

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid  
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Center for Medicare and Medicaid Innovation

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**DATE:** March 10, 2026

**TO:** All Part D Sponsors and Pharmaceutical Manufacturers

**FROM:** Nicholas Minter, Acting Director, Seamless Care Models Group  
Center for Medicare and Medicaid Innovation

**SUBJECT: Contract Year 2027 BALANCE Model Prescription Drug Event Reporting and Bid Submission Guidance**

CMS is providing information and clarifying guidance to Part D sponsors, including outlining the application provisional approval process, the Part D bid submission process, and providing Prescription Drug Event (PDE) reporting information for Part D sponsors that intend to submit an application to the BALANCE Model (model) for Calendar Year (CY) 2027.

**Part D sponsors must do the following to finalize participation in the model through their Part D bid submission, due by 11:59 PDT on June 1<sup>st</sup>, 2026:**

- Eligible Part D parent organizations seeking to participate in the model must submit their completed application and any supporting documents in Microsoft Excel Format by 11:59pm PDT on April 20<sup>th</sup>, 2026 to [BALANCEModel@cms.hhs.gov](mailto:BALANCEModel@cms.hhs.gov).
  - Applications must be submitted on behalf of the Part D parent organization.
  - The format for the application template in response to the CY 2027 Request for Application (RFA) to the BALANCE Model can be found on the model's CMS webpage [here](#).
  - CMS will notify all applicants if the participation threshold is met by April 30<sup>th</sup>, 2026. More information on the participation specifications can be found in the CY 2027 Part D RFA.
  - BALANCE Model provisional approval letters will be sent to applicants no later than May 18<sup>th</sup>, 2026.
  - Final model participation terms will be provided in the CY 2027 BALANCE Model Contract Addendum (CA) with CMS to participate in late 2026.
- Provisionally approved Part D sponsors must indicate participation by marking “Yes” to participating in BALANCE Model in the Set-up Plans section of HPMS. The navigation

path in HPMS is as follows: Plan Bids>Bid Submission> CY 2027 > Set-up Plans > Select applicable contract/plan ID > Answer “Yes” to the question “Is this plan participating in the BALANCE Model?”

- Eligible Part D sponsors must populate the participation indicator in the CY 2027 Part D Bid Pricing Tool (BPT). The input is located in “I. General Information”, Section 17 and is labeled “BAL-D.”
- Please note the contracts and PBPs included in both PBP and BPT must be consistent with the contracts and PBPs included in model’s provisional approval letter. If there are any updates after the provisional approval letter, including the addition of new contract(s) or PBPs, the Part D sponsor must ensure the modification request is shared with the model at [BALANCEModel@cms.hhs.gov](mailto:BALANCEModel@cms.hhs.gov) and incorporated in the bid no later than June 1<sup>st</sup>, 2026 at 11:59pm PDT.

### *2027 BALANCE Model Participation Specifications*

Applicants are encouraged to refer to information on the participation specifications for CY 2027 which can be found in the CY 2027 Part D RFA.

- Actuarially Equivalent (AE) and Basic Alternative (BA) Plans: During the initial coverage phase, patients pay no more than \$125 per 28-30 day supply for model drugs (Appendix C of the CY 2027 RFA) at in-network pharmacies. Sponsors may offer lower cost-sharing amounts; however, the reduced amount must apply for all model drugs, consistent with offering uniform cost-sharing.
- Enhanced Alternative (EA) and Employer Group Waiver Plans (EGWPs): During the initial coverage phase, patients pay no more than \$50 per 28-30 day supply for model drugs (Appendix C of the CY 2027 RFA) at in-network pharmacies. Sponsors may offer lower amount as long as the reduced copayment is uniform across all model drugs. EA plans must comply with tier cost-sharing requirements in federal law and consistent with the Medicare Prescription Drug Benefit Manual.
  - Weight management drug coverage through the model does not qualify as a supplemental benefit or satisfy EA coverage requirements.
- Defined Standard (DS) plans are not eligible to participate in the BALANCE Model.
- Certain Dual Eligible Special Needs Plans (D-SNPs) are eligible to participate in this model and are excluded from the reduced beneficiary cost-sharing requirements.
  - D-SNPs in the U.S. territories are eligible to participate in this model and must comply with the cost-sharing requirements based on their benefit design.
  - Defined Standard D-SNPs are not eligible to participate.
  - Additional details on LICS calculation and examples for LIS beneficiaries in D-SNPs will be forthcoming.
- Additional details on cost-sharing and coverage criteria are outlined in Section 2 of the CY 2027 RFA.

### *Payment Effectuation*

The price the participating manufacturer agrees to offer to all participating Part D plans net of all applicable discounts, rebates, and other price concessions for one month supply of an eligible model drug for CY 2027 is \$245. The net price (including discounts available through the Manufacturer Discount Program [MDP]) equals the prices specified in Appendix C of the CY 2027 RFA which includes the complete list of model drugs.

Under this framework, manufacturers would offer a rebate (i.e., via Direct and Indirect Remuneration (DIR)) to participating plans such that, after accounting for the MDP payments for applicable discounts, the net price of the drug would equal the price negotiated under the model plus a dispensing fee and sales tax (as applicable).

For model drugs that are selected drugs with maximum fair prices negotiated by CMS under the Negotiation Program, CMMI will waive the requirement, pursuant to section 1860D-2(d)(1)(D) of the Act, that the negotiated price of a selected drug must be no greater than the maximum fair price for such drug and any dispensing fee, such that the gross drug costs will be based on the wholesale acquisition cost (WAC). Plans will not receive a selected drug subsidy for model drugs; however, all model drugs will be subjected to the MDP.

Payment effectuation under the model will be facilitated through a new PDE field, titled "**Facilitated DIR**" (FAD). This field will be used to calculate manufacturer rebates owed by determining the difference between:

- The ingredient cost reported by the plan sponsor on the PDE, and
- The sum of the GLP-1 Discounted Price (see Appendix C in the CY 2027 RFA) plus the MDP amount.

Participating manufacturers will be invoiced quarterly through the existing Manufacturer Payment Portal used for MDP, via separate model-specific invoices. This new process will have no impact on existing MDP participation. Part D plans will **not** be required to report the rebate amount captured in the FAD field on the DIR Report for Payment Reconciliation. However, CMS will incorporate the FAD amount when calculating the annual Part D payment reconciliation. Participants should refer to the CY 2027 RFA for more information.

### **BALANCE Model PDE Reporting Guidance**

CMS is providing PDE reporting guidance to Part D sponsors participating in the BALANCE Model. This guidance is being issued to respond in anticipation to frequently asked questions from participating Part D sponsors. CMS continues to review additional questions not addressed in this document and further technical PDE guidance is forthcoming.

BALANCE-participating sponsors must ensure their PDE calculations and reporting properly account for model drugs dispensed to model-eligible beneficiaries. When a model drug is dispensed to a model-eligible beneficiary, BALANCE-participating sponsors shall continue to follow existing guidance regarding PDE calculation and reporting, with the amendments described in this memorandum. Please note that the included examples do not pertain to PDE reporting outside of the model and should not be relied upon by non-model PBPs.

### *BALANCE Model CY 2027 PDE Examples*

Part D sponsors participating in the BALANCE Model are expected to report PDEs for model drugs in the Initial Coverage Phase (ICP) and Catastrophic Phase of the Part D Benefit in accordance with otherwise applicable standard PDE reporting rules and requirements (with the exception of the Part D Model Indicator mentioned below). Specifically, plans reporting model drugs in the ICP should refer to examples in previously published PDE guidance demonstrating reporting rules for a copay benefit.<sup>1</sup>

PDE guidance for model drugs will differ from standard PDE reporting guidance when the beneficiary is in the Deductible Phase of the Part D Benefit. This is because a beneficiary can pay no more than the GLP-1 discounted price (\$245.00 for a one-month supply, Appendix A) plus the dispensing fee and sales tax (as applicable) on a single Part D claim. Part D sponsors will not be required to cover the difference between the GLP-1 discounted price plus the dispensing fee and sales tax and the remaining beneficiary deductible. It is expected that a rebate at the point of sale will be applied to facilitate deductible claims. Additional PDE guidance for model drug PDEs in the Deductible Phase is forthcoming.

All BALANCE Model PDEs must be submitted with a Part D Model Indicator equal to '02'. When the Drug Data Processing System (DDPS) receives and accepts a PDE with this model indicator, a FAD amount will be calculated by CMS and populated on the outbound PDE file returned to plans. This new outbound PDE field, FAD, will be calculated as the ingredient cost submitted on the PDE minus the Reported Manufacturer Discount amount<sup>2</sup> and the GLP-1 discounted price (\$245.00 for a one-month supply).<sup>3</sup>

Lastly, the rebates payable under the model will be adjusted downward by an amount not to exceed 5%, to account in part for the extent to which participating manufacturers will be paying

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<sup>1</sup> See the HPMS memorandum, *Prescription Drug Event Record Reporting Instructions for the Implementation of the Inflation Drug Act for Contract Year 2025*, published on April 15, 2024.

<sup>2</sup> PDEs for model drugs that would otherwise have been considered selected drugs, but for a plan's participation in the model, should not be reported with a Selected Drug Subsidy. Instead, these model drugs are subject to the Manufacturer Discount Program (MDP) and must be reported with a manufacturer discount amount when applicable.

<sup>3</sup> CMS will release forthcoming PDE guidance detailing how the FAD amount is calculated when rebates are applied at the POS in the Deductible Phase.

model-associated rebates on units purchased by covered entities participating in the 340B Drug Pricing Program at discounted prices.

To assist plans with cost estimates, CMS is providing summarized PDE examples for ICP and Catastrophic Phase claims. CMS will share additional technical guidance in the coming weeks. Please direct questions regarding this memo to [BALANCEModel@cms.hhs.gov](mailto:BALANCEModel@cms.hhs.gov).

### **Enhanced Alternative (EA) Plan or Employer Group Waiver Plan (EGWP)**

The participating plan places a model drug on a tier with a \$47.00 copay for a one-month supply (ingredient cost = \$499.00, dispensing fee = \$5.00) and a tier with a \$130.00 copay for a three-month supply (ingredient cost = \$1,497.00, dispensing fee = \$5.00).

#### *One-month supply*

ICP: The beneficiary pays \$47.00, the manufacturer discount is \$50.40 ( $\$504.00 * 0.10$ ) the Covered D Plan Paid Amount (CPP) is \$327.60 ( $\$504.00 * 0.65$ ), and the Non Covered Plan Paid Amount (NPP) is \$79.00 ( $\$504.00 - \$47.00 - \$50.40 - \$327.60$ ). CMS calculates the FAD amount as \$193.42 ( $0.95 * (\$499.00 - \$245.00 - \$50.40)$ ) and returns this amount to the plan on the outbound PDE file.

Catastrophic Phase: The beneficiary pays \$0.00, the manufacturer discount is \$100.80 ( $\$504.00 * 0.20$ ), CPP is \$403.20 ( $\$504.00 * 0.80$ ), and NPP is \$0.00 ( $\$504.00 - \$0.00 - \$100.80 - \$403.20$ ). CMS calculates the FAD amount as \$145.54 ( $0.95 * (\$499.00 - \$245.00 - \$100.80)$ ) and returns this amount to the plan on the outbound PDE file.

#### *Three-month supply*

ICP: The beneficiary pays \$130.00, the manufacturer discount is \$150.20 ( $\$1,502.00 * 0.10$ ), CPP is \$976.30 ( $\$1,502.00 * 0.65$ ), and NPP is \$245.50 ( $\$1,502.00 - \$130.00 - \$150.20 - \$976.30$ ). CMS calculates the FAD amount as \$581.21 ( $0.95 * (\$1,497.00 - \$735.00 - \$150.20)$ ) and returns this amount to the plan on the outbound PDE file.

Catastrophic Phase: The beneficiary pays \$0.00, the manufacturer discount is \$300.40 ( $\$1,502.00 * 0.20$ ), CPP is \$1,201.60 ( $\$1,502.00 * 0.80$ ), and NPP is \$0.00 ( $\$1,502.00 - \$0.00 - \$300.40 - \$1,201.60$ ). CMS calculates the FAD amount as \$438.52 ( $0.95 * (\$1,497.00 - \$735.00 - \$300.40)$ ) and returns this amount to the plan on the outbound PDE file.

### **Actuarially Equivalent (AE) Plan or Basic Alternative (BA) Plan**

In these examples, a participating plan places a model drug on a tier with a \$125.00 copay for a one-month supply (ingredient cost = \$499.00, dispensing fee = \$5.00) and a tier with a \$300.00 copay for a three-month supply (ingredient cost = \$1,497.00, dispensing fee = \$5.00).

One-month supply

ICP: The beneficiary pays \$125.00, the manufacturer discount is \$50.40 ( $\$504.00 * 0.10$ ) and CPP is \$328.60 ( $\$504.00 - \$125.00 - \$50.40$ ). CMS calculates the FAD amount as \$193.42 ( $0.95 * (\$499.00 - \$245.00 - \$50.40)$ ) and returns this amount to the plan on the outbound PDE file.

Catastrophic Phase: The beneficiary pays \$0.00, the manufacturer discount is \$100.80 ( $\$504.00 * 0.20$ ) and CPP is \$403.20 ( $\$504.00 * 0.80$ ). CMS calculates the FAD amount as \$145.54 ( $0.95 * (\$499.00 - \$245.00 - \$100.80)$ ) and returns this amount to the plan on the outbound PDE file.

Three-month supply

ICP: The beneficiary pays \$300.00, the manufacturer discount is \$150.20 ( $\$1,502.00 * 0.10$ ) and CPP is \$1,051.80 ( $\$1,502.00 - \$300.00 - \$150.20$ ). CMS calculates the FAD amount as \$581.21 ( $0.95 * (\$1,497.00 - \$735.00 - \$150.20)$ ) and returns this amount to the plan on the outbound PDE file.

Catastrophic Phase: The beneficiary pays \$0.00, the manufacturer discount is \$300.40 ( $\$1,502.00 * 0.20$ ) and CPP is \$1,201.60 ( $\$1,502.00 * 0.80$ ). CMS calculates the FAD amount as \$438.52 ( $0.95 * (\$1,497.00 - \$735.00 - \$300.40)$ ) and returns this amount to the plan on the outbound PDE file.

**Appendix A: 2027 BALANCE Model Drugs**

<b>Drug Manufacturer</b>	<b>GLP-1 Product</b>	<b>2027 List Price per Month Supply</b>	<b>Included Formulations</b>	<b>Included National Drug Code (NDC)s</b>	<b>Included RXCUIs</b>	<b>GLP-1 Discounted Price</b>
<b>Eli Lilly</b>	Zepbound®	\$499 (for 2.5mg, 5mg, 7.5mg)  \$699 (for 10, 12.5 and 15mg)	KwikPen® presentations	0002-3566-11 0002-3555-11 0002-3544-11 0002-3533-11 0002-3522-11 0002-3511-11	TBD	\$245 per month supply
	Mounjaro®	\$1112.16	All presentations	0002-1495-80 0002-1484-80 0002-1471-80 0002-1460-80 0002-1457-80 0002-1506-80	2601746 2601785 2601770 2601776 2601758 2601764	
	Orforglipron* <i>pending FDA approval</i>	TBD	Tablets	0002-4178-31 0002-4503-31 0002-4794-31 0002-4803-31 0002-4839-31 0002-4953-31	TBD	
<b>Novo Nordisk Inc.</b>	Ozempic®	\$675.00	All presentations	0169-4181-13	2619154	
				0169-4130-13	2398842	
				0169-4772-12	2599365	
	Rybelsus®	\$675.00	All presentations	0169-4314-30	2200650	
				0169-4303-30	2200654	
				0169-4307-30	2200658	
	Wegovy®	\$675.00	All presentations	0169-4415-31	2730161	
				0169-4404-31	2730167	
				0169-4409-31	2730169	
0169-4425-31				2730165		
00169-4525-14				2553506		
00169-4505-14				2553603		
00169-4501-14				2553803		
00169-4517-14				2553903		
00169-4524-14	2554104					
			00169-4572-14	TBD		