

Key Changes to Medicare Part D in 2025: *An Overview for PACE Organizations*

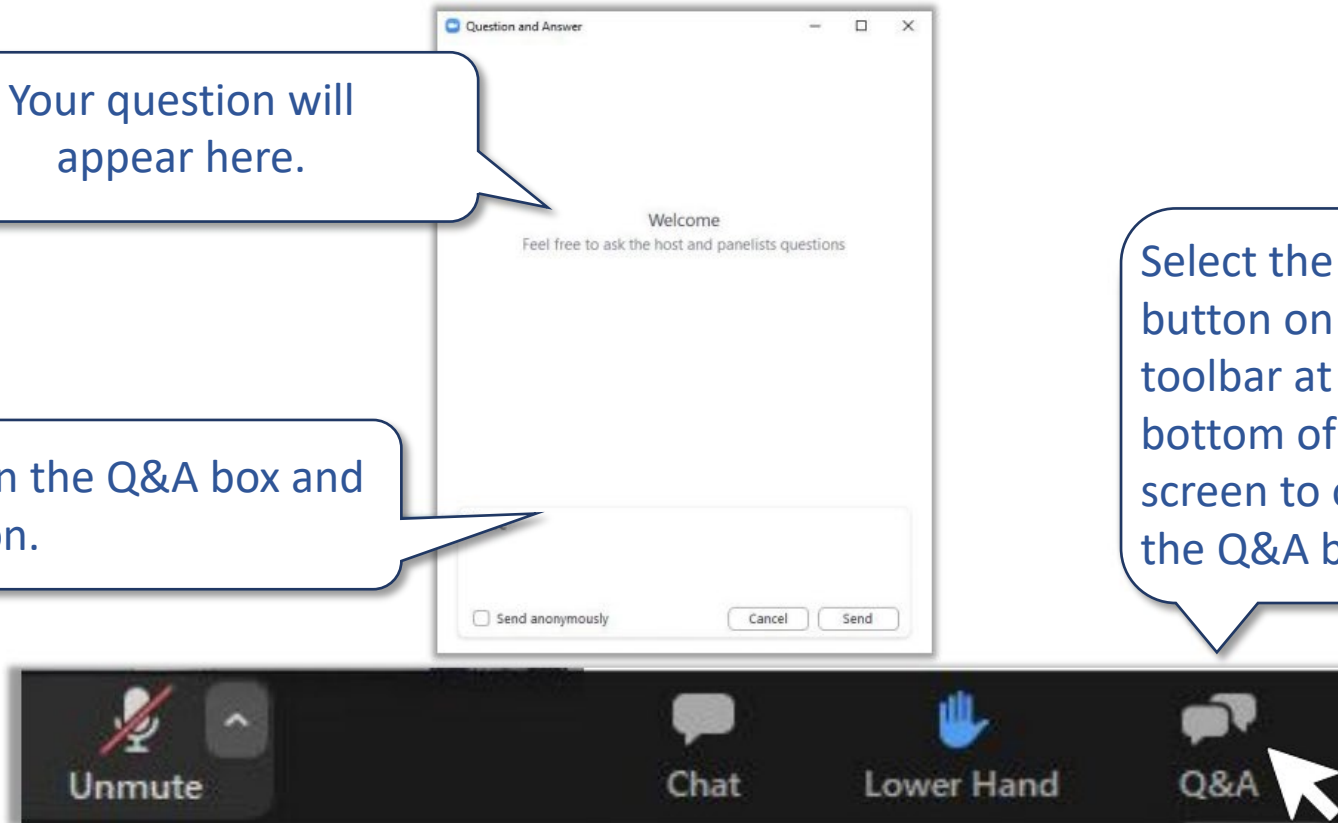
April 16, 2024

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Objectives and Agenda

Objectives:

- Provide overview of upcoming Part D changes that will be critical to PACE organization operations and payment in calendar year (CY) 2025
- Support PACE organizations in preparation for these changes

Agenda:

- Review Part D payment and benefit structure
- Review Inflation Reduction Act of 2022 (IRA) changes to the Part D benefit for CY 2025
- Key takeaways for PACE organizations
- Q&A
- Additional resources

Overview of 2024 Part D Benefit



There are **four coverage phases** in the Part D benefit. Payment responsibilities for enrollees and plan sponsors differ in each phase. During the calendar year, enrollees' progression through benefit phases depends on how much is spent for their drugs.

2024 Part D Payment Overview

- Medicare Part D payments are based on bids that Part D plan sponsors submit to CMS

- Enrollees pay a portion of costs through **their premiums**
- The government pays the remainder through the **direct subsidy**

The Part D **Low-Income Premium Subsidy** covers monthly premiums for dual-eligible PACE participants

- Part D plans receive separate payments from the government to cover:

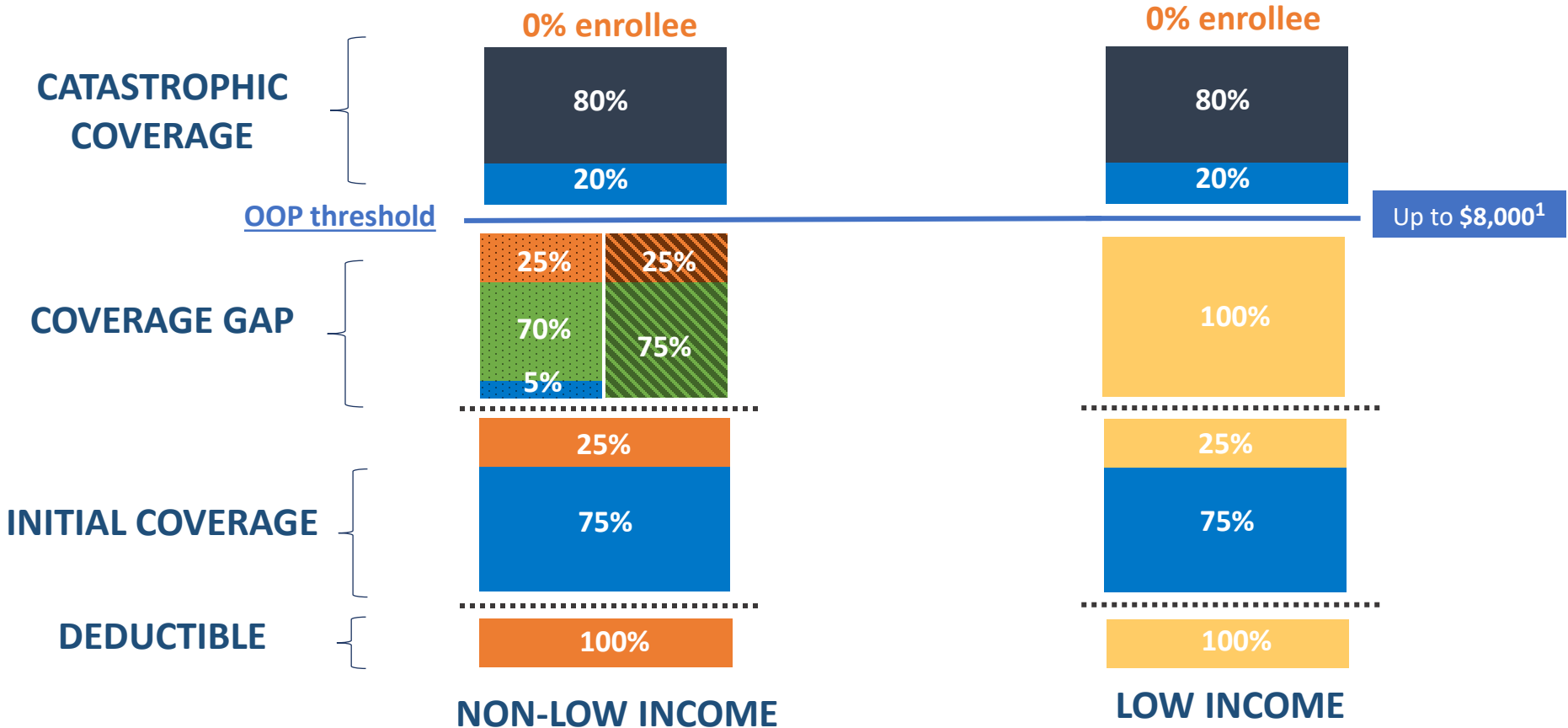
- Certain expenses for enrollees with high drug costs (**reinsurance**)
- Reduced out-of-pocket costs for low-income beneficiaries (**low-income cost sharing subsidy**)

- Part D plans also receive statutorily-mandated discounts from pharmaceutical manufacturers for brand drugs

The current Coverage Gap Discount Program **does not** apply to PACE, but the Manufacturer Discount Program effective 2025 **will** apply to PACE.

CMS also covers the **nominal cost sharing** due from non-institutionalized LIS beneficiaries by paying PACE organizations an **additional monthly capitated payment** equal to 2% of costs below the out-of-pocket threshold in an approved bid

Part D Standard Benefit – 2024



Legend:

- Enrollee (Orange circle)
- Part D Plan (Blue circle)
- Reinsurance (Government) (Dark Grey circle)
- Manufacturer discount (Manufacturers) (Green circle)
- LIS Subsidy (Government)² (Yellow circle)

Applicable Drugs: (Orange, Blue, Dark Grey, Green, Yellow circles)

Non-Applicable Drugs: (Orange with diagonal lines, Blue with diagonal lines, Dark Grey with diagonal lines, Green with diagonal lines, Yellow with diagonal lines)

¹: Out of pocket thresholds vary based on utilization

²: Beneficiaries of the Low-Income Subsidy (LIS) may still be responsible for nominal copayments

Medicare Coverage Gap Discount Program (CGDP) in 2024

2024

- The Affordable Care Act required manufacturers to provide **discounts on brand drugs in the coverage gap for enrollees who do not receive low-income subsidies**

- **CGDP does not apply to PACE organizations** because all PACE participants receive either the low-income subsidy or receive supplemental coverage that always brings cost sharing down to zero in the coverage gap, but the Manufacturer Discount Program effective 2025 will apply to PACE



True Out-of-Pocket Costs (TrOOP) in 2024

- TrOOP is the portion of spending on covered Part D drugs **made by the enrollee or on their behalf** by certain third parties
- **TrOOP costs include:**
 - Low-income cost sharing subsidies
 - Qualified State Pharmaceutical Assistance Programs
 - AIDS Drug Assistance Programs
 - Indian Health Service payments

Medicare Reinsurance Subsidy in 2024

- The Reinsurance Subsidy covers **80% of allowed drug costs** incurred in the catastrophic phase
- Sponsors estimate per-member-per-month cost for the Reinsurance Subsidy in their annual bid submissions
- CMS makes **monthly prospective reinsurance payments** to sponsors during the year based on their bid estimates
- 100% cost-based reconciliation: After the coverage year is over, CMS reconciles the prospective reinsurance payments with actual reinsurance amounts (as reported on PDEs), net of manufacturer rebates and other applicable Direct and Indirect Remuneration (DIR)



Low-Income Cost Sharing Subsidy in 2024

- The LIS benefit provides cost sharing assistance to certain low-income enrollees across the Part D coverage phases
- **Low-income cost sharing subsidies (LICS)** = cost-sharing assistance provided at the point of sale
- Throughout the year, CMS pays per-member-per-month LICS amounts based on estimate included in the bid
- After the year is over, CMS reconciles prospective LICS payments and actual LICS costs

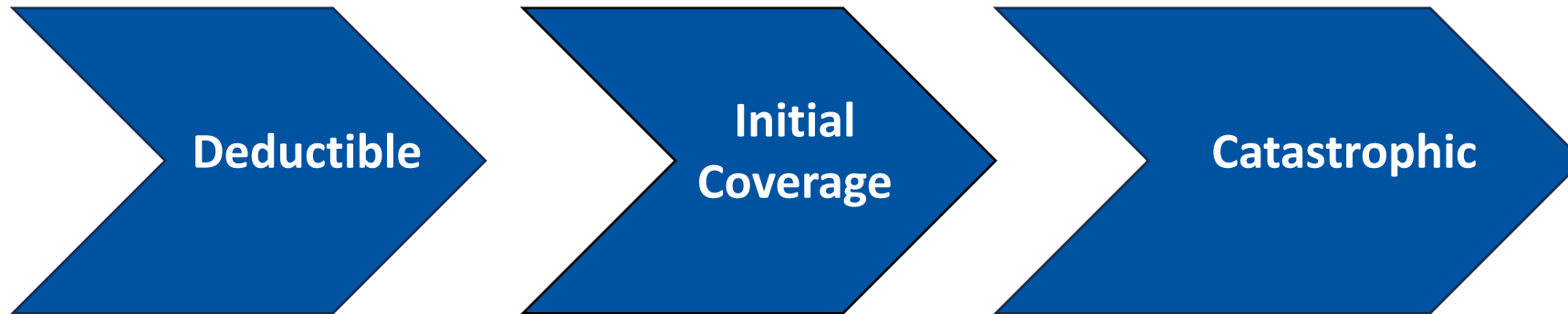
CMS also covers the **nominal cost sharing** due from non-institutionalized LIS enrollees by paying PACE organizations an **additional monthly capitated payment** equal to 2% of costs below the out-of-pocket threshold in an approved bid



Inflation Reduction Act

Changes to the 2025 Part D Benefit

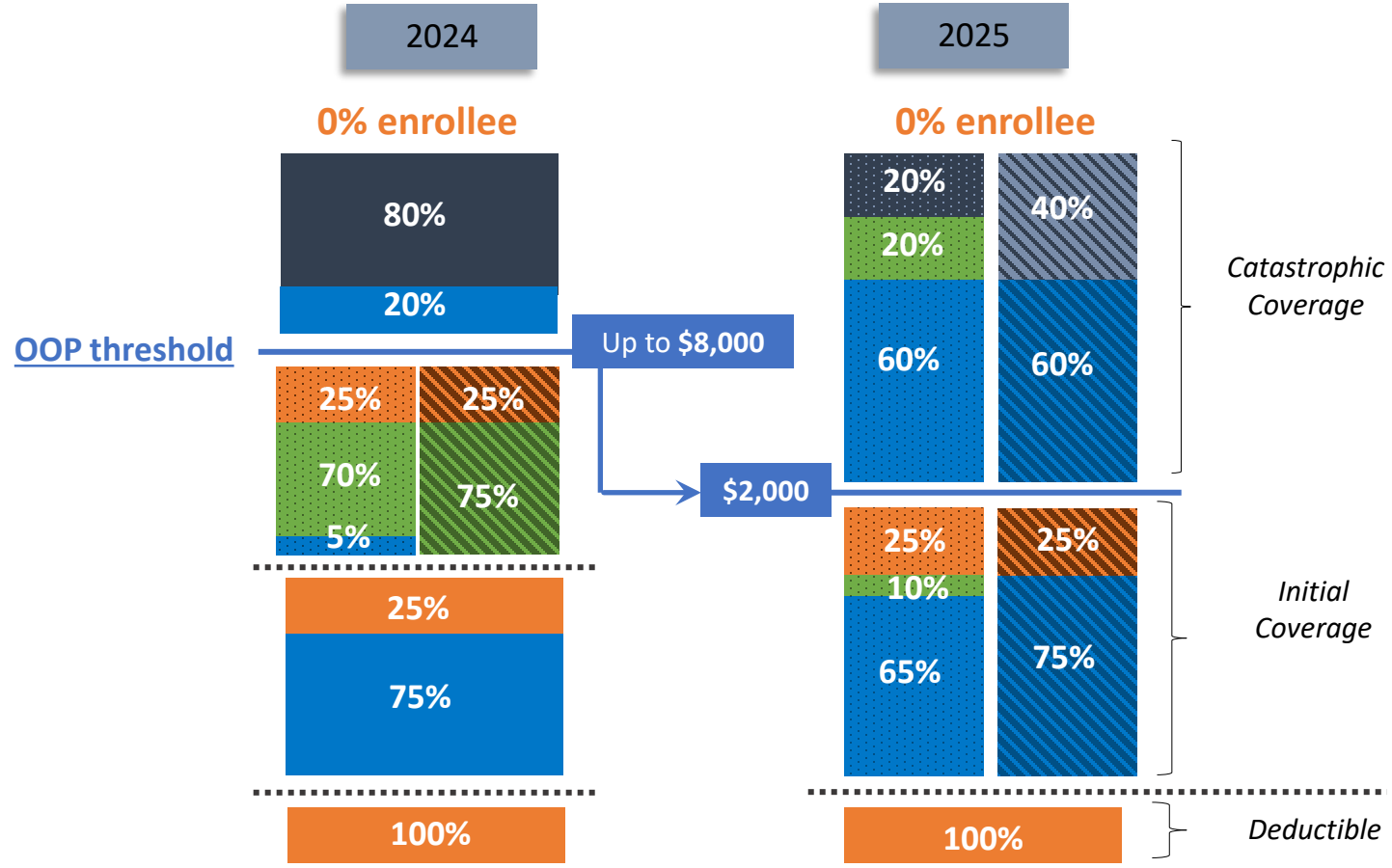
Overview of 2025 Part D Benefit



In 2025, the **Coverage Gap phase is eliminated** and the Part D benefit will consist of **three phases**.

Update to Standard Benefit Structure: Overview

2025



Legend:

- Enrollee (Orange circle)
- Part D Plan (Blue circle)
- Reinsurance (Government) (Dark Grey circle)
- Manufacturer discount (Manufacturers) (Green circle)

Applicable Drugs: (Orange, Blue, Dark Grey, Green circles)

Non-Applicable Drugs: (Orange, Blue, Dark Grey, Green circles with diagonal lines)

2025 Part D Benefit Redesign

- **Establishment of the Manufacturer Discount Program:** the Coverage Gap Discount Program is replaced with the Manufacturer Discount Program (Discount Program), which requires manufacturers to discount applicable drugs by 10% in the initial coverage phase and by 20% in the catastrophic phase.
 - The Discount Program applies regardless of whether the Part D enrollee is entitled to LIS
 - Manufacturer discounts are calculated *before* supplemental coverage is applied
 - Consequently, the Discount Program will apply to PACE organizations
- **Reduced annual out-of-pocket threshold for drug costs to \$2,000 in 2025**
 - Additionally, enrollee cost sharing is capped at \$35 per month's supply of a **covered insulin product** and eliminated for **adult vaccines** recommended by the Advisory Committee on Immunization Practices (ACIP)
- **Changes to the liability of enrollees, sponsors, manufacturers, and CMS**

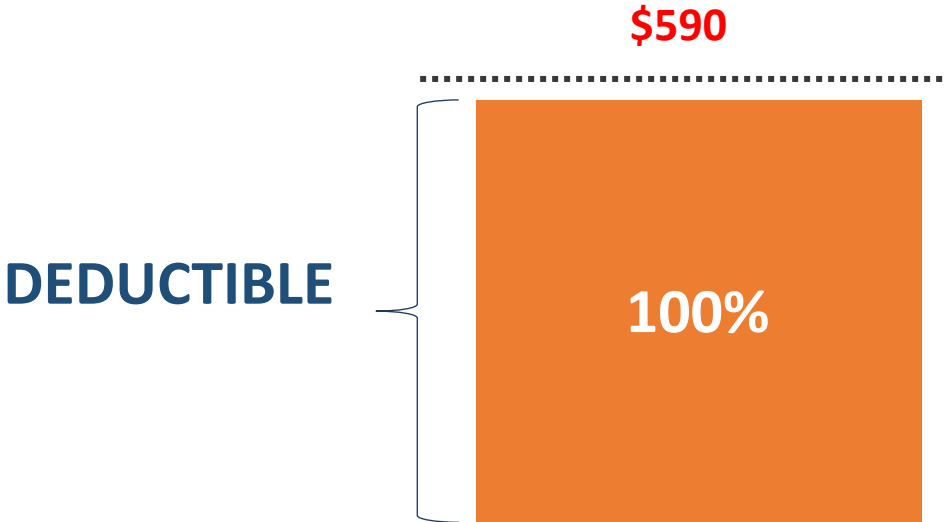
Note on Cost Sharing for PACE Participants

2025

- This overview of the 2025 defined standard Part D benefit includes changes to enrollee cost sharing liability
- PACE participants have **no** cost sharing liability in any phase of the Part D benefit
 - For dual-eligible PACE participants: cost sharing is largely covered by LICS
 - For Medicare-only PACE participants: cost-sharing is considered a non-covered plan paid amount
- It will still be important for PACE organizations to understand how participants progress through the phases of the defined standard benefit in order to submit accurate Prescription Drug Event (PDE) data

2025 Standard Benefit Structure: Deductible

2025



 Enrollee

- In the deductible phase, Part D enrollees will still pay 100% of their drug costs (up to \$590 in 2025)
- As of January 2023, the deductible does not apply to any Part D covered insulin products or any adult vaccine recommended by ACIP

All PACE participants have \$0 cost sharing and are not responsible for drug costs in the deductible phase.

2025 Standard Benefit Structure: Initial Coverage Phase

2025

INITIAL COVERAGE

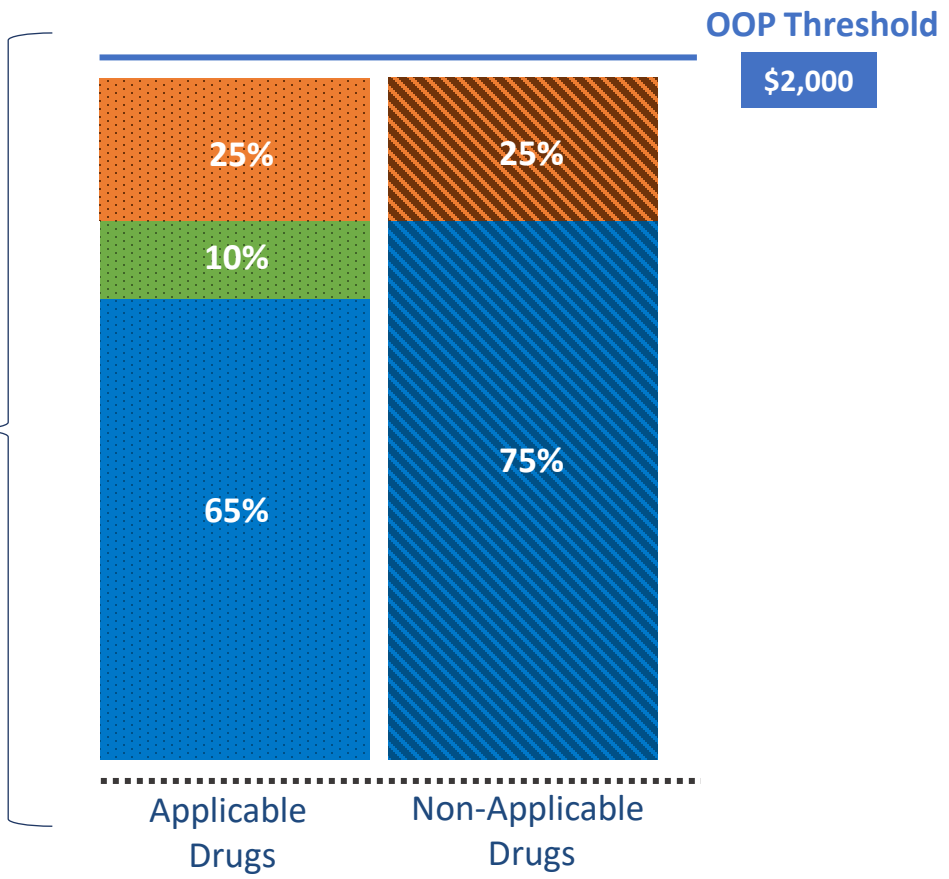
● Enrollee
● Part D Plan
● Manufacturer discount (Manufacturers)

Applicable Drugs:

● ● ●
● ● ●

Non-Applicable Drugs:

● ● ●
● ● ●



- In the initial coverage phase, Part D enrollees pay 25% of total drug costs
- Plan and manufacturer liability is different for brand versus generic drugs (“applicable” and “non-applicable”)¹
- For applicable drugs: the plan pays 65% and the manufacturer, through the Discount Program, pays 10%²
- For non-applicable drugs: the plan pays 75%

All PACE participants have \$0 cost sharing and are not responsible for drug costs in the initial coverage phase.

¹: Applicable drugs under the Discount Program are all Part D drugs approved under a new drug application or biologics license application, including biosimilar products licensed under section 351(k) of the Public Health Service Act, other than a selected drug dispensed during a price applicability period, even if a Part D sponsor treats the product as a generic under its benefits.

²: For certain drugs of qualifying drug manufacturers, the manufacturer discount is phased in over a multi-year period (2025 through 2031).

2025 Standard Benefit Structure: Catastrophic Coverage Phase

2025

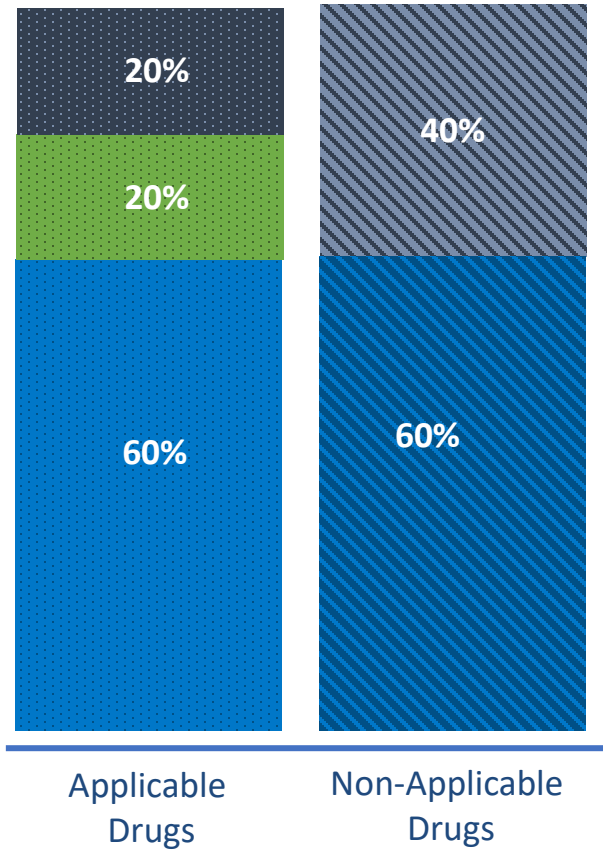
0% enrollee

CATASTROPHIC COVERAGE

Reinsurance (Government)
 Part D Plan
 Manufacturer discount (Manufacturers)

Applicable Drugs:

Non-Applicable Drugs:

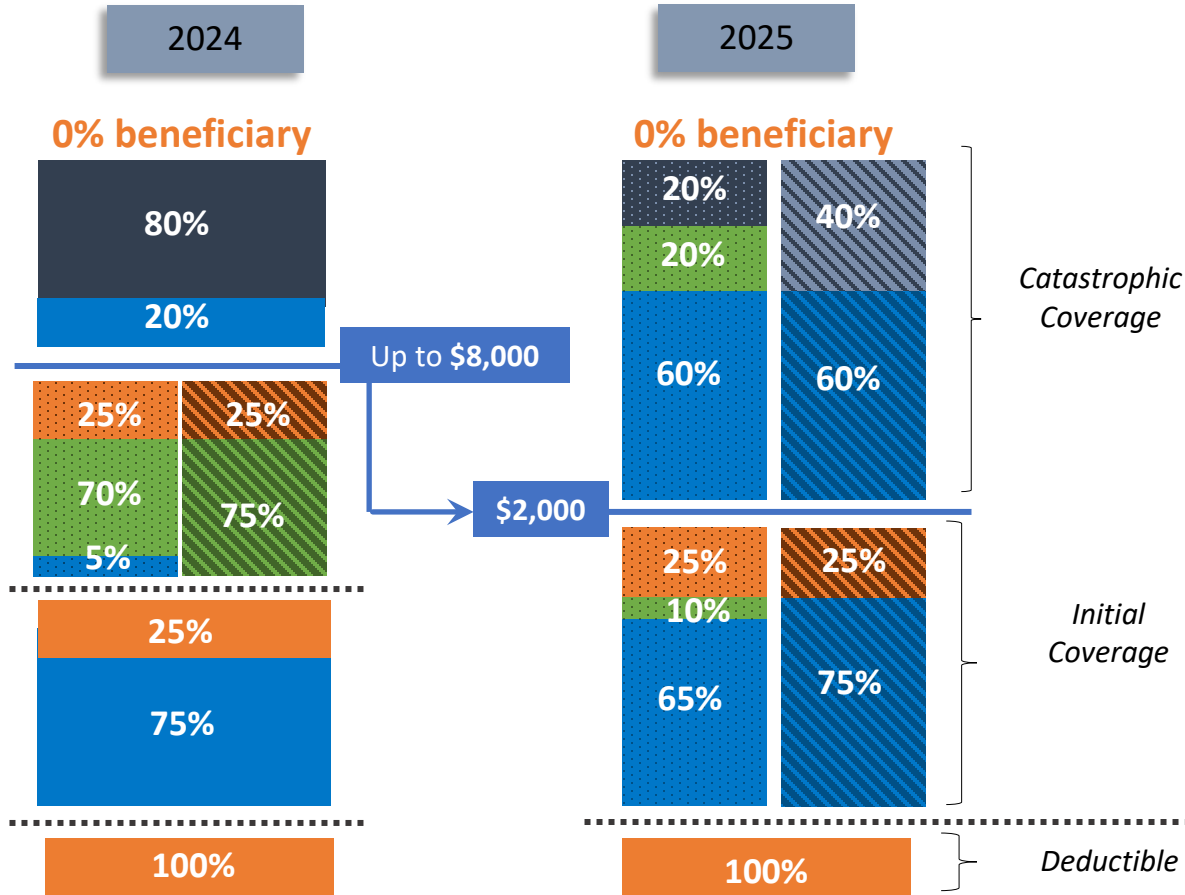


All PACE participants have \$0 cost sharing.

- Part D enrollees' out-of-pocket costs will be capped at \$2,000
- Plans are responsible for paying a higher share of costs in the catastrophic phase, while the government's share is reduced
- For applicable drugs: the plan pays 60%. The manufacturer, through the Discount Program, pays 20%. The government pays a reinsurance subsidy of 20%.
- For non-applicable drugs: the plan pays 60% and the government pays a reinsurance subsidy of 40%

Impact on Plan Liability under the 2025 Standard Benefit Structure

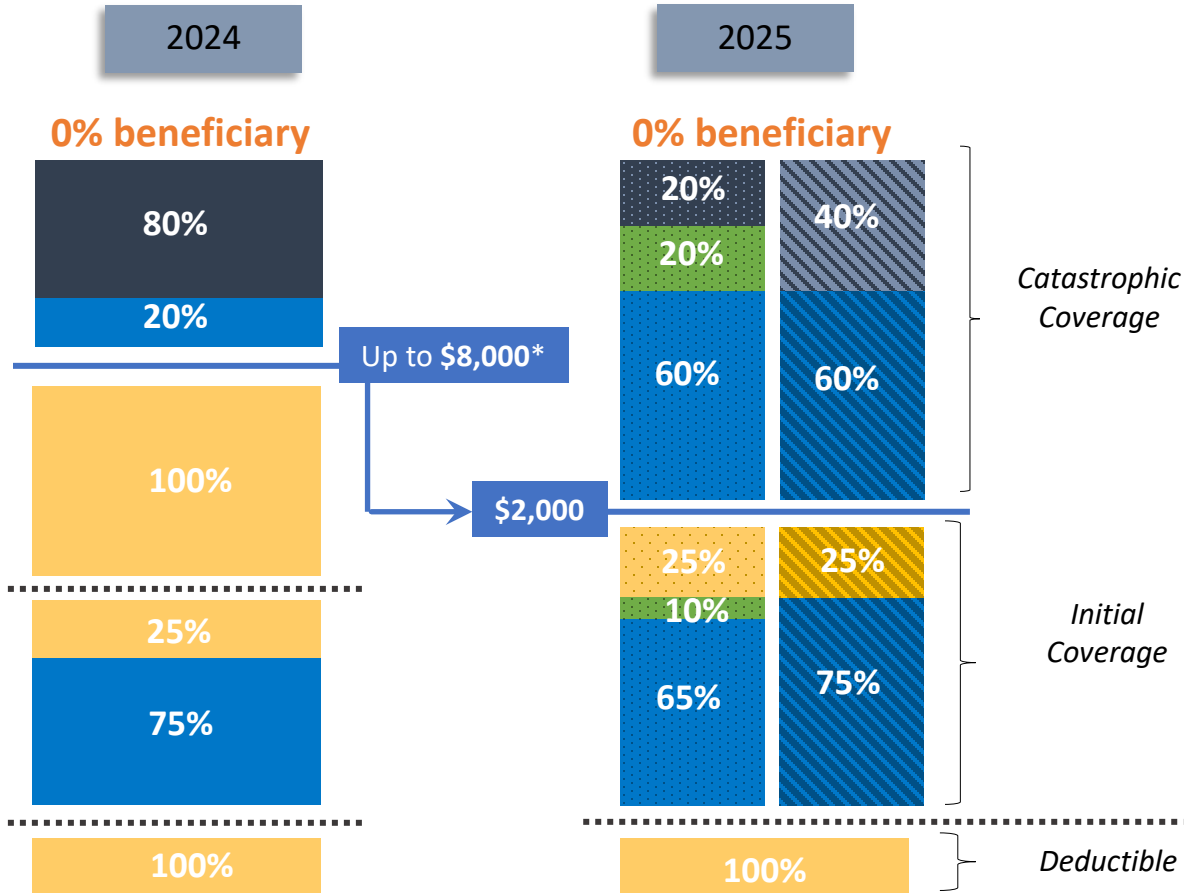
2025



- IRA changes to the Part D benefit increase plan liability, particularly in the catastrophic phase
- Lowering the out-of-pocket threshold is expected to result in **more enrollees reaching the catastrophic coverage phase** (where government reinsurance proportions are decreasing)
- The Discount Program covers a portion of costs for applicable drugs in the initial coverage and catastrophic phases

Impact on Plan Liability for Low-Income Enrollees in 2025

2025



- The elimination of the coverage gap phase results in an increase in plan liability for low-income enrollees that is **larger** than the increase in plan liability for non-low-income enrollees
- Previously, the low-income subsidy covered all costs during the coverage gap phase
- With the elimination of the coverage gap phase, drug costs previously covered by the low-income subsidy will largely shift to plan liability
- Under the Discount Program, plans will receive manufacturer discounts for low-income enrollees in the initial coverage and catastrophic phases

● LIS Subsidy (Government)
 ● Part D Plan
 ● Reinsurance (Government)
 ● Manufacturer discount (Manufacturers)
 Applicable Drugs: ● ● ● ●
 Non-Applicable Drugs: ● ● ● ●

Relevance for PACE Organizations

- While PACE organizations do not participate in the Coverage Gap Discount Program, the new Discount Program will apply to PACE
- Discount Program participation will require PACE organizations to report a significant amount of additional information on PDE records in 2025
 - **PACE organizations must understand and track participants' progress through the Part D benefit to estimate expected manufacturer discounts and report more granular payment information on PDEs**
 - **Accurate PDE reporting is critical for PACE organizations to receive correct and timely payment**

Relevance for PACE Organizations, continued

- PACE organizations will also need to prepare for additional requirements associated with Discount Program operations, including establishing a relationship with the Discount Program Third Party Administrator (TPA)
- High-level payment process:
 1. Part D sponsors receive prospective payments from CMS based on plan bids
 2. Part D sponsors front the manufacturer discounts when they pay pharmacies
 3. Part D sponsors report discounts to CMS via PDEs
 4. TPA sends quarterly invoices to manufacturers
 5. CMS offsets future prospective payment amounts by the amount invoiced
 6. Manufacturers pay Part D sponsors
- For certain drugs of qualifying drug manufacturers, the manufacturer discount is phased in over a multi-year period (2025 through 2031)

Next Steps

Stay tuned for additional training and technical assistance opportunities from CMS

- Specific operational 2025 PDE reporting guidance for PACE organizations expected around May 2024
- Certification (CERT) Testing for 2025 for PACE organizations planned to begin on September 1, 2024
- Additional operational guidance on the Manufacturer Discount Program will be forthcoming

Q&A

Additional Resources

- Guidance:
 - **PACE Participation in the Manufacturer Discount Program guidance, published January 26, 2024**, notes changes to PDE reporting required for the Discount Program (Access to this memo [here](#))
 - **Guidance on 2025 PDE Reporting Changes for PACE, published March 8, 2024**, details new fields and additional information PACE organizations must populate on PDEs submitted on and after January 1, 2025 (Access to this memo [here](#))
- Questions:
 - **Send general questions regarding the Discount Program to PartDManufacturerDiscountProgram@cms.hhs.gov**
 - **Send questions specifically regarding PACE payments and PDE reporting to PACEPartDPayment@cms.hhs.gov**