Inflation Reduction Act of 2022
Prescription Drug Provisions

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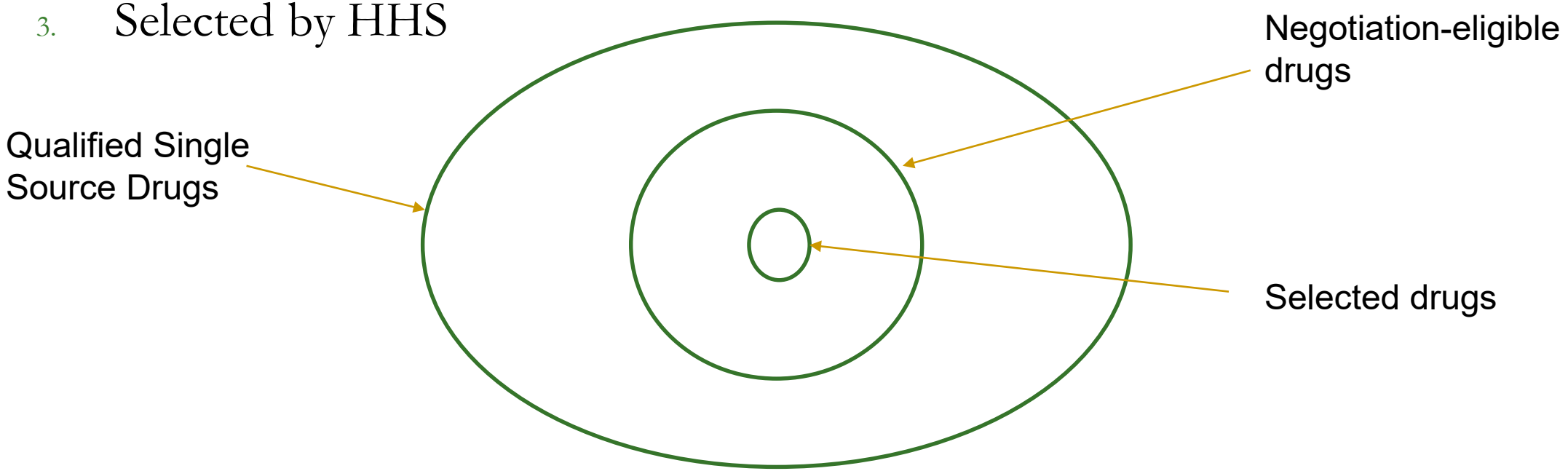
I. Price Negotiation Under Medicare Parts B and D

Overview

- Establishes HHS authority to negotiate selling price (the "Maximum Fair Price," or MFP) for selected high expenditure single-source Medicare Part B and Part D drugs and biologics
- Though MFP is negotiated, it is capped at a statutory ceiling
- MFP ceiling is a varying percentage of Non-Federal Average Manufacturer Price (NFAMP), such that the MFP ceiling is lower the greater the time since approval
- MFP may not apply to a drug until 9 years post-approval, or to a biologic until 13 years post-approval
- Takes effect in 2026

What Drugs Will Be Subject to MFP Negotiation?

- To be subject to MFP negotiation, a drug or biological must be:
  1. A Qualified Single Source Drug that is
  2. A Negotiation-Eligible Drug that is
  3. Selected by HHS



What is a "Qualified Single Source Drug" (QSS)?

- A QSS drug is:
  - A drug that was approved at least 7 years prior to selection and is not a listed drug for a drug approved and marketed under an ANDA
  - A biologic that was licensed at least 11 years prior to selection and is not a reference drug for a licensed biosimilar
- A QSS drug is not:
  - Single-indication orphan drug
  - Plasma or plasma derived product
  - A "low spend Medicare drug": total Part B and D expenditures during specified period < $200M, adjusted for inflation from 2021

Which QSS drugs are "Negotiation-Eligible" Drugs?

- A Negotiation-Eligible Drug is:
  - Among the 50 QSS drugs identified each year by HHS as having the highest expenditures under Medicare Parts B and D, respectively, for the most recent 12-month period for which data are available before the selection year
    - Expenditures for a drug take into account all dosage forms, strengths, and package sizes of drug or biologic, including authorized generics of both drugs and biologics
- A Negotiation-Eligible Drug is not:
  - A "small biotech drug":
    - Expenditures for the drug under Part B or D (as the case may be) are less than 1% of total expenditures for all drugs, and
    - Expenditures for the drug are ≥ 80% of total expenditures for all of the manufacturer's drugs covered under Part B or D (as the case may be)
    - Small biotech drug excludes vaccines and new formulations
    - Small biotech drug exception applies only in 2026 through 2028

Which Negotiation-Eligible Drugs are Selected Drugs?

- For each price applicability year, HHS will select a specified number of Negotiation-Eligible Drugs for which Part B and D expenditures are greatest for the12-month period for which cost data are available before selection year
- Number of selected drugs is
  - 2026: 10 Part D drugs
  - 2027: 15 Part D drugs
  - 2028: 15 Part B and 15 Part D drugs
  - 2029 and subsequent years: 20 Part B and 20 Part D drugs
- Selected drug remains selected until the beginning of the first calendar year that follows 9 months after market entry of an ANDA drug or biosimilar
- Selected drugs accumulate each year

What is the Process for Selection and Negotiation?

- HHS publishes list of selected drugs on Feb. 1 of 2nd year preceding the price applicability year (or Sept. 1, 2023 for the 2026 price applicability year)
- Negotiation period begins Feb. 28 of the selection year (or Oct. 1, 2023 for the 2026 price applicability year)
- By Feb. 28 of the selection year (or by Oct. 1, 2023 for the 2026 price applicability year), manufacturer signs an agreement
- By March 1 of the selection year (or by Oct. 2, 2023 for the 2026 price applicability year), manufacturer submits NFAMP and other required information in form and manner specified by HHS
- By June 1 of the selection year (or by Feb. 1, 2024 for the 2026 price applicability year), CMS proposes MFP with rationale
- Within 30 days, manufacturer accepts or counter-offers (with rationale)
- CMS responds to counter-offer (if any)
- Negotiation period ends Nov. 1 of the selection year (or Aug. 1, 2024 for 2026 price applicability year)
- By Nov. 30 of the selection year (or by Sept. 1, 2024 for the 2026 price applicability year), CMS publishes MFPs

What is the Maximum Fair Price (MFP) Ceiling?

- MFP ceiling is the lower of:
  1. Ceiling based on Non-Federal Average Manufacturer Price (NFAMP) as reported by manufacturer to Department of Veterans Affairs
     - Lower of
       - The applicable percentage of NFAMP for 2021 (or for new drugs, for first full year of marketing), adjusted for inflation
       - The applicable percentage of NFAMP for the year before the selection date (this does not apply in 2026)
     - Applicable percentage is
       - 40% for long-monopoly drugs (≥ 16 years post approval)
       - 65% extended-monopoly drugs (≤ 12 < 16 years post approval)
       - 75% for short-monopoly drugs (< 12 years post approval)
  2. Ceiling based on current payment
     - Part B drug: ASP for year before selection date
     - Part D drug: weighted Part D negotiated price among all Part D plans

What Factors May HHS Consider During Negotiations?

- Costs of R&D, production, distribution
- Market data
- Federal financial support
- Patents and exclusivity
- Sales data
- Clinical trial information
- Comparative effectiveness
- Does drug represent a therapeutic advance or address an unmet medical need

Manufacturer Agreement

- Manufacturer agrees to:
  - Negotiate MFP with HHS (up to MFP ceiling)
  - Sell at or below MFP to hospitals, physicians and other providers (Part B) or pharmacies or other dispensers (Part D)
  - Submit NFAMP information and other information required by HHS in order to negotiate MFP
- Agreement terminates when drug is no longer a selected drug

How Does MFP Affect Part B and D Reimbursement?

- Part B: Payment amount is MFP + 6%
- Part D: Plan's negotiated price cannot exceed MFP

Can MFP Change After it is First Negotiated?

- In years after the initial MFP applicability year for a drug, the MFP is adjusted for inflation
- Renegotiation
  - HHS must require MFP to be renegotiated when selected drug changes from short- to extended-monopoly drug, or from extended- to long-monopoly drug (see p. 10)
  - HHS may require MFP to be renegotiated if
    - New indication is approved
    - There is material change in negotiation factors (see p. 11)
- Process is the same as original negotiation

When Does MFP Become Effective?

- First year in which MFP applies to any drug is 2026
- For a particular drug, no MFP before 9 years post-approval for drug, 13 years post-approval for a biologic

What Are the Penalties for Non-Compliance?

- Failure to sell at or below MFP: 10 times the difference between the price charged and the MFP, for every unit furnished or dispensed to Part B or D beneficiary
- Failure to provide information required by HHS for negotiation: $1M per day
- Providing false information: $100M per false item
- Excise taxes on sale of selected drug during period in which manufacturer:
  - Has not entered into an agreement after March 1 of selection year
  - Has not agreed to MFP after Nov. 1 of selection year
  - Has not timely submitting required information
  - The longer the delay the greater the excise tax

Conforming Amendments

- Exception to Part D non-negotiation clause for selected drugs
- MFP is included in Medicaid best price, excluded from AMP
- Part D plan formularies must include selected drugs, subject to current CMS regulations permitting substitution of brand name drugs with newly marketed, therapeutically equivalent generic drugs.

Temporary Delay in Selection of Biologic Where Biosimilar Application Has Been Submitted

- Biosimilar manufacturer can request 1-year delay in selection of the reference biologic. Request is made before the selection date
- CMS decides whether there is "high likelihood" that the biosimilar will be marketed within 2 years following selection date. High likelihood exists if:
  - Biosimilar application has been accepted or approved by FDA
  - Manufacturer provides clear and convincing evidence that biosimilar will be marketed within 2 years, based on manufacturing schedule and SEC or shareholder disclosures
- If HHS finds high likelihood, selection of reference biologic is delayed until following year
- If HHS does not find high likelihood, reference biologic is selected in the following year but subject to rebate for first year

Temporary Delay (cont.)

- If biosimilar is still not marketed before following year's selection date, manufacturer can request another year's delay in selection of reference biologic
  - Must show it has made "significant progress" in licensure and marketing
- If HHS finds significant progress, selection of biologic is delayed for second year
- If HHS does not find significant progress, reference biologic is selected in 3rd year but subject to rebate for 2nd year

Temporary Delay (cont.)

- Rebate owed by manufacturer of reference biologic for price applicability year in which unwarranted delay occurred
  - Part D drug: 75% x (AMP minus MFP)
  - Part B drug: 80% x (Part B payment amount minus MFP)
- Penalty for non-payment of rebates = 10 x rebate amount owed

II. Medicare Part B Inflation Rebates

Overview

- Law imposes quarterly rebates on single source Part B drugs and biologicals with price increases exceeding the rate of inflation
- Rebates are mandatory for covered drugs – no voluntary agreement as under other government drug discount programs
- Effective 1Q 2023

What Drugs are Subject to Part B Inflation Rebates?

- "Part B Rebatable Drug"
  - Single source drugs and biologicals covered under Medicare Part B
  - Single source drug or biological is
    1. A drug approved under an NDA that has no A-rated therapeutic equivalents on the market; or
    2. A licensed biological, including a biosimilar unless excepted (see below)
- Excludes
  - A biosimilar entitled to 5 years of increased add-on payment (see p. 53)
  - A drug whose average total allowed charges per year for an individual are less than $100 (adjusted for inflation in 2024 and subsequent years)
  - A pneumococcal, influenza, or hepatitis B vaccine
- Waiver: CMS may waive or reduce rebates for drugs on FDA's shortage list and biosimilars subject to supply chain disruption from a unique or unexpected event, as determined by CMS.

How is the rebate calculated?

- The rebate for a drug assigned to a billing and payment code (HCPCS code) for a quarter = (the Part B payment amount for the billing and payment code for that quarter) minus (the Part B payment amount for a benchmark quarter multiplied by an inflation adjustment)
  - The Part B payment amount for a quarter is ASP+6%, or, for a biosimilar, ASP + 6% of the ASP of the reference biological (or 8% for certain biosimilars – see p. 53)
  - The inflation adjustment is the CPI-U for the current quarter divided by the CPI-U for the benchmark quarter

How is the Rebate Calculated (cont.)?

- The benchmark quarter and benchmark CPI-U vary for different categories of drugs
  - For drugs approved on or before Dec. 1, 2020:
    - Benchmark quarter is 3Q 2021
    - Benchmark CPI-U is CPI-U for Jan. 2021
  - For drugs approved after Dec. 1, 2020:
    - Benchmark quarter is 3rd full quarter after date of first marketing
    - Benchmark CPI-U is CPI-U for the 1st month of the 1st full quarter after date of first marketing
  - For drugs that were subject to MFP price in the previous year but are no longer:
    - Benchmark quarter is 1st quarter of the previous year
    - Benchmark CPI-U is CPI-U for July of the year before the previous year

Which Units of a Part B Drug are Rebatable?

- To determine the total inflation rebate owed for a quarter for a drug assigned to a HCPCS code, CMS will multiply the per-unit rebate described on page 24 times the number of "billing units"
- To determine the number of billing units, CMS will:
  - Take the number of units for an NDC-11 reported by the manufacturer in its ASP report for two quarters before the rebate quarter, and subtract the number of units for which Medicaid rebates were paid during that earlier quarter; then
  - Divide the resulting number of units of the NDC-11 by the billing unit for the drug's HCPCS code
  - Add up the billing units for each NDC-11 included in the HCPCS code for the drug

Rebate Invoicing and Payment Process

- Manufacturer will owe inflation rebates beginning --
  - For drugs approved on or before Dec. 1, 2020: 1Q 2023
  - For drugs approved after Dec. 1, 2020: the 6th full quarter after the date of first marketing
- Within 6 months after the end of each rebate quarter, CMS will send manufacturers a report showing the total number of billing units for which rebates are owed, the rebate per unit, and the total rebate amount owed for the quarter
  - The deadline for CMS reports for quarters in 2023 and 2024 may be extended until Sept. 30, 2025
- Within 30 days after receipt of the statement, manufacturer must pay the inflation rebate
- Far from providing for dispute resolution, the statute prohibits administrative or judicial review of CMS' determination of units, whether a drug is rebatable drug, or the rebate amount

Effect of Inflation Rebates on Other Government Prices

- Part B inflation rebates are excluded from ASP and Medicaid best price and AMP

Penalty

- Civil monetary penalty for failure to pay Part B inflation rebate is at least 125% of the rebate amount owed

III. Medicare Part D Inflation Rebates

Overview

- Law imposes annual rebates on certain Part D drugs and biologicals with price increases exceeding the rate of inflation
- Rebates are paid for 12-month period beginning Oct. 1 each year
- First Part D rebate period is Oct. 1, 2022 through Sept. 30, 2023
- Rebates are mandatory for covered drugs – no voluntary agreement as under other government drug discount programs

What Drugs are Subject to Part D Inflation Rebates?

- "Part D Rebatable Drug"
  - A drug approved under NDA
  - A drug approved under an ANDA, but only if:
    - The reference listed drug (including any authorized generic) is not being marketed
    - No other A-rated drug is being marketed
    - The drug does not have 180-day exclusivity
    - The drug is not a "first approved applicant" entitled to 180-day exclusivity for a competitive generic therapy
  - A licensed biological (including a biosimilar)
- Excludes
  - Drug whose average total allowed charges per year for an individual are less than $100 (adjusted for inflation in 2024 and subsequent years)
- Waiver: CMS may waive or reduce Part D inflation rebates for:
  - Drugs on FDA's shortage list
  - Drugs likely to be on FDA's shortage list in the future absent a reduction or waiver, as determined by CMS
  - Generics or biosimilars subject to supply chain disruption from a unique or unexpected event, as determined by CMS

How is the rebate calculated?

- Rebates are paid for an "applicable period," which is the 12-month period beginning Oct. 1 of each year
- The per-unit rebate for a dosage form and strength of a Part D rebatable drug for an applicable period is the Annual Manufacturer Price for the applicable period, minus the Annual Manufacturer Price for a benchmark period multiplied by an inflation adjustment
  - The Annual Manufacturer Price is a weighted average of the Medicaid rebate average manufacturer prices (AMPs) for the four quarters of the applicable period
  - The inflation adjustment is the CPI-U for the applicable period divided by the CPI-U for the benchmark period

How is the Rebate Calculated? (cont.)

- The benchmark quarter and benchmark CPI-U vary for different categories of drugs
  - For drugs approved on or before Oct. 1, 2021:
    - Benchmark period is the period from Jan. 1 through Sept. 30, 2021
    - Benchmark CPI-U is CPI-U for Jan. 2021
  - For drugs approved after Oct. 1, 2021:
    - Benchmark period is the first calendar year after the date of first marketing
    - Benchmark CPI-U is CPI-U for January of the first full calendar year after the date of first marketing
  - For drugs that were subject to MFP price in the previous year but are no longer:
    - Benchmark period is the previous year
    - Benchmark CPI-U is CPI-U for January of the previous year

How is the Rebate Calculated? (cont.)

- Line extensions
  - CMS must establish a rebate formula consistent with the alternative rebate formula for line extensions under the Medicaid Drug Rebate Program (MDRP)
  - "Line extension" definition is identical to the definition in the MDRP statute

Which units of a Part D Drug are Rebatable?

- To determine the total inflation rebate owed for an applicable period for a dosage form and strength of a drug, CMS will multiply the per-unit rebate described on page 33 by the number of units
- Units are the same as the units reported under the MDRP (i.e., smallest dispensable amount, such as tablet, capsule, mL, gram)
- Units exclude units sold under the 340B Drug Discount Program

Rebate Invoicing and Payment Process

- Manufacturer will owe inflation rebates beginning with the Oct. 1, 2022 – Sept. 30, 2023 applicable period
- Within 9 months after the end of each applicable period, CMS will send manufacturers a report showing the rebate per unit, and the total rebate amount owed for the applicable period
  - The deadline for CMS reports for the first two applicable periods (2022-23 and 2023-24) may be extended until Dec. 31, 2025
- Within 30 days after receipt of the statement, manufacturer must pay the inflation rebate

No Rebate Corrections!

- Statute does not provide for any dispute resolution procedure
- Statute prohibits administrative or judicial review of CMS' determination of number of units, whether a drug is Part D rebatable drug, or the rebate amount
- Statute provides for CMS to adjust rebate amounts and reconcile any overpayments and underpayments, but only where a Part D plan submits revisions to the number of units dispensed
- In the frequent case where a manufacturer recalculates and restates previously reported AMP, there is no provision for Annual Manufacturer Price or Part D inflation rebate amount to be revised

Effect of Inflation Rebates on Other Government Prices

- Part B inflation rebates are excluded from ASP and Medicaid best price and AMP

Penalty

- Civil monetary penalty for failure to pay Part D inflation rebate is 125% of the rebate amount owed

IV. Medicare Part D Redesign and Manufacturer Discount Program

Overview

- Medicare redesign provisions go into effect in 2025
- Medicare coverage gap is closed
  - The initial coverage limit is eliminated
  - The annual out-of-pocket (OOP) threshold ("catastrophic coverage threshold") is decreased to $2,000, subject to annual adjustment
- Beneficiaries pay no copayment or coinsurance for drug costs greater than $2000 a year
- Bill changes respective contributions of Medicare, plan, enrollee, and manufacturer for each phase of enrollee's coverage each year

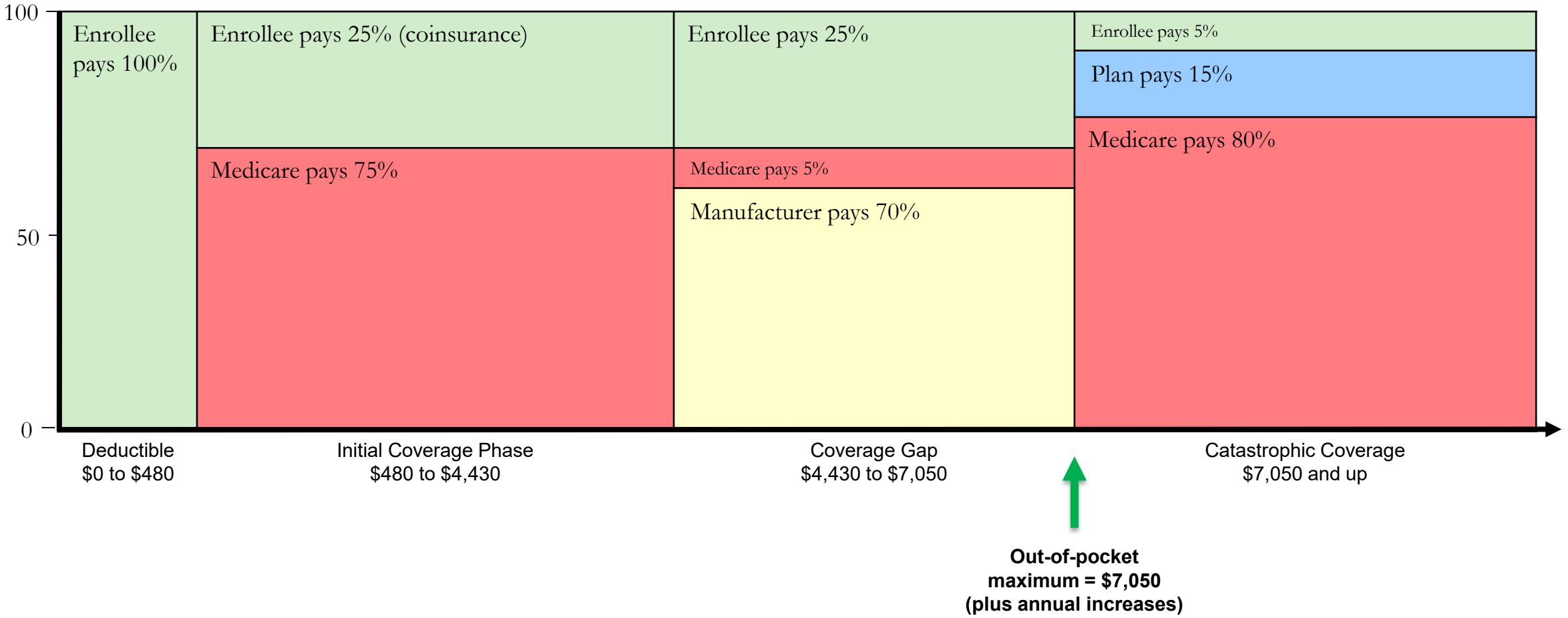
What Are the Changes to the Current Part D Coverage Phases for Part D Brand Drug Coverage?

- Deductible ($480 in 2022)
  - Current: enrollee pays 100% of negotiated price
  - New: same
- Initial coverage phase
  - Current:
    - Phase is from $480 deductible to $4,430 (in 2022) in total drug spend by Medicare and enrollee
    - Medicare pays 75%, enrollee pays 25% coinsurance, plan pays zero, manufacturer pays zero
  - New:
    - Phase will extend from deductible limit to catastrophic coverage
    - Medicare pays 65%, enrollee pays 25%, manufacturer pays 10%

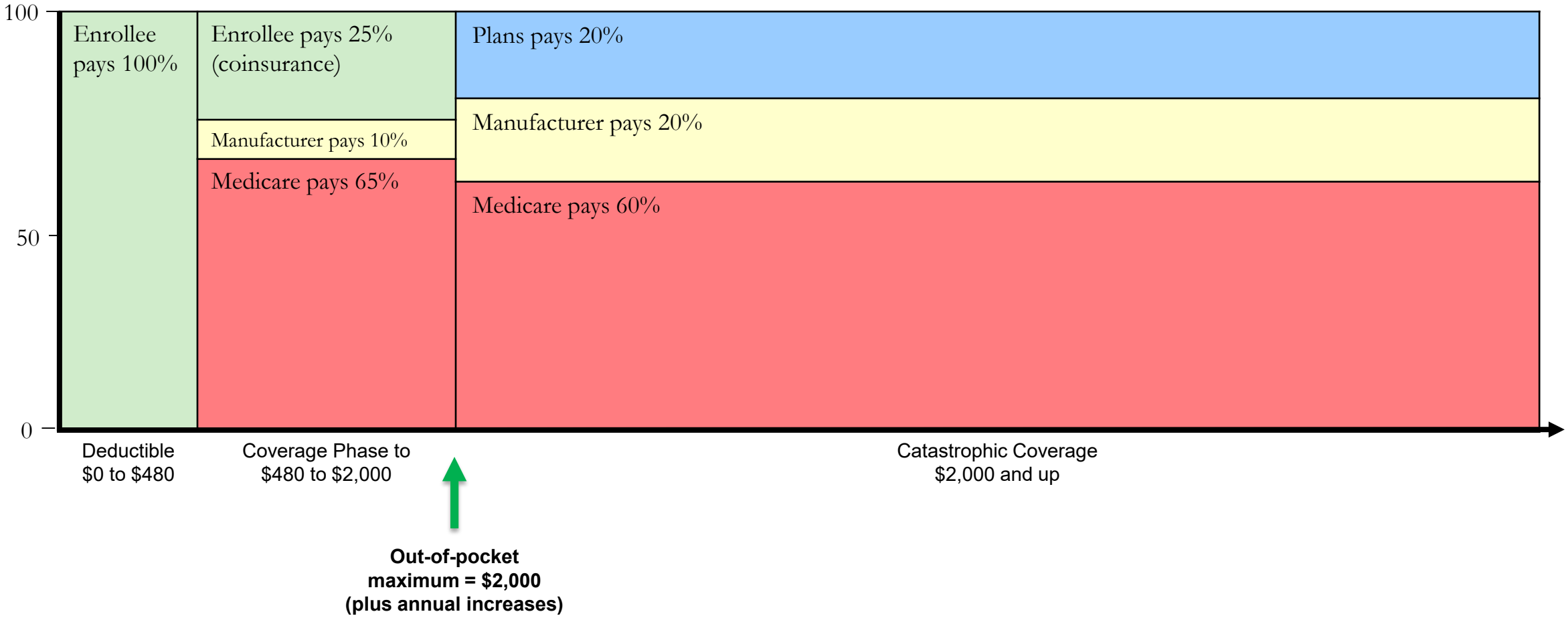
What Are the Changes to the Current Part D Coverage Phases for Part D Brand Drug Coverage? (cont.)

- Coverage gap
  - Current:
    - Phase is from $4,430 in total drug spending (2022) until catastrophic coverage is reached
    - Medicare pays 5%, manufacturer pays 70% through Coverage Gap Discount Program, enrollee pays 25% coinsurance
  - New:
    - Coverage gap eliminated; initial coverage phase extends until catastrophic coverage
- Catastrophic coverage
  - Current:
    - Begins at $7,050 in out-of-pocket (OOP) expenses (in 2022)
    - Medicare pays 80%, plan pays 15%, enrollee pays 5% coinsurance, manufacturer pays zero
  - New:
    - OOP spending cap reduced to $2,000 in 2025, adjusted annually thereafter
    - Medicare pays 60%, plan pays 20%, manufacturer pays 20%, enrollee pays zero

Medicare Part D under Current Law (2022)



Medicare Part D under IRA (2025)



Manufacturer Discount Program

- New discount program (not to be confused with Part D inflation rebates) is vehicle for manufacturers to subsidize 10% of enrollees' brand drug costs below OOP limit, and 20% of costs above OOP limit under redesigned Part D coverage phases
  - Current Coverage Gap Discount Program (CGDP) will sunset on Dec. 31, 2024
    - CGDP is current vehicle for manufacturers to subsidize 70% of the negotiated price of NDA drugs and biologics obtained by enrollees in the coverage gap
- Manufacturers must sign a discount agreement in order for their "applicable drugs" to be covered under Medicare Part D
- For the 2025 calendar year, manufacturers must enter into the agreement by March 1, 2024; CMS will set deadlines for subsequent years

Agreement

- Manufacturer obligations
  - Beginning Jan. 1, manufacturer agrees to discount "applicable drugs" to a price that is
    - 90% of the negotiated price below the enrollee's OOP threshold
    - 80% of the negotiated price at or above the enrollee's annual OOP threshold
  - "Applicable Drug" is a drug or biologic that is
    - Approved under an NDA or licensed under a BLA, and
    - Maintained on the Part D plan formulary or otherwise covered or provided by the plan
    - Does not include a "selected drug" subject to MFP
  - Manufacturer must "collect and have available appropriate data" to comply with the discount program

Agreement (cont.)

- CMS obligations
  - Determine a discounted price of an applicable drug of a manufacturer
  - Establish procedures to timely reimburse pharmacies
    - Reimbursement will be equal to the difference between the negotiated price of the applicable drug (i.e., payment amount from plan excluding dispensing fee) and the discounted price of the applicable drug
    - CMS must reimburse pharmacy within 14 days after claim submitted electronically, or 30 days after claim submitted otherwise
  - Establish a reasonable dispute resolution mechanism
  - Monitor compliance by manufacturers with the terms of the agreement
- Termination
  - CMS can terminate the agreement with a 30-day notice for good cause, including knowingly violating the agreement; manufacturer can terminate the agreement for any reason

Enforcement

- Manufacturers that fail to provide discounted prices after entering into an agreement will be subject to civil money penalties:
  - The amount owed, which will be used to pay the discount
  - An additional 25% of such amount
  - Civil Money Penalties under Social Security Act § 1128A will also apply

Phase-In of Discount Program

- Discount is phased-in for certain small manufacturers
  - Discounted price starts from 99% of the negotiated price in 2025 and goes down to 90% by 2029 for enrollees whose costs are below the OOP threshold, and down to 80% by 2031 for enrollees whose costs are above the threshold
  - Small manufacturer is
    - A manufacturer that had a Coverage Gap Discount Agreement in 2021
    - Whose brand drugs represented less than 1% of the total brand drug expenditures under both Part B and Part D; and
    - Any one of whose drugs offered under a new Part D discount agreement exceeds 80% of the total Part D expenditures for all brand drugs covered under the manufacturer's agreement

V. Other Provisions

Temporary Increase in Medicare Part B Payment for Certain Biosimilars

- For Qualifying Biosimilar Biological Products, during the Applicable 5-Year Period, the current 6% of ASP add-on to the payment rate is increased to 8%
- Qualifying Biosimilar Biological Products are products for which the ASP of the biosimilar for a calendar quarter during the 5-year period is not more than the ASP for the reference product for that quarter
- Applicable 5-Year Period
  - For products for which payment was made as of Sept. 30, 2022, the 5-year period begins Oct. 1, 2022
  - For products for which payment is first made between Oct. 1, 2022 and Dec. 31, 2027, the 5-year period begins on the first day of the calendar quarter during which such payment is first made

Insulin: Cost-Sharing under Medicare Part D

- Covered insulin product is an insulin product approved by the FDA via an NDA or BLA that is a Part D drug covered under the PDP or MA-PD plan
- Deductible
  - No deductible for plan year 2023 and subsequent years
- Copay
  - Plan years 2023-2025: $35
  - Plan year 2026 and subsequent years: the lesser of: $35; 25% of the MFP; 25% of the negotiated price for the covered insulin product
- Cost-sharing
  - Plan years 2023-2024: coverage provides benefits regardless of whether individual has reached initial coverage limit or out-of-pocket threshold, with cost-sharing for a month's supply not to exceed copay amount
  - Plan year 2025 and subsequent years: coverage provides benefits prior to individual reaching out-of-pocket threshold, with cost-sharing for a month's supply not to exceed copay amount

Insulin: Coinsurance under Medicare Part B for Insulin Furnished through DME

- Limitation on monthly coinsurance and adjustments to supplier payment under Medicare Part B for insulin furnished through DME
  - Deductible shall not apply
  - Copay cannot exceed $35
  - Applies to insulin furnished through an item of covered DME on or after July 1, 2023

Vaccines

- Provision to ensure Part D coverage of approved adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP)
  - No deductible or coinsurance or other cost sharing for adult vaccines recommended by ACIP
  - Applies to plan years beginning on or after Jan. 1, 2023
- Provision to improve access to adult vaccines under Medicaid and CHIP
  - Medicaid
    - State plans must make available approved adult vaccines recommended by ACIP
    - No deduction, cost sharing, or similar charge will be imposed under the plan with respect to such vaccines and their administration
  - CHIP
    - If state CHIP or waiver provides child health assistance to in individual who is 19 or older, such assistance must include coverage of approved adult vaccines recommended by ACIP
    - No deductibles, coinsurance, or other cost sharing may be imposed for such vaccines or their administration
  - Effective Oct. 1, 2023

Miscellaneous Provisions

- Moratorium extended on Nov. 30, 2020 HHS OIG regulation removing safe harbor protections for manufacturer rebates to Part D plans and their PBMs unless passed through to pharmacies
  - Cannot be implemented until January 1, 2032
- Payment methodology under Part B for biosimilars during initial period of marketing when insufficient data to calculate ASP
  - Currently capped at 103% of WAC of the biosimilar
  - Adds a provision to make it the lesser of 103% of WAC of the biosimilar or 106% of the ASP of the reference product
  - Applies to biosimilar products furnished on or after July 1, 2024