Part D Senior Savings Model Overview

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CMS Innovation Center

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Agenda

- Current State and Approach
- Model Design
- Application Process
- Question and Answer

Current State and Approach

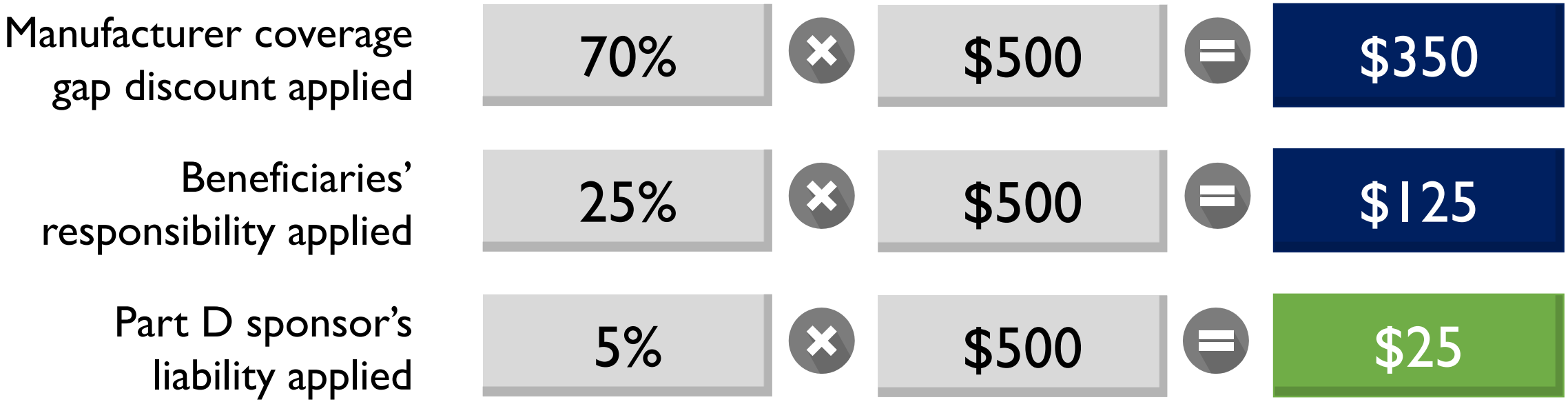
Manufacturer Coverage Gap Discount Program

Special Rule for Supplemental Benefits -1860D-14A(c)(2) of the Act and 42 C.F.R. § 423.2325(e)

"…where an applicable beneficiary has supplemental benefits with respect to applicable drugs under the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in, the applicable beneficiary shall not be provided a discounted price for an applicable drug under this section until after such supplemental benefits have been applied with respect to the applicable drug" - Social Security Act 1860D-14A(c)(2)

Example 1 – No gap supplemental benefits

Coverage gap payments for each prescription for an applicable drug with a $500 negotiated price and no supplemental benefits



Example 2 – Gap Supplemental Benefits

If a plan wanted to offer a reduced copay of $35 in the coverage gap under current law for the same $500 applicable drug per prescription

First, Part D sponsor's liability assumed	$500	−	$35	=	$465
*Second, m*anufacturer discount applied	70%	×	$35	=	$24.50
Remainder is paid by the enrollee	$500	−	($465+$24.50)	=	$10.50

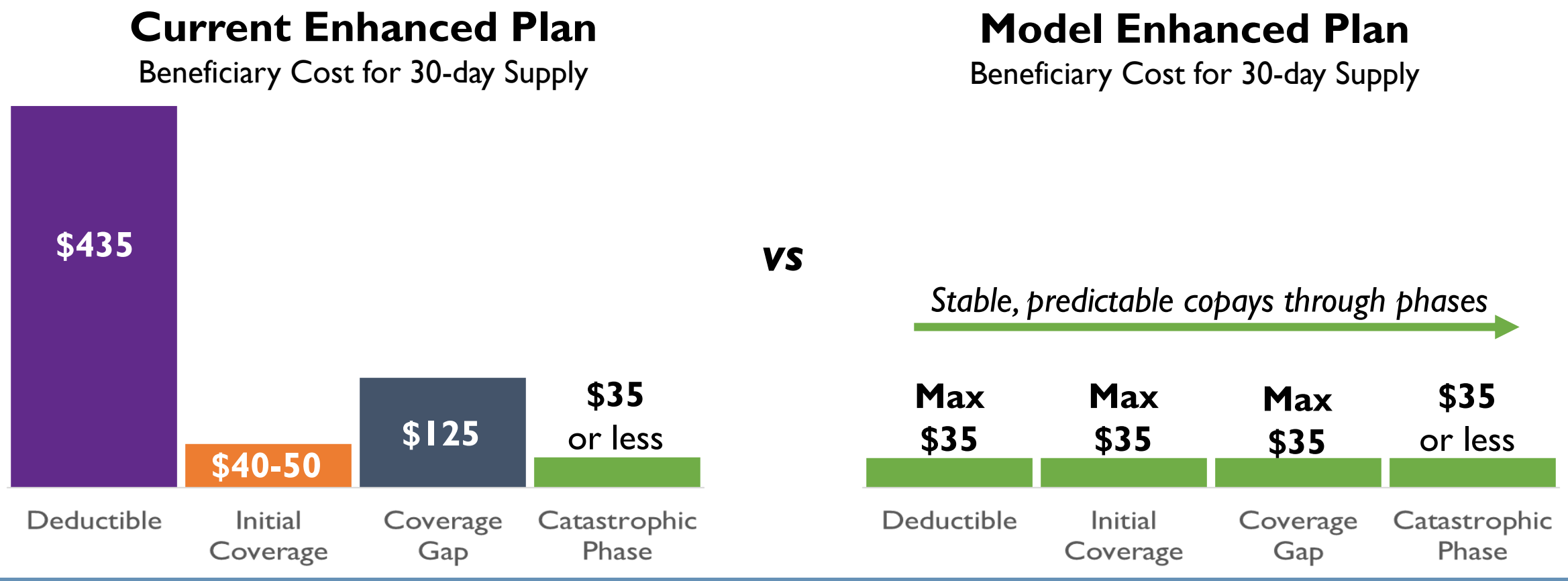
Model Design

Goal: Lower Out-of-Pocket Costs

Broad set of formulary insulins available at a stable, predictable $35 copay for a 30-days' supply in the deductible, initial coverage, and coverage gap phases

- Voluntary for eligible manufacturers, Part D sponsors, and beneficiaries for the 2021 plan year.
- Enhanced alternative standalone prescription drug plans (PDPs) and Medicare Advantage plans that offer prescription drug coverage (MA-PDs).
- Address the current coverage gap financial disincentive in the manufacturer coverage gap discount program.
- Applies to enrollees who do not qualify for the Part D low-income subsidy.
- Limited to applicable drugs that are, or contain, a drug classified as insulin, where the manufacturer participates and the Part D sponsor offers supplemental benefits for.

Insulin Costs for Beneficiaries



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Financial Impacts from the Model

CMS's initial projections, with specific modeling assumptions, show the following:

- Beneficiaries pay a stable, predictable copay of $35 for a 30-days' supply in the deductible, initial coverage, and coverage gap phases. **On average, out-of-pockets costs for insulin will decrease over 66 percent for beneficiaries that join a Model participating PBP.**
- Because beneficiaries will have additional claims in the coverage gap, manufacturers will pay the 70 percent coverage gap discount more times. Manufacturers should pay ~$250 million in additional coverage gap discounts over the course of the Model.
- Similarly, because beneficiaries have additional claims in the coverage gap, with manufacturers paying additional discounts, the federal government may pay ~$250 million less in federal reinsurance subsides over the course of the Model.
- There is a slight decrease in the basic premium and a ~$1 PMPM increase in supplemental premium due to additional plan liability from lowering out-of-pocket costs.

Voluntary Manufacturer Participation

- **Eligibility:** Pharmaceutical manufacturers that currently have a Medicare Coverage Gap Discount Program Agreement & label and market an applicable drug that is, or contains, a drug classified as insulin in American Hospital Formulary Service (AHFS) Drug Information or DRUGDEX Information System compendia.
- **Requirements:** Agree to include all marketed drugs that are, or contain, insulin and that meet the definition of covered Part D drug set forth in section 1860D-2(e) of the Act.

Eligible manufacturers may voluntarily participate and agree that any plan supplemental benefits apply after the 70 percent manufacturer discount is applied to the full negotiated price

Voluntary Plan Participation

- **Eligibility:** Enhanced alternative plan benefit packages (PBPs) offered either as standalone prescription drug plans or through Medicare Advantage plans that offer prescription drug coverage. Chronic condition and institutional special needs plans may also join.
- **Requirements:** Include at least one vial and pen dosage form for each of the different types of Model insulins, where available – rapid-acting, short-acting, intermediate-acting, and long-acting – at a maximum $35 copay for 30-days' supply, through the deductible, initial coverage, and coverage gap phases of the benefit at all pharmacy types (preferred and non-preferred) and locations (retail and mail).
- **Standard Coverage for All Formulary Insulins:** CMS strongly encourages Part D sponsors to follow the same coverage rules for all Model insulins offered on formulary

Voluntary Beneficiary Participation

- **Eligibility:** Beneficiaries may choose an enhanced alternative plan that is participating in the Model to benefit from a stable, predictable $35 copay.
- **Annual Enrollment Option:** Beneficiaries have a choice of plans to enroll in annually, generally during the Open Enrollment Period.
- **Medicare Plan Finder:** CMS intends to make information on Model-participating PBPs readily available to all beneficiaries on Medicare Plan Finder, through open enrollment communications, and by all other means that CMS deems necessary for beneficiaries to be able to enroll in participating plans. CMS will provide additional information in the coming months.

Through the Model, Manufacturers and Part D sponsors have the immediate opportunity to partner together to put patients before profits and lower out-of-pocket costs for insulin.

Narrower First Risk Corridor Threshold

Option to opt-in to be eligible for a 2.5% first risk corridor threshold

- **Opt-in:** This is optional for Part D sponsors and its participating PBPs.
- **Eligibility:** PBP has a greater number of insulin-dependent diabetics, relative to other similar PBP types (PDPs; MA-PDs; C-SNPs; I-SNPs), on at least one Model insulin.
- **Model Adoption**: This optional narrowing of the first risk corridor threshold provides the additional risk protection that allows broad Model adoption by Part D sponsors.

Part D Rewards and Incentives (RI) Programs

Permissible Part D RI program designs, with focus on promoting improved health outcomes, medication adherence, and the efficient use of health care resources:

- May be designed to target enrollees with pre-diabetes or diabetes who participate in a disease state management programs specific for pre-diabetes or diabetes.
- Provide RI for plan sponsor medication therapy management program participation, including review of all of an enrollee's medications & focus on pre-diabetes or diabetes.
- Provide RI for enrollees with pre-diabetes or diabetes who participate in preventive health services, such as receiving Part D covered vaccines
- Allow enrollees with pre-diabetes or diabetes to engage and better understand their Part D plan benefit, costs, and clinically-appropriate coverage alternatives

Quality and Performance Monitoring

Monitoring focus on changes to drug list price, beneficiary access, beneficiary enrollment and any potential impacts on affordability and adherence, including:

- Beneficiary experience and drug access
- Plan participant enrollment
- Prescription drug list price
- Direct and indirect remuneration and prescription drug net price
- Premiums
- Additional unintended consequences

Application Process

Application Process

Pharmaceutical manufacturers

will submit an executed contract addendum to the Manufacturer Coverage Gap Discount Agreement, for all NDCs for currently marketed Model insulins by each of the manufacturer's labeler codes.

CMS

will approve applications and execute the contract addendum for each approved applicant and the list of participating manufacturers and NDCs will be available on the Model website for Part D sponsors.

Part D Sponsors

will submit a non-binding letter of intent in April, followed by an application in May. Part D sponsors will finalize participation in the Part D bid process on June 1st.

Application Timeline

1 Pharmaceutical manufacturers apply

2 CMS confirms pharmaceutical manufacturer participation by publicly making list of participating manufacturers available via Model website

3 Initial Letter of Intent Submission for Part D Sponsors

4 Part D sponsors apply to the Model

5 Part D sponsors finalize Model participation through bid submission

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Thank you for joining.

CMS welcomes feedback and engagement from all stakeholders in working together to lower prescription drug costs.

Please engage directly with us by emailing us at PartDSavingsModel@cms.hhs.gov

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