recorded in a standardized currency across countries within that data source, and which corresponds to the price for an actual or calculated transaction between a seller and a purchaser of a drug or biological product.

(6) Have mechanisms in place to maintain, update, validate, and correct, if necessary, the information on international drug pricing in the data source on at least a quarterly basis.

(7) Be maintained by an organization that seeks to limit the lag inherent in data to no more than 90 calendar days from the end of the calendar quarter for which drug pricing information is compiled to the time that the organization makes the updates available to users of the data source.

(c) *Selection of data source.* Subject to paragraphs (c)(1) and (2) of this section, for each GUARD Model drug, CMS selects a data source that CMS has access to that fulfills the requirements from paragraph (b) of this section, and, if available, obtains the data, to then calculate the GUARD Model default international benchmark for each GUARD Model drug as described in § 514.410(c).

(1) If there is more than one data source for a GUARD Model drug, CMS selects the data source at the highest level of the hierarchy described in paragraph (c)(2) of this section and if there is still more than one data source for a GUARD Model drug at the same level, CMS selects a single data source based on an assessment of the relative reliability and generalizability of the data from each available data source.

(2) *Data selection hierarchy.*

(i) For each GUARD Model drug included in the first performance year, the following hierarchy is used to select the data source of international drug pricing information:

(A) The data source contains coordinated sales and volume data for the set of international analogs in the highest number of reference countries, identified in § 514.220(d), for—

(*1*) Any duration of the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year; or

(*2*) If data for the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year is not available, data for any duration of the most recent available prior 12-month period beginning on or after January 1, 2024, is used.

(B) The data source contains coordinated prices and volume data the set of international analogs in the highest number of reference countries, identified in § 514.220(d), for—

(*1*) Any duration of the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year; or

(*2*) If data for the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year is not available, data for any duration of the most recent available prior 12-month period beginning on or after January 1, 2024, is used.

(C) The data source contains price data for the set of international analogs in the highest number of reference countries, identified in § 514.220, for—

(*1*) Any duration of the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year; or

(*2*) If data for the 12-month period corresponding to the 12-month calendar year prior to the start of the first performance year is not available, data for any duration of the most recent

available prior 12-month period beginning on or after January 1, 2024, is used.

(ii) For each GUARD Model drug included in a subsequent performance year, and not in any prior performance year, or that did not have a GUARD Model default international benchmark in a previous performance year, the same hierarchy described in paragraph (c)(2)(i) of this section is used, but it would read ''subsequent performance year'' instead of ''first performance year.''

§ 514.220 Identifying reference countries.

(a) *General.* For the GUARD Model performance period, CMS will determine reference countries in accordance with paragraph (d) of this section using criteria in paragraph (b) of this section and GDP data as characterized in paragraph (c) of this section.

(b) *Reference country identification criteria.* CMS identifies countries that meet all of the following:

(1) Were non-U.S. Organization for Economic Co-operation and Development (OECD) member countries as of October 1, 2025.

(2) Had an aggregate GDP (PPP) of at least $400 billion U.S. dollars as of October 1, 2025.

(3) Had a per capita GDP (PPP) that is at least 60 percent of the U.S. GDP per capita as of October 1, 2025.

(c) *GDP data.* GDP data used in paragraph (b) of this section—

(1) Corresponds to the most recent country data available in the U.S. CIA World Factbook as of October 1, 2025; and

(2) The country's per capita GDP (PPP) for that country and U.S. GDP per capita are for the same calendar year.

(d) *Reference countries.* Subject to paragraph (b) of this section, CMS determines the set of reference countries for the GUARD Model performance period are as follows:

(1) Australia.
(2) Austria.
(3) Belgium.
(4) Canada.
(5) Czech Republic.
(6) Denmark.
(7) France.
(8) Germany.
(9) Ireland.
(10) Israel.
(11) Italy.
(12) Japan.
(13) The Netherlands.
(14) Norway.
(15) South Korea.
(16) Spain.
(17) Sweden.
(18) Switzerland.
(19) United Kingdom.

Subpart D—Manufacturer Submitted Data

§ 514.300 Definitions.

For the purpose of this subpart the following definitions are applicable unless otherwise stated:

Authorized representative means an individual, designated by a manufacturer, as responsible for submitting international drug net pricing data, and who is also responsible for managing all communications related to the submission on behalf of the manufacturer.

Average net-to-gross ratio means for a reference country, the total net sales for international products that are part of a GUARD Model drug's set of international analogs in a reference country divided by the corresponding total gross sales for the corresponding international products.

Country-level net price means a weighted average net price, that excludes price concessions, for all international products sold in a reference country that are part of a GUARD Model drug's set of international analogs during a submission's corresponding performance year, where the weights are the corresponding volumes of international products sold, expressed as a per unit price, where the units are the GUARD Model drug's NCPDP units.

Gross sales amount means the amount of money paid, inclusive of any price concessions, for the purchase of an international product in a reference country.

International regulatory approval status means any information relevant and sufficient for CMS to determine whether each international product's approval or licensing status according to the reference country's regulatory framework would make it an international generic, international biosimilar biological product, or neither.

Net price level means, with respect to sales of international products, all sales of an international product in a reference country at the same price and price concession.

Net sales amount means the amount of money paid, exclusive of any price concessions, for the purchase of an international product in a reference country.

Price concession means any discounts, rebates, or other concessions offered by the manufacturer that lowers the amount paid for purchase of an international product in a reference country.

§ 514.310 Manufacturer submission of international drug net pricing data.

(a) *General.*

(1) *Voluntary submission.* Manufacturers may voluntarily elect to submit manufacturer international drug net pricing data, henceforth the *submission,* to CMS in accordance with the data requirements of this section.

(2) *Purpose.* CMS uses applicable submissions, determined in accordance with paragraph (b) of this section, to determine the GUARD Model updated international benchmark per § 514.410(d) for the performance year corresponding to the submission.

(b) *Data requirements.*

(1) *Data agreement.* 90 calendar days prior to the submission, the manufacturer must execute a data agreement with CMS that establishes the terms, conditions, and requirements related to the international drug net pricing data under this section.

(i) The data agreement is only applied for the performance year for which there is a submission.

(ii) A new data agreement is required for every performance year for which the manufacturer elects to submit international drug net pricing data for a GUARD Model Part D rebatable drug.

(2) *Timing of submission.* The submission must be received by CMS no later than 180 calendar days after the end of the performance year for which the manufacturer is making the submission.

(3) *Scope of submission.* Manufacturers may make a submission for one or more GUARD Model drugs. For each GUARD Model drug, the submission must—

(i) Include all international products that are part of the GUARD Model drug's set of international analogs with sales in the reference countries identified in § 514.220(d) that occur during the performance year for which they are making the submission;

(ii) Ensure alignment is consistent with the alignment approach to identify the set of international analogs at § 514.410(c); and

(iii) Ensure that allocation and calculations be done in a manner consistent with the generally acceptable accounting principles (GAAP), international financial reporting standards (IFRS), or other internationally recognized accounting approaches.

(4) *Verification of manufacturer submissions.* CMS will conduct a review of all submissions for completeness and validity, and may request additional data or information before finalizing its review and making a determination of applicability.

(i) *Completeness.* To be verified for completeness, the submission must include all basic data elements as described in paragraph (c) of this section and all net pricing data elements as described in paragraph (d) of this section, unless explained in an acceptable manner according to paragraph (e) of this section, as well as fulfill the following requirements:

(A) Proper and full execution of the manufacturer data agreement.

(B) Proper and full attestation by the manufacturer's authorized representative as described in paragraph (e) of this section.

(C) The submission was done using the proper portal and all security requirements within.

(D) The submission was executed in the manner and form required by CMS.

(E) The submission will include supporting documentation that explains how each of the elements of the submission were compiled or calculated and any reasonable assumptions that were applied.

(F) If for any element of the basic data elements in paragraph (c) of this section and net pricing data elements in paragraph (d) of this section, third-party individuals and organizations were relied upon to gather, analyze, or submit data, this must be specified for each element and the third-party individual or organization identified.

(ii) *Validity.* CMS will utilize all available data sources and information to assess the extent to which the submission reflects international drug net pricing in the reference countries. CMS may choose to request additional supporting information from manufacturers before completing assessment of validity of the submission.

(A) CMS will conduct some or all of the following checks, as appropriate:

(*1*) Cross reference against existing international pricing data for the set of international analogs.

(*2*) Check submitted data elements for internal consistency.

(*3*) Conduct cross-validation using external publicly available data.

(*4*) Conduct technical data quality checks.

(*5*) Any other appropriate checks as determined by CMS.

(B) *Request for additional information.* If CMS requests additional supporting information from manufacturers before completing its assessment of a submission's validity, the manufacturer must respond within 15 calendar days. Failure to respond within 15 calendar days will result in CMS being unable to confirm the validity of the submission, and the submission will not be deemed valid.

(5) *Applicable submission.* CMS will determine that a submission is an applicable submission only if the submission is satisfactorily verified per paragraph (b) of this section.

(c) *Basic data elements required.*

(1) A submission must include all the following basic data elements:

(i) GUARD Model drug brand name, nonproprietary name, and NDC–9.

(ii) For every reference country where at least one international product that is part of a GUARD Model drug's set of international analogs was sold during the submission performance year—

(A) Reference country name; and

(B) For every international product part of the GUARD Model drug's set of international analogs sold in the reference country, all of the following:

(*1*) Scientific name and active ingredient(s).

(*2*) Brand name(s) (all variations if there are more than one in the reference country) and nonproprietary name.

(*3*) Names of manufacturers, marketers, licensees, or other entities responsible for selling the international product in the reference country.

(*4*) International regulatory approval status.

(*5*) Route of administration and dosage form as they are expressed in the reference country and in equivalent terms to what is expressed in the NDC directory for the GUARD Model drug.

(*6*) Dosage strength and dosing units as they are expressed in the reference country and in NCPDP equivalent units according to the GUARD Model drug's NCPDP unit.

(*7*) All package forms and sizes available.

(d) *Net pricing data elements required.* A submission must include net pricing elements in complete fulfillment of one of the net pricing data submission options that follow:

(1) *Streamlined option.*

(i) For every reference country where at least one international product part of a GUARD Model drug's set of international analogs was sold during the performance year corresponding to the submission—

(A) For every sale involving an international analog aggregated at the net price level—

(*1*) Gross sales amount in the reference country currency and U.S. dollars;

(*2*) Net sales amount in the reference country currency and U.S. dollars; and

(*3*) Sales volume—in NCPDP units corresponding to the GUARD Model drug's NCPDP unit;

(B) Average net-to-gross ratio;

(C) Exchange rate for currency conversion, as defined at § 514.5 and according to the requirements at § 514.310(e);

(D) Country-level average net price in the reference country currency and U.S. dollars; and

(E) GDP (PPP) adjuster (as defined at § 514.5).

(ii) Across-country average price in U.S. dollars.

(2) *Limited option.*

(i) For every reference country where at least one international product part of a GUARD Model drug's set of international analogs was sold during the performance year corresponding to the submission of all of the following:

(A) Total gross sales amount meaning the sum of all gross sales amounts in the reference country currency and U.S. dollars.

(B) Total net sales amount meaning the sum of all net sales amounts in the reference country currency and U.S. dollars.

(C) Total sales volume—in NCPDP units corresponding to the GUARD Model drug's NCPDP unit—meaning the corresponding volume for the total net sales amount from paragraph (d)(2)(i)(B) of this section.

(D) Average net-to-gross ratio.

(E) Exchange rate for currency conversion, as defined at § 514.5 and according to the requirements at § 514.310(e).

(F) Country-level average net price in the reference country currency and U.S. dollars.

(G) GDP (PPP) adjuster (as defined at § 514.5).

(ii) Across-country average price in U.S. dollars.

(e) *Exchange rate for currency conversion.* The exchange rate used in the submission for currency conversion for the currency of the reference country to U.S. dollars will come from the World Bank Atlas.

(1) The exchange rate must correspond to the submission's corresponding performance year.

(2) The exchange rate must be applied to all data elements requiring currency conversion in the submission.

(f) *Explanation of non-inclusion.* If a manufacturer is unable to include every data element as required (described in paragraphs (c) and (d) of this section) for all international products to be in scope per paragraph (b) of this section, CMS will require a detailed explanation to justify the non-inclusion of for every data element for each international product not included.

(1) CMS will waive the data element requirements for each data element not included if CMS determines the

explanation is sufficient to justify non-inclusion.

(2) CMS will consider the submission for a GUARD Model drug to be in scope if CMS determines the explanation is sufficient to justify the non-inclusion of the excluded international products.

(g) *Data integrity and quality assurance*—(1) *Corrections and restatements.* Manufacturers may submit corrections and restatements of applicable submissions, provided the corrections and restatements are made in accordance with the requirements in paragraphs (b) through (f) of this section and are submitted within—

(i) 30 calendar days after the submission deadline; or

(ii) If responding to a CMS request, within 15 calendar days of the request.

(2) *Attestation requirements.* Each submission must include an attestation by the authorized representative certifying the completeness and validity of the data submission on behalf of the manufacturer and any third-party entities relied upon for gathering, analyzing, or submitting the manufacturer net pricing data. The attestation requires the authorized representative to—

(i) Provide contact information; and

(ii) Attest that—

(A) The submission is accurate and complete to the best of the manufacturer's knowledge;

(B) The submission is prepared in full compliance with all requirements of this section; and

(C) The authorized representative has the authority to make the attestation on behalf of the manufacturer.

(h) *Confidentiality and data protections.* CMS will maintain the confidentiality of information submitted under this section to the extent permitted by law and in accordance with applicable privacy and security requirements.

(i) *Submission platform and security requirements.* The authorized representative must gain access to the Health Plan Management System (HPMS) or other CMS system that will be used for submission, comply with all encryption and submission requirements established by CMS, and submit using the appropriate system and in the manner and form as determined by CMS.

Subpart E—Determination of the GUARD Model Applicable International Benchmark

§ 514.410 Determination of the GUARD Model Applicable International Benchmark

(a) *General.* For each GUARD Model drug, according to paragraph (b) of this section, CMS will designate a GUARD Model applicable international benchmark.

(b) *Determination of the GUARD Model applicable international benchmark*—

(1) CMS will identify the greater of the following for a GUARD Model drug for a performance year—

(i) The GUARD Model default international benchmark (as determined in § 514.410(c)), as available; or

(ii) The GUARD Model updated international benchmark (as determined in § 514.410(d)), as available.

(2) CMS will multiply the identified benchmark from paragraph (b)(1) of this section by the applicable adjustment factor (as determined in paragraph (e) of this section) and designate the result as the GUARD Model applicable international benchmark.

(c) *Determination of the GUARD default international benchmark.* (1) The GUARD Model default international benchmark is calculated for every GUARD Model drug using the selected data source according to § 514.210 prior to the GUARD Model rebate payment amount determination for the first performance year, according to the calculation steps in paragraph (c)(3) of this section, and this will be the default international benchmark for the performance period.

(2) For any GUARD Model drug included in a subsequent performance year that was not part of the first performance year, or that did not have a GUARD Model default international benchmark in a previous performance year, the GUARD Model default international benchmark is calculated prior to the GUARD Model rebate payment amount determination for the corresponding subsequent performance year, and in accordance with paragraph (c)(3) of this section, and this is the default international benchmark for the remainder of the performance period.

(3) *Steps in determining the GUARD Model default international benchmark.* CMS will calculate the GUARD Model default international benchmark for each GUARD Model drug when there is available international drug pricing data from the selected data sources described in § 514.210 for at least one reference country among those identified in § 514.220(d).

(i) *Identification of records from international drug pricing data.* CMS will identify records for every international product that is part of a GUARD Model drug's set of international analogs in the available 12-months of international drug pricing data.

(A) CMS will find records for international products that align with the GUARD Model drug's active ingredient, route of administration, dosage form, and strength using the data sources' standardized method for identifying scientific names or nonproprietary names, route of administration, dosage forms, and strengths, and CMS will make any necessary adjustments to the records to ensure alignment.

(B) If CMS does not identify any records in paragraph (c)(3)(i)(A) of this section for a reference country, CMS will find records for said reference country for any international products that align with the GUARD Model drug's active ingredient, route of administration, and dosage form using the data sources' standardized method for identifying scientific names or nonproprietary names, route of administration, and dosage forms, and CMS will make any necessary adjustments to the records to ensure alignment. If CMS identifies—

(*1*) Only one international product, then its records are retained.

(*2*) More than one international product, and the relative difference in terms of strength between the two closest (in absolute terms) international product's strengths and the GUARD Model drug's strength compared to the relative difference in prices for those same two strength-misaligned international products is—

(*i*) Equal to or greater than half of the relative strength difference, then CMS will retain the records for the international product whose strength is closest in magnitude to the strength of the GUARD Model drug.

(*ii*) If the relative price difference is less than half of the relative strength difference, then CMS will retain records for both international products with the closest strengths in absolute terms to the GUARD Model drug.

(*iii*) In the case of ties, CMS will default to retaining records for the lower-strength international product.

(C) CMS will identify among the records retained from paragraph (c)(3)(i)(A) and (B) of this section, records for international products that the data source reports as an international generic or an international biosimilar biological product according to the reference country's regulatory framework. CMS will exclude these records from the calculation of the GUARD Model default international benchmark.

(D) CMS will identify among the records retained from paragraph (c)(3)(i)(A) and (B) of this section, records for international products where

the data source reports pricing information with a value of zero or less than zero.

(ii) *Data sufficiency for GUARD Model default international benchmark calculation.* If the data resulting from paragraph (c)(3)(i) of this section—

(A) Has records for at least one international product in any reference country, CMS will proceed to the calculation in paragraph (c)(3)(iii) of this section.

(B) Has no records for any international product in any reference country, the GUARD Model drug does not have a GUARD Model default international benchmark and therefore no GUARD Model rebate payment is calculated for that performance year.

(iii) *Steps for calculation of the GUARD Model default international benchmark*—(A) *Calculation of the country-level average price.* For each reference country with records identified per paragraph (c)(3)(i) of this section, CMS will calculate an average price per NCPDP unit of the GUARD Model drug using all records for that reference country.

(*1*) If the data source contains coordinated sales and volume or coordinated prices and volume, for each record of selected data for a reference country, CMS will—

(*i*) If contained in the data source and appropriate, CMS will convert sales amounts so that the sales amount is expressed in terms of the GUARD Model drug's NCPDP unit;

(*ii*) If contained in the data source and appropriate, CMS will multiply prices by the corresponding volume, where the volume is expressed in terms of the GUARD Model drug's NCPDP unit;

(*iii*) If the resulting amounts from paragraph (c)(3)(iii)(A)(*1*)(*i*) or (*ii*) are not in U.S. dollars, CMS will convert the local currency to U.S. dollars using the exchange rate for currency conversion from the selected data source.

(*iv*) CMS will multiply the results from paragraph (c)(3)(iii)(A)(*1*)(*iii*) by the GDP (PPP) adjuster as defined at § 514.5.

(*v*) CMS will calculate the total volume as a sum of all the volumes for each record of selected data for a reference country, converted if needed to be expressed in terms of the GUARD Model drug's NCPDP unit.

(*vi*) CMS will calculate the total volume-weighted price as a sum of all the volume-weighted prices from paragraph (c)(3)(iii)(A)(*1*)(*iv*) of this section.

(*vii*) CMS will divide the total volume-weighted prices from paragraph (c)(3)(iii)(A)(*1*)(*vi*) of this section by the total volume described in paragraph (c)(3)(iii)(A)(*1*)(*v*) of this section to obtain a country-level average price.

(*2*) If the data source contains only prices, for each record of selected data for a reference country, CMS will do all of the following:

(*i*) Sum of all the prices for each record of selected data for a reference country, converted if needed to be expressed in terms of the GUARD Model drug's NCPDP unit, converting if needed from a local currency to U.S. dollars using the exchange rate for currency conversion from the selected data source.

(*ii*) Multiply the results from paragraph (c)(3)(iii)(A)(*2*)(*i*) of this section by the GDP (PPP) adjuster as defined at § 514.5.

(*iii*) Divide the result from paragraph (c)(3)(iii)(A)(*2*)(*ii*) of this section by the number of records used in from paragraph (c)(3)(iii)(A)(*2*)(*i*) to obtain the country-level average price.

(B) *Selection of the GUARD Model default international benchmark.* Among all the country-level average prices obtained from paragraph (c)(3)(iii)(A) of this section, the lowest amount, in absolute terms, is designated as the GUARD Model default international benchmark.

(d) *Determination of the GUARD Model updated international benchmark.*

(1) CMS determines the GUARD Model updated international benchmark for each GUARD Model drug, when there is an applicable submission per § 514.310, prior to the GUARD Model rebate payment amount determination for a performance year.

(2) The across-country average net price data element from the net pricing data elements of an applicable submission as described in § 514.310, is the GUARD Model updated international benchmark.

(e) *Applicable adjustment factor.* When the GUARD Model applicable international benchmark is based on the—

(1) GUARD Model default international benchmark, the applicable adjustment factor is 102 percent.

(2) GUARD Model updated international benchmark, the applicable adjustment factor is 105 percent.

Subpart F—Determination of the GUARD Model Rebate Payment Amount

§ 514.500 Definitions.

For the purpose of this part, the following definitions are applicable unless otherwise stated:

Applicable drug has the meaning set forth in section 1860D–14C(g)(2) of the Act.

Applicable period has the meaning set forth in 42 CFR 428.20.

Currently in shortage has the same meaning set forth in 42 CFR 428.300.

Drug shortage or shortage has the same meaning set forth in 42 CFR 428.300.

Line extension has the meaning set forth in 42 CFR 428.200.

Medicare Part D Manufacturer Discount Program has the meaning set forth in section 1860D–14C of the Act.

Part D rebatable drug has the meaning set forth in 42 CFR 428.20.

Performance year per unit Part D inflation rebate amount means the per unit Part D inflation rebate amount determined under 42 CFR 428.202(a) and 428.204(c), expressed as a performance year amount and converted from per-AMP unit terms to per-NCPDP unit terms, calculated as follows:

(1) Subject to paragraph (3) of this definition, for a GUARD Model drug that is not a line extension as defined in this subpart, the performance year per unit Part D inflation rebate amount is equal to the sum of the following:

(i) The product of—

(A) The per unit Part D inflation rebate amount associated with the applicable period beginning October of the calendar year prior to the performance year as set forth in 42 CFR 428.202(a);

(B) 0.75; and

(C) NCPDP unit conversion factor.

(ii) The product of—

(A) The per unit Part D inflation rebate amount associated with the applicable period beginning October of the performance year, as set forth in 42 CFR 428.202(a);

(B) 0.25; and

(C) NCPDP conversion factor.

(2) Subject to paragraph (4) of this definition, for a GUARD Model drug that is a line extension as defined in this subpart, the performance year per unit Part D inflation rebate amount is equal to the sum of the following:

(i) The product of—

(A) The greater of the per unit Part D inflation rebate amount associated with the applicable period beginning October of the calendar year prior to the performance year, as set forth in 42 CFR 428.202(a), or the product of the amounts determined under 42 CFR 428.204(c)(1) and (2) for the applicable period;

(B) 0.75; and

(C) NCPDP unit conversion factor.

(ii) The product of—

(A) The greater of the per unit Part D inflation rebate amount associated with

the applicable period beginning October of the performance year, as set forth in 42 CFR 428.202(a), or the product of the amounts determined under 42 CFR 428.204(c)(1) and (2) for the applicable period;

(B) 0.25; and

(C) NCPDP conversion factor.

(3) Notwithstanding paragraph (1) of this definition, for a GUARD Model drug that is not a line extension as defined in this subpart, for which the GUARD Model drug is a Part D rebatable drug only during the months in which one of the applicable periods overlaps with the performance year, the performance year per unit Part D inflation rebate amount is equal to the per unit Part D inflation rebate amount associated with the applicable period and expressed in NCPDP units (that is, multiplied by the NCPDP conversion factor) in which the GUARD Model drug is a Part D rebatable drug, as set forth in 42 CFR 428.202(a).

(4) Notwithstanding paragraph (2) of this definition, for a GUARD Model drug that is a line extension as defined in this subpart, for which the GUARD Model drug is a Part D rebatable drug only during the months in which one of the applicable periods overlaps with the performance year, the performance year per unit Part D inflation rebate amount is equal to the greater of the per unit Part D inflation rebate amount associated with the applicable period in which the GUARD Model drug is a Part D rebatable drug, as set forth in 42 CFR 428.202(a), or the product of the amounts determined under 42 CFR 428.204(c)(1) and (2) for the applicable period.

§ 514.510 Determination of the GUARD Model Rebate Amount for GUARD Model Drugs.

(a) *Calculation of the total GUARD Model rebate payment amount.* The total GUARD Model rebate for a GUARD Model drug, identified as set forth in § 514.120, for a performance year is equal to the product of the per unit GUARD Model rebate amount for the drug, as determined under paragraph (b) of this section, and the total units of the GUARD Model drug dispensed under Part D for GUARD Model beneficiaries, as determined under paragraph (d) of this section.

(b) *Formula for calculating the per unit GUARD Model rebate amount.* Subject to paragraph (b)(2) of this section, CMS will calculate the per unit GUARD Model rebate payment amount for a GUARD Model drug by determining the amount by which the performance year Medicare net price for the drug, as calculated in accordance with paragraph (b)(1) of this section, exceeds the applicable international benchmark.

(1) *Calculation of the performance year Medicare net price.* CMS will calculate the performance year Medicare net price by using WAC to calculate the performance year aggregate gross price, subtracting certain manufacturer rebates (from DIR) and discounts (from the Manufacturer Discount Program) from that aggregate price to produce the performance year aggregate net price, and dividing that net price by the quantity dispensed to produce a per unit price.

(i) *Performance year aggregate gross price.* For each GUARD Model drug, CMS will identify all PDE records for all NDC–11s associated with the NDC–9 of the GUARD Model drug with dates of service during the performance year. The performance year aggregate gross price is equal to the WAC for the GUARD Model drug, multiplied by the quantity dispensed reported on the PDE record, summed across all PDE records identified.

(A) For each PDE record, CMS will use third party sources to identify the WAC using the NDC–11. If there was no WAC available for an NDC–11, but there is an available WAC for another NDC–11 associated with the NDC–9 of the GUARD Model drug, CMS will use this available WAC.

(B) For each PDE record, CMS will identify the WAC in effect on the date of service reported on the PDE record.

(*1*) If there is not an effective WAC as of the date of service for any PDE records during the performance year, CMS will use the most recently effective WAC available.

(*2*) If the GUARD Model drug has some PDE records during the performance year for which there is an effective WAC as of the date of service, but other PDE records during the performance year for which there is not an effective WAC as of the date of service, CMS will impute a WAC for the latter category of PDE records based on the available WAC that was in effect most recently before the date of service on the PDE record.

(*3*) If there was no WAC in effect before the date of service on the PDE record, but there was a WAC in effect after the date of service, CMS will use the WAC that was in effect after the date of service and this would be applied to that PDE record.

(C) If there is no WAC available for any NDC–11 associated with the NDC–9 of the GUARD Model drug, CMS will not calculate a performance year aggregate gross price or issue a GUARD Model Rebate Report for that performance year.

(ii) *Performance year aggregate net price.* The performance year aggregate net price is equal to the performance year aggregate gross price determined under paragraph (i) of this section, minus the following amounts:

(A) The sum of manufacturer rebates found in the Detailed DIR Report for the performance year across all plans for all NDC–11s associated with the NDC–9 of a GUARD Model Part D rebatable drug.

(B) Manufacturer discounts provided under the Medicare Part D Manufacturer Discount Program and obtained from the amounts reported on PDE records for the GUARD Model drug for the performance year. For a GUARD Model drug eligible for the phase-in under section 1860D–14C(g)(4)(B) or 1860D–14C(g)(4)(C) of the Act, the amount determined under this paragraph is equal to the amount the manufacturer would have paid in discounts under the Medicare Part D Manufacturer Discount Program during the performance year if the GUARD Model Part D rebatable drug had not been eligible for the phase-in.

(iii) *Convert to a per unit price.* The performance year Medicare net price is equal to the amount determined under paragraph (b)(1)(ii) of this section, divided by the sum of the amounts reported in the quantity dispensed field across all PDE records identified in paragraph (d) of this section.

(2) *Exception.* In instances when the applicable international benchmark set forth at § 514.410 is equal to zero, the per unit GUARD Model rebate payment amount is equal to zero.

(c) *Calculation of the incremental per unit GUARD Model rebate amount and the Total Incremental GUARD Model rebate amount*—(1) *Incremental per unit GUARD Model rebate amount.* (i) Subject to paragraph (c)(1)(ii) of this section, the incremental per unit GUARD Model rebate amount is equal to the per unit GUARD Model rebate payment amount, as set forth in paragraph (b) of this section, minus the performance year per unit Part D inflation rebate amount, as set forth at § 514.500 for the GUARD Model drug.

(ii) To the extent the amount determined under paragraph (c)(1)(i) of this section is less than or equal to zero, the incremental per unit GUARD Model rebate amount is equal to zero.

(2) *Total Incremental GUARD Model rebate amount.* (i) The Total Incremental GUARD Model rebate amount is equal to the product of the incremental per unit GUARD Model rebate amount determined under paragraph (c)(1) of this section and the total units of the GUARD Model drug

dispensed under Part D for GUARD Model beneficiaries determined under paragraph (d) of this section.

(ii) The Total Incremental total GUARD Model rebate amount for the GUARD Model drug may be reduced in accordance with § 514.520 or adjusted in accordance with subpart G of this part.

(d) *Determination of the total units of the GUARD Model drug dispensed under Part D for GUARD Model beneficiaries.* For each GUARD Model drug, CMS will determine the total number of units as follows:

(1) CMS will apply the methodology set forth at 42 CFR 428.203, inclusive of the removal of certain units as set forth at 42 CFR 428.203(b) and subject to the following adjustments:

(i) The methodology applies as if references to ''applicable period'' are references to ''performance year.''

(ii) The methodology does not apply as set forth at 42 CFR 428.203(a)(2) to crosswalk to AMP units.

(2) From the total units identified in paragraph (d)(1) of this section, CMS will remove units for PDE records that are not associated with a GUARD Model beneficiary.

§ 514.520 Reducing the Total Incremental GUARD Model rebate amount for GUARD Model drugs in shortage or when there is a severe supply chain disruption or likely shortage.

(a) *Reducing the Total Incremental GUARD Model rebate amount for GUARD Model drugs currently in shortage.* (1) *General.* CMS will reduce the Total Incremental GUARD Model rebate amount determined under § 514.510(c)(2), if any is owed, for a GUARD Model drug that is currently in shortage, as set forth in 42 CFR 428.300, at any point during the performance year.

(2) *Calculation of reduction.* The reduced Total Incremental GUARD Model rebate amount is equal to the following:

(i) For a GUARD Model drug that was a Part D rebatable drug during both applicable periods that overlap with the performance year, the sum of—

(A) The product of—

(*1*) The Total Incremental GUARD Model rebate amount;

(*2*) 0.75;

(*3*) 1 minus the product of—

(*i*) The applicable percent reduction determined under 42 CFR 428.301(b)(2) for the applicable period that overlaps with the first three quarters of the performance year; and

(*ii*) The percentage of time the GUARD Model drug was currently in shortage during the first three quarters of the performance year determined by CMS under 42 CFR 428.301(b)(3).

(B) The product of—

(*1*) The Total Incremental GUARD Model rebate amount;

(2) 0.25;

(*3*) One minus the product of—

(*i*) The applicable percent reduction determined under 42 CFR 428.301(b)(2) for the applicable period that overlaps with the last quarter of the performance year; and

(*ii*) The percentage of time the GUARD Model drug was currently in shortage during the last quarter of the performance year determined by CMS under 42 CFR 428.301(b)(3).

(ii) For a GUARD Model drug that was a Part D rebatable drug during only one of the applicable periods that overlap with the performance year, the product of—

(A) The Total Incremental GUARD Model rebate amount;

(B) One minus the product of—

(*1*) The applicable percent reduction determined under 42 CFR 428.301(b)(2) for the applicable period that overlaps with the performance year and during which the GUARD Model drug was a Part D rebatable drug; and

(2) The percentage of time the GUARD Model drug was currently in shortage during that applicable period determined by CMS under 42 CFR 428.301(b)(3).

(3) *Application of reduction.* CMS will apply a reduction of the Total Incremental GUARD Model rebate amount as determined under paragraph (a)(2) of this section to the GUARD Model drug at the NDC–9 level.

(b) *Reducing the Total Incremental GUARD Model rebate amount for certain GUARD Model drugs when there is a severe supply chain disruption*—(1) *General.* CMS will reduce the Total Incremental GUARD Model rebate amount determined under § 514.510(c)(2) for a generic GUARD Model drug or biosimilar biological product if CMS determines that a severe supply chain disruption occurred during an applicable period that overlaps with the performance year. A severe supply chain disruption includes disruptions caused by a natural disaster or other unique or unexpected event as set forth in § 428.300.

(2) *Calculation of reduction.* For a GUARD Model drug that is a generic or biosimilar biological product as described at 42 CFR 428.300, the reduced Total Incremental GUARD Model rebate amount is equal to the following:

(i) For a GUARD Model drug that was a Part D rebatable drug during both applicable periods that overlap with the performance year, the sum of—

(A) The product of—

(*1*) The Total Incremental GUARD Model rebate amount;

(*2*) The percentage reduction applied under 42 CFR 428.302 for the applicable period that overlaps with the first three quarters of the performance year; and

(*3*) 0.75.

(B) The product of—

(*1*) The Total Incremental GUARD Model rebate amount;

(*2*) The percentage reduction applied under 42 CFR 428.302 for the applicable period that overlaps with the last quarter of the performance year; and

(*3*) 0.25.

(ii) For a GUARD Model drug that was a Part D rebatable drug during only one of the applicable periods that overlaps with the performance year, the product of—

(A) The Total Incremental GUARD Model rebate amount;

(B) The percentage reduction applied under 42 CFR 428.302 for the applicable period that overlaps with the performance year and during which the GUARD Model drug was a Part D rebatable drug.

(3) *Limitation on GUARD Model rebate reductions.* The limitations set forth in 42 CFR 428.302(b)(4) on multiple rebate reductions for the same GUARD Model drug and performance year apply to this subpart.

(c) *Reducing the Total Incremental GUARD Model rebate amount for generic GUARD Model drugs likely to be in shortage*—(1) *General.* CMS will reduce the Total Incremental GUARD Model rebate amount determined under § 514.510(c)(2) for a generic GUARD Model drug when CMS determines that the generic GUARD Model drug is likely to be in shortage during an applicable period that overlaps with the performance year. CMS will make likely to be in shortage determinations in accordance with the criteria set forth in 42 CFR 428.300 and 428.303.

(2) *Calculation of reduction.* For a GUARD Model drug that is a generic Part D rebatable drug as described at 42 CFR 428.300, the reduced Total Incremental GUARD Model rebate amount is equal to the following:

(i) For a GUARD Model drug that was a Part D rebatable drugs during both applicable periods that overlap with the performance year, the sum of—

(A) The product of—

(*1*) The Total Incremental GUARD Model rebate amount;

(*2*) The percentage reduction applied under 42 CFR 428.303 for the applicable period that overlaps with the first three quarters of the performance year; and

(*3*) 0.75.

(B) The product of—

(*1*) The Total Incremental GUARD Model rebate amount;

(*2*) The percentage reduction applied under 42 CFR 428.303 for the applicable period that overlaps with the last quarter of the performance year; and

(*3*) 0.25.

(ii) For a GUARD Model drug that was a Part D rebatable drug during only one of the applicable periods that overlaps with the performance year, the product of—

(A) The Total Incremental GUARD Model rebate amount; and

(B) The percentage reduction applied under 42 CFR 428.303 for the applicable period that overlaps with the performance year and during which the GUARD Model drug was a Part D rebatable drug.

(3) *Limitation on GUARD Model rebate reductions.* The limitations set forth in 42 CFR 428.303(b)(4) on multiple rebate reductions for the same GUARD Model drug and performance year apply to this subpart.

Subpart G—Reports of Total Rebate Payment Amounts, Reconciliation, Suggestion of Error, and Payments

§ 514.600 Definitions.

For the purpose of this part, the following definitions are applicable unless otherwise stated:

Date of receipt is the calendar day following the day in which a report of a Total Incremental GUARD Model rebate amount (as set forth in § 514.610) is made available to the manufacturer of a GUARD Model drug by CMS.

§ 514.610 Rebate report and suggestion of error.

(a) *General.* This section applies to GUARD Model drugs for all GUARD Model performance years and payment years.

(b) *Preliminary GUARD Model rebate report.* (1) A preliminary GUARD Model rebate report is provided to each manufacturer of a GUARD Model drug not later than 20 months after the end of a performance year.

(2) The preliminary GUARD Model rebate report for each GUARD Model drug includes the following information:

(i) Information related to the Part D inflation rebate amount for quarters corresponding to the relevant performance year.

(ii) The NDC(s) for the GUARD Model drug as defined under § 514.120(a).

(iii) The total number of units dispensed under Part D for the GUARD Model drug for the performance year as determined in § 514.510(d).

(iv) The GUARD Model applicable international benchmark as described in § 514.42(d).

(v) The performance year Medicare net price for the GUARD Model drug as determined in § 514.510(b)(1).

(vi) The total GUARD Model rebate amount as determined in proposed § 514.510(a).

(vii) The per unit GUARD Model rebate amount for the GUARD Model drug for the performance year as determined in § 514.510(b).

(viii) The performance year per unit Part D inflation rebate amount as described in § 514.500.

(ix) The incremental per unit GUARD Model rebate amount as determined in § 514.510(c)(1).

(x) Any applied reductions as described in § 514.520.

(xi) The total Part D inflation rebate amount as determined in 42 CFR 428.201(a).

(xii) The Total Incremental GUARD Model rebate amount due as determined in § 514.510(c)(2).

(c) *GUARD Model rebate report.* A GUARD Model rebate report will be provided to each manufacturer of a GUARD Model drug not later than 22 months after the end of each performance year.

(1) The GUARD Model rebate report will include the following:

(i) The information described in paragraph (b)(2) of this section, if applicable.

(ii) Any revisions to the information in paragraph (c)(1)(i) of this section resulting from CMS' review of a suggestion of error as set forth in § 514.620, if applicable.

(iii) Any CMS-determined recalculations from paragraph (d)(2) of this section.

(2) The GUARD Model rebate report is the invoice of a manufacturer's Total Incremental GUARD Model rebate amount due as calculated in § 514.510(c)(2), if any, for a GUARD Model drug for a performance year.

(3) The GUARD Model rebate amount due will be reported as a dollar amount that is rounded to the nearest cent.

(d) *Reconciliation of the Total Incremental GUARD Model rebate amount.* CMS will perform reconciliation of the Total Incremental GUARD Model rebate amount provided in a GUARD Model rebate report specified in paragraph (c) of this section for a performance year in the following circumstances:

(1) *Regular reconciliation.* CMS will perform a reconciliation of the Total Incremental GUARD Model rebate amount not later than 12 months after the date of receipt of the GUARD Model Rebate Report for a performance year and a second reconciliation not later than 36 months after the date of receipt of the GUARD Model rebate report for a performance year to include revisions to the information used to calculate the Total Incremental GUARD Model rebate amount as specified in paragraph (c)(1) of this section.

(i) *Preliminary reconciliation.* Not more than 60 calendar days prior to the issuance of a report with the reconciled Total Incremental GUARD Model rebate amount for a performance year specified in paragraph (d)(1)(ii) of this section, CMS will conduct a preliminary reconciliation of the Total Incremental GUARD Model rebate amount for a performance year based on the information specified in paragraphs (d)(1)(i)(A) through (H) of this section, and CMS will provide the information specified in paragraphs (d)(1)(i)(A) through (H) of this section to the manufacturer of a GUARD Model drug for the performance year, if applicable—

(A) Updated total number of rebatable units, including updates submitted by a PDP or MA–PD plan sponsor and updates to 340B units and updates to units excluded as specified in § 514.510(d);

(B) Updated WAC for the performance year;

(C) The reconciled per unit GUARD Model rebate amount as determined in § 514.510(b);

(D) The reconciled incremental per unit GUARD Model rebate amount for the performance year as determined in § 514.510(c)(1);

(E) The reconciled Total Incremental GUARD Model rebate amount as determined in § 514.510(c)(2);

(F) The reconciled total GUARD Model rebate amount as determined in proposed § 514.510(a);

(G) The difference between the Total Incremental GUARD Model rebate amount due as specified on the GUARD Model rebate report set forth at § 514.510(c)(2) and the reconciled Total Incremental GUARD Model rebate amount as set forth in paragraph (d)(1)(i) of this section; and

(H) Any other data elements that may be updated as a result of manufacturer misreporting.

(ii) *Report with a reconciled rebate amount.* With the inclusion of any additional revisions to the information resulting from CMS' review of a suggestion of error as set forth in § 514.620, if applicable, a report with the reconciled Total Incremental GUARD Model rebate amount is provided to each manufacturer of a GUARD Model drug within 12 months and 36 months after receipt of the

GUARD Model rebate report described in paragraph (c) of this section.

(2) *CMS identification of an error or manufacturer misreporting.* CMS may recalculate a Total Incremental GUARD Model rebate amount and provide the manufacturer of a GUARD Model drug with a report of a reconciled Total Incremental GUARD Model rebate amount if—

(i) CMS identifies an error in the information specified in paragraphs (c) and (d)(1) of this section, including reporting system or coding errors, not later than 5 years from the date of receipt by a manufacturer of a GUARD Model rebate report for the performance year; or

(ii) CMS determines at any time that the information used by CMS to calculate the Total Incremental GUARD Model rebate amount was inaccurate due to manufacturer misreporting.

(3) *Impact of reconciliation on rebate amount.* A reconciliation as set forth in paragraph (d) of this section may result in an increase, decrease, or no change to the Total Incremental GUARD Model rebate amount as calculated under § 514.510(c)(2) owed by a manufacturer for the performance year for the GUARD Model drug.

(i) A report with a reconciled Total Incremental GUARD Model rebate amount that is an increase to the Total Incremental GUARD Model rebate amount is the invoice for the additional amount due on the manufacturer's Total Incremental GUARD Model rebate amount as set forth in § 514.510(c)(2) for a GUARD Model drug for a performance year.

(ii) [Reserved]

(4) *Drugs included in a reconciliation.* A drug covered under Part D that does not meet the requirements of a GUARD Model drug specified in § 514.120(a) for performance year is not included in a reconciliation under paragraph (d) of this section.

§ 514.620 Suggestion of error.

(a) *General.* Manufacturers of GUARD Model drugs may submit to CMS a request to correct errors in the preliminary GUARD Model rebate report (suggestion of error) or the report detailing the preliminary reconciliation of the Total Incremental GUARD Model rebate amount if the manufacturer believes that there is a mathematical error or errors to be corrected before the GUARD Model Rebate Report or a subsequent reconciliation, as applicable, is finalized. CMS will consider such request at its discretion before finalizing the GUARD Model rebate report or subsequent reconciliation.

(1) Section 1860D–14B(f) of the Act applies to preclude administrative or judicial review of the following:

(i) The determination of units as set forth in § 514.510(d).

(ii) The calculation of the Total Incremental GUARD Model rebate amount as set forth in § 514.510(c)(2) inclusive of any reconciled Total Incremental GUARD Model rebate amount.

(2) Section 1115A(d)(2) of the Act precludes administrative or judicial review of CMS' determination of whether a drug is a GUARD Model drug, as set forth in § 514.510(c)(2).

(b) *Process of submission.* Subject to the scope and timing requirements specified in paragraphs (a) and (c) of this section, manufacturers may submit the suggestion of error and provide supporting documentation (if applicable).

(c) *Timing.* A manufacturer must submit its suggestion of error for the performance year within 10 calendar days from the date of receipt of a preliminary GUARD Model rebate report or a preliminary reconciliation of a Total Incremental GUARD Model rebate amount using the method and process established by CMS in paragraph (b) of this section.

(d) *Notice.* CMS will—

(1) Include any revisions to the calculation of the Total Incremental GUARD Model rebate amount, if determined necessary by CMS based on the suggestion of error submitted under this section prior to issuance of the GUARD Model rebate report as set forth in § 514.610 as well as any report of a reconciled Total Incremental GUARD Model rebate amount as set forth in § 514.610.

(2) Notify the manufacturer whether CMS revises its calculation of the Total Incremental GUARD Model rebate amount based on the suggestion of error.

§ 514.630 Manufacturer access to rebate reports.

(a) *General.* CMS will establish a method and process for a manufacturer of the GUARD Model drug to do the following:

(1) Access the GUARD Model rebate report as set forth in § 514.610 including any report of a reconciled Total Incremental GUARD Model rebate amount as set forth in § 514.610);

(2) Submit a suggestion of error as set forth in § 514.620; and

(3) Pay a Total Incremental GUARD Model rebate amount as set forth in § 514.510(c)(2).

(b) [Reserved.]

§ 514.640 Deadline and process for payment of rebate amount.

(a) *Total Incremental GUARD Model Rebate amounts owed by a manufacturer.* For payment of a Total Incremental GUARD Model rebate amount owed by a manufacturer:

(1) Upon receipt of a Total Incremental GUARD Model rebate amount, payment is due no later than 11:59 p.m. Pacific Time on the 30th calendar day after the date of receipt of information regarding the Total Incremental GUARD Model rebate amount on—

(i) A rebate report specified in § 514.610; or

(ii) A report of a reconciled Total Incremental GUARD Model rebate amount specified in § 514.610.

(2) Failure to pay a Total Incremental GUARD Model rebate amount timely and in full may result in an enforcement action as described in § 514.650 and subpart H of this part.

(b) *Refund to the manufacturer.* If a GUARD Model reconciled Total Incremental GUARD Model rebate amount for a performance year as specified in § 514.610 is less than what the manufacturer paid for that performance year, CMS will initiate the process to provide a refund equal to the excess amount paid within 60 calendar days of the date of receipt of the report with the reconciled Total Incremental GUARD Model rebate amount.

§*514.650 Civil money penalty notice and appeals procedures.

General. The provisions of 42 CFR 428.500 regarding the imposition of civil money penalties also apply with respect to this subchapter to the same extent as they are applicable with respect to part 428, except that, in applying such provisions with respect to this part, any reference therein to the rebate amount determined in § 428.201(a) shall be considered a reference to the Total Incremental GUARD Model rebate amount calculated pursuant to § 514.510(c).

Subpart H—Beneficiary Protections, Quality Strategy, and Monitoring and Compliance Activities

§ 514.710 Beneficiary protections.

(a) *General.* The requirements set forth in 42 CFR part 512, including those related to beneficiary protections, monitoring, and compliance shall apply to this model.

(b) *Reporting and analysis of issues.*

(1) For tracking purposes, CMS will utilize the existing Complaints Tracking Module so that beneficiaries and other stakeholders can report access or other issues related to GUARD Model drugs.

(2) CMS will utilize 1–800–MEDICARE for beneficiaries, providers, or other stakeholders to submit reports that a GUARD Model drug has been harder to source or obtain after the implementation of the GUARD Model.

(3) CMS will analyze information from the Complaints Tracking Module System and 1–800–MEDICARE to identify any complaints or issues related to the GUARD Model drugs. CMS may conduct investigations to verify and assess the reported access issues and implement appropriate remedial measures, as set forth at § 514.750(a), based on investigation findings to ensure beneficiary access to GUARD Model drugs.

§ 514.720 Quality of care.

(a) *General.* Consistent with section 1115A(b)(4) of the Act, CMS will monitor and evaluate the impact of the GUARD Model on quality of care. CMS may examine, at least annually or more frequently, as deemed appropriate by CMS, multiple domains of quality, including but not limited to beneficiary out-of-pocket costs, enrollment trends, drug utilization, health care utilization, access to GUARD Model drugs, patient experience, and other quality measures and other quality measures.

(1) Model rebate payment amounts are not adjusted based on quality of care.

(2) [Reserved].

(b) *Collection or analyses of measures.* CMS may collect or analyze any of the following data to monitor changes in quality of care associated with the GUARD Model:

(1) Existing administrative claims-based measures.

(2) Existing information on Part D, including but not limited to the Part D formulary reference files.

(3) Existing patient experience surveys, such as the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey or the Medicare Current Beneficiary Survey (MCBS), from a sample of beneficiaries who receive a GUARD Model drug.

(4) Survey(s) to a sample of GUARD Model stakeholders administered by CMS.

(5) Manufacturer sales data available to CMS from existing or submitted data sources.

(6) Other data sources or information deemed appropriate by CMS.

§ 514.730 Monitoring and compliance.

The GUARD Model manufacturers must comply with all applicable Federal laws and regulations, including requirements set forth at § 512.130 and § 512.150.

§ 514.740 Audits and record retention.

The audit rights, access requirements, and record retention requirements set forth in § 512.135 shall apply to the GUARD Model.

§ 514.750 Enforcement authority and remediation.

(a) *Remedial action.* As stated in § 512.160, CMS may take one or more remedial actions described in § 512.160(b) if CMS determines that a GUARD Model participant has done any of the actions described in § 512.160(a).

(b) *Notice.* A manufacturer of a GUARD Model drug must notify CMS within 15 calendar days after becoming aware that the manufacturer is subject to investigation or sanction by the federal, state, or local government, or any licensing authority.

Subpart I—Waivers

§ 514.800 Waiver of Medicare Program requirements for purposes of testing the GUARD Model.

CMS waives the Medicare program requirements in the following provisions to the extent necessary solely for the purposes of testing the GUARD Model:

(a) *Waiving the Part D inflation rebate calculation to the extent necessary.* Section 1860D–14B(b)(1) of the Act regarding the Medicare Part D inflation rebate calculation to the extent necessary, in order to permit testing of an alternative rebate calculation and rebate amount for GUARD Model drugs.

(b) *Waiver of invoice timing requirements to the extent necessary.* Section 1860D–14B(a)(1) of the Act regarding invoicing timing requirements to the extent necessary to establish deadlines, effective dates, and time period requirements for invoicing of the Total Incremental GUARD Rebate Amount.

Subpart J—Severability and Model Terminations

§ 514.900 Severability

If any provision of this part to be held invalid or unenforceable by its terms, or as applied to any person or circumstance, that provision is severable from this part. The invalidity or unenforceability will not affect the remainder of this part or any other part of this subchapter, or the application of the provision to other persons not similarly situated or to other dissimilar circumstances.

§ 514.910 Termination of the GUARD Model.

(a) *Termination.* CMS may terminate the GUARD Model for the reasons as set forth in § 512.165(a). CMS will comply with the notification requirements as set forth in § 512.165(b).

(b) *Review.* Consistent with section 1115A(d)(2) of the Act, termination of the GUARD Model is not subject to administrative or judicial review.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

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