



Centers for Medicare & Medicaid Services  
Center for Medicare and Medicaid Innovation  
Seamless Care Models Group  
7500 Security Blvd  
Baltimore, MD 21244



**Better Approaches to Lifestyle and  
Nutrition for Comprehensive hEalth  
(BALANCE) Model**

Request for Applications  
Part D Plan Sponsors

Last Modified: March 2026

## Contents

<b>1. Background and General Information .....</b>	<b>3</b>
<b>1.1 Model Scope.....</b>	<b>3</b>
<b>1.2 Statutory Authority .....</b>	<b>4</b>
<b>1.3 Waiver Authority .....</b>	<b>5</b>
<b>1.4 Medicare Program and Payment Waivers .....</b>	<b>5</b>
<b>1.5 CMS-Sponsored Model Safe Harbor .....</b>	<b>6</b>
<b>2. Description of Model.....</b>	<b>7</b>
<b>2.1 Model Drug Eligibility and Manufacturer Participation .....</b>	<b>7</b>
<b>2.2 Medicare Part D Plan Sponsor Participation.....</b>	<b>7</b>
<b>2.3 Participation Specifications.....</b>	<b>13</b>
<b>2.4. Incentives for Plan Participation .....</b>	<b>15</b>
<b>2.5 Marketing and Communications .....</b>	<b>16</b>
<b>2.6 Changes to Model Design in Current or Future Model Years.....</b>	<b>16</b>
<b>3. Quality and Performance Monitoring .....</b>	<b>16</b>
<b>3.1 CMS Responsibility, Enrollee Protections and Oversight.....</b>	<b>16</b>
<b>4. Evaluation.....</b>	<b>17</b>
<b>5. Application.....</b>	<b>17</b>
<b>5.1 Application Process and Selection .....</b>	<b>17</b>
<b>5.2 Rights in Data and Intellectual Property .....</b>	<b>18</b>
<b>5.3 Submission of Information .....</b>	<b>18</b>
<b>5.4 Model Timeline.....</b>	<b>19</b>
<b>5.5 Withdrawal of Application.....</b>	<b>20</b>
<b>5.6 Amendment of RFA .....</b>	<b>20</b>
<b>Appendix A: Application Template.....</b>	<b>21</b>
<b>Appendix B: DEFINITIONS .....</b>	<b>22</b>
<b>Appendix C: Model Drugs for CY 2027 .....</b>	<b>23</b>
<b>Appendix D: Narrowed Risk Corridor Triggering Event Methodology .....</b>	<b>24</b>

## 1. Background and General Information

### 1.1 Model Scope

The Centers for Medicare & Medicaid Services (CMS), through the Center for Medicare & Medicaid Innovation (CMS Innovation Center), is seeking applications from eligible Medicare Part D plan sponsors<sup>1</sup> to participate in the Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth (BALANCE) Model (the model).

BALANCE is a voluntary model starting in January 2027 in Medicare Part D that tests whether CMS can preserve or enhance quality of care for beneficiaries while reducing or maintaining program spending by negotiating expanded coverage of medications for weight management paired with beneficiary access to healthy lifestyle supports.<sup>2</sup>

The model will test this approach by:

- Incentivizing coverage of GLP-1 medications<sup>3</sup> to improve metabolic health and weight management;
- Negotiating reduced net prices in Medicare for GLP-1 medications in order to lower program spending, through lower net expenditures on currently covered medically accepted indications (such as, type 2 diabetes and cardiovascular disease), or indirectly, mainly through reduced health care utilization; and
- Expanding access to evidence-based healthy lifestyle supports that promote prevention or improvement of cardiometabolic conditions.

Part D plan sponsors in all states and territories will be eligible to participate in the model if they meet the eligibility requirements outlined in Section 2.2. Participation is voluntary for eligible Part D sponsors. Participation will be on a Part D sponsor parent organization level, where Part D plan sponsors may elect to participate through qualifying plan benefit packages (PBPs) consistent with the requirements outlined in this request for applications (RFA).

The BALANCE Model performance period for Medicare Part D plans will begin January 1, 2027, and end December 31, 2031. Applying for the BALANCE model for Contract Year (CY) 2027 does not commit a Part D plan sponsor to participation in future years; Part D plan sponsors must apply to participate for each year of the model. This RFA describes model design elements, eligibility criteria, and additional requirements for Part D plan sponsors interested in participating in BALANCE in CY 2027.

---

<sup>1</sup> See [42 CFR 423.4](#) for definition of Part D plan sponsor.

<sup>2</sup> CMS will also be negotiating on behalf of state Medicaid agencies to expand coverage of medications for weight management in the Medicaid program.

<sup>3</sup> This document will use the terms “GLP-1” and “GLP-1 medications” to refer to medications containing glucagon-like peptide-1 receptor agonists, including liraglutide and semaglutide, as well as drugs containing tirzepatide, which is a dual GIP/GLP-1 receptor agonist.

**1.1.1 General Approach:** This model offers a unique opportunity for Part D plan sponsors to offer beneficiaries coverage of selected GLP-1 medications for weight management. By participating in the model, Part D plan sponsors will benefit from the CMS-negotiated terms with manufacturers,<sup>4</sup> including a set of model drugs, listed in Appendix C; net prices, listed in Appendix C; and coverage criteria, described in Section 2.2. By aligning coverage criteria and conditioning model launch on participation by a critical mass of Part D plan sponsors, as outlined in Section 2.3, CMS is creating an opportunity for Part D plan sponsors to offer this additional coverage to beneficiaries while mitigating concerns around adverse selection. Additionally, Part D plan sponsors may opt for a modified risk corridor associated with the model, described in Section 2.4.

All Part D plan sponsors who meet the eligibility requirements outlined in Section 2.2 are invited to submit an application. Part D plan sponsors can participate in the model by successfully submitting responses to the RFA, submitting bids consistent with participation in the model, and subsequently executing a Part D Contract Addendum (CA). The model will run for five calendar years, beginning January 1, 2027.

Quality and monitoring are central to the model. CMS will conduct oversight through monitoring activities to ensure compliance by all participants, reconciliation of financial and other outcomes, and a focus on quality-of-care preservation and enhancement. An independent contractor will conduct a robust model evaluation. From an operational and bid perspective, CMS will provide support by handling monitoring, reconciliation, and evaluation, reducing administrative burden for plans.

**1.1.2 Key deadlines** include the model start date of January 1, 2027; the Part D plan sponsor application deadline of April 20, 2026; and the target date of April 30, 2026, for CMS notification to plans of whether CMS will move forward with implementation of the BALANCE Model, as described in Section 2.3.1. Part D plan sponsors should review the full RFA, assess their interest in participating, prepare to execute a Part D CA with CMS, and monitor CMS communications regarding manufacturer agreements. The terms set forth in this RFA may differ from the terms set forth in the finalized CAs for the model.

## **1.2 Statutory Authority**

The authority for the model is section 1115A of the Social Security Act (the Act) (42 U.S.C. § 1315a, added by section 3021 of the Patient Protection and Affordable Care Act). Section 1115A of the Act authorizes CMS to test innovative healthcare payment and service delivery models

---

<sup>4</sup> These terms include the central parameters of the agreement negotiated with CMS, including pricing, rebate calculation and amounts, the duration of the agreement, data sharing arrangements, and any options or variations, that will form the basis for individual agreements between the manufacturer and participating States and Part D plan sponsors.

that have the potential to lower Medicare, Medicaid, and CHIP spending while maintaining or improving the quality of beneficiaries' care.

The CMS Innovation Center evaluates quality of care (including patient-level outcomes, patient satisfaction, and other patient-centeredness criteria) and changes in federal spending in each model. The Secretary of Health and Human Services (HHS) is authorized to expand the scope and duration of successful models, through rulemaking, that reduces spending without reducing quality of care, or that improves the quality of patient care without increasing spending.<sup>5</sup>

### **1.3 Waiver Authority**

Under section 1115A(d)(1) of the Act, the Department of Health and Human Services (the Department) may waive such requirements of Titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5) of such section) as may be necessary solely for purposes of carrying out section 1115A with respect to testing models described in section 1115A(b).

### **1.4 Medicare Program and Payment Waivers**

In support of this model, the Department is considering waiving certain requirements under Title XVIII of the Act and its implementing regulations for model participants for purposes of testing the model. The Department similarly intends to waive certain requirements under Title XVIII of the Act and its implementing regulations for new manufacturer applicants that join the model for the purpose of testing the model. No waivers of any kind are being issued in this document, which merely describes the waivers contemplated at this time for manufacturer applicants that join the model and Part D plan sponsor participants in the model.

Programmatic waivers under consideration are the following for participating Part D plans in the BALANCE Model for CY2027:

- Section 1860D-2(e) of the Act to the extent necessary to allow Part D coverage of statutorily excluded drugs, specifically agents when used for weight loss.
- Section 1860D-2(a)(3) of the Act; and 42 C.F.R. §§ 423.104(b)(2) and 423.265(c) to the extent necessary to permit Part D plan sponsors to offer model-specific cost-sharing on model drugs.
- 42 C.F.R. § 423.578(a) to the extent necessary to permit Part D plan sponsors to exclude from their tiering exceptions process any requests to apply model cost sharing for a drug for which model benefits are not offered, regardless of whether such drug meets the definition of model drug.

---

<sup>5</sup> Social Security Act § 1115A [42 U.S.C. § 1315a], "Center for Medicare and Medicaid Innovation."

- Section 1860D-11(b) of the Act, to the extent necessary solely to permit Part D plan sponsors to add model drugs during the plan year, consistent with existing Part D formulary requirements.
- Section 1860D-11(i) of the Act, to the extent necessary to work with drug manufacturers, pharmacies, and Part D plan sponsors as they negotiate within the bounds of the model to require a minimum pharmacy reimbursement on model drug fills, as described in Section 2.2.9.
- Section 1860D-4(a)(1) of the Act and 42 C.F.R. § 423.128 waived to the extent necessary for a Part D plan sponsor to comply with the model test design’s unique marketing requirements.
- Section 1860D-15(f) of the Act to the extent necessary to permit CMS to use Part D bid and payment data for purposes of conducting and evaluating the model.
- Section 1860D-2(d)(1)(D) of the Act to the extent necessary to require Part D plan sponsors to reimburse pharmacies for model drugs at a specified rate that exceeds the maximum fair price plus dispensing fee for the drug that was negotiated under the Medicare Drug Price Negotiation Program (“Negotiation Program”).
- Sections 1191 to 1198 of the Act (and additional waivers of Negotiation Program requirements such as program instructions) to the extent necessary to allow participating manufacturers to provide rebates associated with model pricing for model drugs dispensed to beneficiaries enrolled in model-participating plans in alternative to the maximum fair price requirements of the Negotiation Program.
- 42 CFR § 423.104(d)(2)(iii) to the extent necessary to permit participating basic plans to offer cost-sharing on model drugs of up to \$125 for the model, as described in Section 2.2, notwithstanding that such cost-sharing may otherwise be considered discriminatory based on annual CMS determinations.
- 42 CFR § 423.336, to the extent necessary to permit CMS to modify the established risk corridors as an incentive for participation in the model, acknowledging uncertainty in the plan bidding process.

Fraud or abuse waivers are not being issued in this document. Thus, notwithstanding any other provisions of this RFA, all individuals and entities must comply with all applicable laws and regulations, except as explicitly provided in such separately documented waiver issued pursuant to section 1115A(d)(1) specifically for the model, as may be amended from time to time (e.g., to reflect programmatic changes). Such waivers apply solely to the model and could differ in scope or design from waivers granted for other programs or models.

### **1.5 CMS-Sponsored Model Safe Harbor**

Participating manufacturers will be required to financially support an option for a defined scope lifestyle support platform at no cost to beneficiaries who receive treatment within the model or model participants.

To be eligible to qualify for protection under the “CMS-sponsored model” safe harbor at 42 CFR § 1001.952(ii), manufacturers must meet program requirements, as outlined in the Manufacturer Participation Agreement, as well as the regulatory requirements of 42 CFR § 1001.952(ii). The CMS-sponsored model safe harbors allow for certain remuneration to be provided in connection with a CMS-sponsored model, and in this case, eliminates the need for a separate and distinct fraud and abuse waiver. CMS may detail additional safeguards and reporting requirements regarding these activities in the Manufacturer Participation Agreement. Notwithstanding any other provisions of this RFA, all individuals and entities must comply with all applicable laws and regulations.

Please note that any safe harbor protections for activities in this model apply solely to the BALANCE Model and could differ in scope or design from waivers and safe harbor protections in other situations, including other programs or models.

## **2. Description of Model**

### **2.1 Model Drug Eligibility and Manufacturer Participation**

Eligible manufacturers for the initial negotiations were those manufacturers that market, or expect to market by January 1, 2027, an eligible product.

An eligible product must:

- a) have an active ingredient that has been approved by the Food and Drug Administration (FDA) for weight management (or products with the same active ingredient that have been previously approved for weight management or, have an active ingredient that is expected to be approved by the FDA for weight management by no later than January 1, 2027);
- b) be, or act as, a gastric inhibitory polypeptide (GIP) receptor agonist, glucagon-like peptide-1 (GLP-1) receptor agonist, glucagon receptor agonist, or in any combination; and
- c) have clinical evidence that, at an FDA-approved dose, the product reduces body weight by at least 9.5% on average according to the primary or secondary endpoint in a randomized clinical trial.

Eligible GLP-1 medications that met the criteria are defined in Appendix C (hereinafter “model drugs”). Participating manufacturers of these model drugs must offer the standard pricing to all participating Part D plan sponsors, as described in Appendix C with respect to CY 2027. Prices, model drugs, and other parameters may vary in future years.

### **2.2 Medicare Part D Plan Sponsor Participation**

Under the model, coverage of the model drugs would be provided as part of the basic benefit structure with established model cost sharing limits for beneficiaries that meet the eligibility criteria as described in this section. CMS is waiving the coverage exclusion for drugs used for

weight loss within the definition of a covered Part D drug at section 1860D-2(e)(2)(A) of the Act for participating plans.

The model test will provide coverage at the National Drug Code (NDC) level, applying certain cost-sharing thresholds to all indications, which includes currently covered medically accepted indications under Part D and weight management subject to the prior authorization criteria discussed in Section 2.2.5, with required coverage of all model drugs from all participating manufacturers for participating Part D plan sponsors.

**2.2.1 Eligible Plan Types:** Part D plan sponsors in all states and territories will be eligible to participate in the model, through certain PDPs and/or through Medicare Advantage (MA) coordinated care plans (i.e., HMO, HMOPOS, and Local and Regional PPO plans) that offer prescription drug coverage (MA-PD plans), including certain Special Needs Plans (SNPs) and all employer/union group waiver plans (EGWPs) that offer Part D coverage. Part D plan sponsors that apply and are approved to participate in the model will be required to provide model drugs to every eligible beneficiary (including Low Income Subsidy (LIS) beneficiaries) in alignment with the negotiated cost-sharing terms.

Plans with defined standard benefit type, Private fee-for-service plans, section 1876 cost contract plans, section 1833 health care prepayment plans, Program of All-inclusive Care for the Elderly (PACE) organizations, Limited Income Newly Eligible Transition (LI NET), fallback plans, and religious fraternal benefit plans will not be eligible to participate.

**Dual Special Needs Plans (D-SNPs):** D-SNPs, other than Defined Standard D-SNPs, are eligible to participate in this model. Eligible D-SNPs are not subject to the reduced cost-sharing requirements in Table 1, except for eligible D-SNPs in the U.S. territories, which are subject to the reduced cost-sharing requirements in Table 1.

**Defined Standard (DS) Plans:** DS plans are not eligible to participate in the BALANCE Model, as they cannot provide reduced cost-sharing for model beneficiaries and maintain their status as a DS plan. Part D plan sponsors may choose to convert DS plans to Basic Alternative (BA) or Actuarially Equivalent (AE) benefit types for 2027 in order to meet the requirements for parent-organization level participation, as described further in Section 2.3.

**2.2.2 Cost Sharing Requirements on Model Drugs:** For CY 2027, participating Part D plan sponsors must meet the following cost-sharing thresholds for plan benefit packages that they choose to include in the model. Cost sharing thresholds vary by benefit type in the initial coverage phase as outlined below. Cost sharing in subsequent years will be subject to the annual renegotiation process.

Table 1. Phases of the Part D Benefit specific to BALANCE

Phases of the Part D Benefit	Deductible Phase	Initial Coverage Phase	Catastrophic Phase
<b>Beneficiary Cost Sharing</b>	Participating plans should ensure that beneficiaries pay no more than \$245 plus a dispensing fee for a 28-day or 30-day fill of a model drug in the deductible phase.	Once true out-of-pocket (TrOOP)-eligible costs exceed the annual plan defined deductible, the participating plan will be required to offer model drugs at or below the agreed-upon beneficiary cost-sharing threshold for eligible beneficiaries, as described below.	Standard catastrophic phase rules apply, such that during this period, the beneficiary will pay \$0 for covered model drugs.

**Enhanced Alternative (EA) and EGWPs:** Participating Part D plan sponsors must ensure that no covered patient in an participating EA plan or EGWP, while in the initial coverage phase of the Part D benefit, pays more than \$50 per 28- or 30-day supply in total out-of-pocket costs (including co-pay, co-insurance, or other direct costs) to receive any model drug listed in Appendix C from an in-network pharmacy.

A participating Part D plan sponsor may choose to further enhance its benefit with a lower amount than \$50 for all model drugs, as this amount serves as a maximum for model-participating plan benefit packages (PBPs). However, the reduced amount must apply for all model drugs, consistent with offering uniform cost sharing.

Participating EA plans must comply with the tier cost sharing requirements in federal law and consistent with the Medicare Prescription Drug Benefit Manual. Coverage of drugs for weight management through the model does not meet the definition of a supplemental benefit and therefore will not satisfy EA coverage requirements.

**AE and BA Plans:** Participating Part D plan sponsors must ensure that no covered patient in an AE or BA plan, while in the initial coverage phase of the Part D benefit, pays more than \$125 per 28- or 30-day supply in total out-of-pocket costs to receive any model drug listed in Appendix C from an in-network pharmacy. A participating Part D plan sponsor may choose to decrease the co-payment to lower than \$125, as this amount serves as a maximum for model-PBPs. However, the reduced amount must apply for all model drugs, consistent with offering uniform cost sharing.

CMMI will waive the provision that outlines tiered cost sharing for non-defined standard benefit designs may not exceed levels annually determined by CMS, specifically for model drugs.

**In Network Cost Sharing:** For CY 2027, participating Part D plan sponsors must offer a cost-sharing no greater than the applicable maximums, described above, at all in-network pharmacy types (preferred and non-preferred) and locations (retail and mail) for all model drugs where offered, as specified in the participating PBP.

**Out-of-Network Cost Sharing:** Model drugs will be subject to the out of network (OON) cost sharing consistent with the requirements of the Part D program rather than the cost sharing thresholds described in Table 1.

**2.2.3 Dosages and Day Supply:** Model drugs are generally dispensed in either (a) a pack that is a 28-day supply that contains four doses, for injectable products such as some forms of Wegovy<sup>®</sup> and Zepbound<sup>®</sup> or (b) a 30-day monthly supply for orally administered model drugs, such as some forms of Wegovy<sup>®</sup> and, pending FDA approval, orforglipron. However, 60- or 90-day fills are available for eligible model drugs furnished for eligible beneficiaries as long as they comply with the cost sharing maximums (which are described above in terms of cost per 28- or 30-day fill but would be scaled as appropriate to determine cost-sharing maximums for extended day fills). Daily cost sharing may also be permissible for eligible beneficiaries.

Dose escalation consistent with FDA-approved labeling will be permitted, including fills of different strengths within the same month. Standard refill-too-soon logic will be applied to refills of the same strength. When a dose is reduced or adjusted due to documented intolerance or clinical necessity, a refill-too-soon override consistent with Part D practices will be allowed to avoid interruption in therapy, provided applicable prior authorization requirements are met. The standard cost sharing maximums depending on the plan benefit type will apply to each fill, including fills dispensed for a dose adjustment.

**2.2.4 Formulary and Tier Placement:** Participating plans must cover all model drugs for all enrolled, eligible Medicare Part D beneficiaries, in compliance with the following requirements:

- All model drugs must be placed on the same Part D formulary tier within the PBP;
- All model drugs must be offered at a uniform cost sharing amount;
- Model drugs must not be disadvantaged relative to other model drugs in terms of the coverage criteria applied, provided however that variations in coverage criteria across model drugs that correspond to differences in the FDA-approved labels for model drugs shall not be considered disadvantaging;
- The prior authorization criteria applied must be: (i) no more burdensome than the criteria listed in Section 2.2.5; (ii) without step therapy that is more burdensome than the applicable model drug's FDA-approved label; and (iii) for FDA-approved indications only.

Part D formulary requirements must still be met, and Part D plan sponsors must provide formulary exceptions where applicable at the approved cost sharing for the designated formulary exceptions tier(s). Therefore, if an enrollee is granted access to a non-formulary drug through the formulary exceptions process, Part D plan sponsors are not required to offer the model cost sharing. Part D plan sponsors are not required to offer a tiering exception to the copay for model drugs for one month's-supply for any model drug or non-model drug.

All current CMS program regulations and guidance apply, including maintaining all current Part D formulary, tier, and utilization management requirements, except as otherwise waived for purposes of testing this model. In addition, mid-year formulary changes to model drugs (i.e., formulary additions, formulary change requests, requests for utilization management updates, etc.) will be reviewed in accordance with existing Part D requirements. Part D bid pricing tool submissions for participants must reflect the coverage of model drugs via the BALANCE Model indicator. CMS will release additional guidance on bidding for participating Part D plans.

**2.2.5 Coverage Standards:** The Prior Authorization (PA) criteria for the model shall be as follows:

Provider attestation that the patient: (a) has type 2 diabetes, or (b) has noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis), or (c) has obstructive sleep apnea (OSA), or (d) is currently on and will continue lifestyle modification (as clinically appropriate)<sup>6</sup> and one or more of the following:

- (i) The patient is at least eighteen (18) years of age and has a Body Mass Index ("BMI") greater than or equal to thirty-five ( $\geq 35$ ) at the time of initiation of therapy, or
- (ii) The patient is at least eighteen (18) years of age and has a BMI greater than or equal to thirty ( $\geq 30$ ) at the time of initiation of therapy with a diagnosis of one or more of the following (a) to (e): (a) heart failure with preserved ejection fraction, (b) uncontrolled hypertension (defined as systolic blood pressure above 140 mm Hg or diastolic blood pressure above 90mm Hg, despite concurrent treatment with two antihypertensive medications), (c) chronic kidney disease stage 3a or above, (d) moderate or severe obstructive sleep apnea (defined as apnea-hypopnea index  $>15$  without central or mixed sleep apnea), or (e) noncirrhotic MASH with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis)<sup>7</sup>, or

---

<sup>6</sup> The lifestyle modification in the physician attestation need not be the specific lifestyle program offered by participating manufacturers as discussed in Section 2.2.6. CMS will defer to the provider's discretion to approve the use of lifestyle support as clinically appropriate.

<sup>7</sup> F2/F3 stage will be confirmed using one guideline-supported test, including: Fib-4, Ultrasound, ELF, Fibroscan, MRE/MRI, or Fibrosure.

- (iii) The patient is at least eighteen (18) years of age and has a BMI greater than or equal to twenty-seven ( $\geq 27$ ) at the time of initiation of therapy with a diagnosis of one or more of the following (a) to (d): (a) pre-diabetes (as defined by American Diabetes Association guidelines), (b) previous myocardial infarction, (c) previous stroke, or (d) symptomatic peripheral artery disease.

Part D plan sponsors shall aim to implement the prior authorization criteria in a way that minimizes health care provider and enrollee burden. To the extent feasible, and to minimize health care provider and enrollee burden, Part D plan sponsors shall attempt to confirm the applicable patient's prior authorization via automated review of such patient's health or medical records to determine whether the records contain an ICD-10 code matching the coverage criteria. (an "Auto-Lookback"). If the Auto-Lookback fails to confirm the diagnosis via ICD-10 code or is not applied, then the Part D plan sponsor must accept an appropriate health care professional's (including prescriber, nurse practitioner, or physician's assistant) attestation of any diagnosis as set forth in this section.

**2.2.6 Lifestyle Support Program:** Participating manufacturers will provide access at no cost to Part D plan sponsors or beneficiaries a lifestyle support program that empowers patients to reach health goals through educational materials, health and lifestyle coaching, and recommendations for exercise and diet modification. Part D plan sponsors may choose to inform beneficiaries of this available resource. CMS expects to revisit lifestyle support requirements annually based on model performance and available program supports and may, at that time, consider shifting responsibility to states and MA-PD plans.

**2.2.7 Payment Effectuation:** Model drugs and their discounted prices available to covered patients are set forth in Appendix C (subject to adjustments per Section 2.2.8). The "GLP-1 discounted price" means the price the participating manufacturer agrees to offer to all participating Part D plans net of all applicable discounts, rebates, and other price concessions. The net price (including discounts available through the Manufacturer Discount Program) equals the prices specified in Appendix C.

Under this framework, participating manufacturers would offer a rebate (i.e., via Direct and Indirect Remuneration (DIR)) to participating plans such that, after accounting for the Manufacturer Discount Program (MDP) payments for applicable discounts, the net price of the model 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 manufacturer discount program (MDP).

Payment effectuation under the model will be facilitated via a new PDE field. This field will be titled “Facilitated DIR” (FAD) and will be used to help calculate the amount of manufacturer rebates owed by calculating the difference between the ingredient cost reported by the plan sponsor on the PDE and the sum of GLP-1 Discounted Price (see Appendix C) plus the MDP amount. Participating manufacturers will be invoiced quarterly for these amounts through the existing Manufacturer Payment Portal used for MDP, with separate model-specific invoices. This new process will not affect existing MDP participation. Part D plans will not be required to report the rebate amount reported in the FAD field on the DIR Report for Payment Reconciliation, though CMS will incorporate the FAD amount when calculating the annual Part D payment reconciliation.

The FAD field provides increased visibility to help ensure plans comply with established price guidance and protects beneficiary and physician data privacy when invoicing manufacturers.

**2.2.8 340B Adjustment:** The rebates payable under the model, to be effectuated by the process described in section 2.2.7, 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 model-associated rebates on units purchased by covered entities participating in the 340B Drug Pricing Program at discounted prices. CMS will provide additional information to participating plans on the adjustment of invoices to reflect the 340B adjustment.

**2.2.9 Pharmacy Reimbursement:** Participating Part D plans will agree to reimburse pharmacies at no less than the WAC plus sales tax and a dispensing fee determined by the participating plan for each claim dispensed under the model for an eligible beneficiary at an in-network pharmacy. Given that Part D plans have separate agreements with OON pharmacies such that reimbursement for OON network pharmacies differs from reimbursement for in-network pharmacies, CMS will not have a mandatory reimbursement requirement for out-of-network pharmacies.

### **2.3 Participation Specifications**

Participation will be at a parent organization level (determined via parent organization ID as indicated on HPMS). To voluntarily participate in the model, a parent organization will be required to apply and participate with respect to all of its enhanced alternative plans. In addition, a parent organization will be required to apply and include in the model 90% of beneficiary enrollment in the organization’s basic plans (DS/BA/AE plans), excluding ineligible plan types (private fee-for-service plans, section 1876 cost contract plans, section 1833 health care prepayment plans, Program of All-inclusive Care for the Elderly (PACE) organizations, Limited Income Newly Eligible Transition (LI NET), fallback plans, and religious fraternal benefit plans)

with the exception of DS plans (which are not eligible to participate but could convert to AE or BA status in order to participate in the model).

Parent organizations electing to convert DS plans to eligible benefit types can indicate the proposed crosswalk via the application template in Appendix A. Plans should project 2027 enrollment on the basis of February 2026 plan reported enrollment, with appropriate adjustments to account for relevant changes in 2027.

To participate in the model, a parent organization is encouraged to, but not required to, apply and participate with respect to its EGWPs. EGWPs can participate in the model on a PBP level as long as their Part D parent organization is participating in the BALANCE Model. PBPs approved to participate in the BALANCE Model will need to indicate in the Health Plan Management System (HPMS) their participation in the model.

**2.3.1 Participation Threshold:** To address concerns of adverse selection, CMS will only move forward with implementation of the BALANCE Model with respect to Medicare if a critical mass of Part D plan sponsors opt to participate.

CMS will calculate the projected participation rate by dividing two numbers:

- (1) the number of beneficiaries enrolled in Part D plans **applying to participate in the model** that are included in the calculation of the National Average Monthly Bid Amount (NAMBA) (that is, all eligible plan types, plus Defined Standard plans, but excluding special needs plans and EGWPs), estimated based on February 2026 enrollment and making appropriate adjustments to project for CY 2027 enrollment.
- (2) the number of beneficiaries enrolled in **all** Part D plans that are included in the calculation of the NAMBA, estimated based on February 2026 enrollment and making appropriate adjustments to project for CY 2027 enrollment.

If this resulting quotient is below 80%, CMS will not move forward with implementation of the BALANCE Model in 2027 in Medicare. CMS will notify all participating manufacturers and plan sponsors as soon as practicable, with a target date of April 30, 2026.

Because of the importance of applications in determining the threshold, CMS expects that any Part D parent organization that applies to participate in the model will participate in the model if approved. A Part D plan sponsor's participation in the model is contingent upon its execution of an approved contract to participate in the Part D program for CY 2027 and a model-specific CA establishing a Part D plan sponsor's obligations for participation in the model for CY 2027. Respondents to the RFA must denote currently sanctioned plans in their application response.

## 2.4. Incentives for Plan Participation

CMS seeks broad Part D plan sponsor participation in this model and thus is considering several incentives to encourage participation.

**2.4.1 Optional Narrowed First Risk Corridor Threshold:** On the application, all participating Part D plan sponsors, with the exception of EGWPs, will have the option to indicate, on a parent organization level, whether they want to be eligible for a 2.5 percent, instead of 5 percent, first upper and lower thresholds for the risk corridor. Please see Appendix D for additional details regarding the eligibility requirements and the structure of the narrowed risk corridors.

CMMI will identify all eligible participating plans (excluding EGWPs) and confirm which plans have chosen the option to be potentially eligible for the narrowed first threshold risk corridor via HPMS. All beneficiaries enrolled in these plans in December of the CY will be identified, and those with at least one prescription drug event (PDE) for a model drug during the CY will be flagged as model drug utilizers. A plan-level utilization rate is calculated by dividing the number of beneficiaries with model drug PDEs by the total number of beneficiaries enrolled during the CY for each plan. The average and standard deviation of these utilization rates are calculated separately for each plan type among eligible model plans that have opted to be eligible for the modified risk corridor. Participating plans that opted in and have utilization rates exceeding one standard deviation above their plan type's mean are deemed eligible for the narrowed risk corridor.

For those model-participating plans that have opted to be eligible for the modified risk corridor and meet the one standard deviation or greater proportion of model drug utilizers, the first risk corridor threshold will begin at +/- 2.5 percent of the target amount instead of the +/-5 percent under current law today. All risk percentages between CMS and Part D plan sponsors—that is 50 percent risk for both CMS and Part D plan sponsors in between the first and second risk corridor threshold, and 80 percent CMS risk and 20 percent Part D plan sponsor risk beyond the second risk corridor—remain the same. CMS will calculate which participating plans will receive a narrower first risk corridor threshold in the months following a completed plan year, with the aim to make those results available to participating Part D plan sponsors in July following the plan year.

Similar to the Part D Senior Savings Model, participating plans would have the option to opt in for the narrowed risk corridors on an annual basis for the first two years of the model. CMMI will determine extending the incentive beyond the initial two years of the model after assessing results.

**2.4.2 Future Incentives:** CMS may explore, for future years of the model, a payment adjustment factor (PAF) that would be incorporated into the direct subsidy payment calculation for participating plans by adding the PAF to the beneficiary risk score. CMS would include adjustments to the beneficiary risk score in participating plan bids. CMS continues to explore options regarding development of the model in future years and welcomes input from interested Part D plan sponsors. CMS may condition eligibility for certain future incentives on participation in the model in CY 2027 and/or continuous participation beginning in a Part D plan sponsor's first eligible model year.

## **2.5 Marketing and Communications**

CMS will share marketing and communications guidance on the model with participating Part D plan sponsors regarding their plan documents in the summer preceding the contract year.

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 on this in the coming months.

## **2.6 Changes to Model Design in Current or Future Model Years**

CMS retains the right to modify any model policy or parameter on an annual basis, or more frequently, in accordance with procedures to be agreed upon in the relevant participation agreements and CAs. CMS retains the right to terminate the model in accordance with provisions to be established in the forthcoming CA.

A participating part D plan sponsor may voluntarily terminate its CA and participation in the model, subject to terms that will be outlined in the CA.

## **3. Quality and Performance Monitoring**

As part of both model implementation and evaluation, CMS will monitor the impact of the model on costs and quality. Specifically, CMS will monitor the model's impact on beneficiary access to model drugs, beneficiary access to other types of care relevant to model drugs, beneficiary health outcomes, beneficiary experience, and any potential impacts on affordability and adherence due to the model. This information will be used to monitor and evaluate the performance of the model.

### **3.1 CMS Responsibility, Enrollee Protections and Oversight**

CMS' responsibilities with regards to Part D plan sponsors will be specified in the CAs with Part D plan sponsors. At a minimum, CMS will be responsible for compiling, monitoring, and analyzing data necessary to support the model, including utilization data, claims data, and patient reported measures. Sources of data utilized by CMS may include but are not limited to PDE data and plan-reported data.

CMS will conduct regular monitoring to review model participant compliance with the terms of the model, particularly related to beneficiary quality of care. CMS will monitor for compliance using existing data sources to the extent practicable and may seek additional information from model participants, particularly in the event that CMS receives a high number of complaints or other indicators of poor performance. CMS expects all model participants to cooperate to the fullest extent possible in requests for relevant data and information. CMS will closely monitor model implementation to ensure that performance is consistent with model parameters. CMS will also monitor the impact the model has on other CMS initiatives.

CMS reserves the right to investigate a model participant if there is evidence that indicates that participation in the model is adversely impacting enrollee quality of care or failure to provide required information and exercise all available remedies in appropriate instances, including potential termination from the model.

#### **4. Evaluation**

CMS will use an independent contractor to conduct an evaluation of the model, which will examine the model's implementation and assess the model's impact on Medicare and Medicaid program spending and the quality of care. All model participants, including participating Part D plan sponsors, will be required to participate in any evaluation activities if requested. CMS anticipates primarily relying on the data sources also utilized in adjudicating rebates in the evaluation of the model.

In certain situations, participating Part D plan sponsors will be required to cooperate with primary data collection activities, which may include participation in surveys, interviews, and other activities that CMS determines necessary to conduct a comprehensive formative and summation evaluation. When the evaluation uses non-publicly available data, CMS will report results at an aggregate-level to avoid the disclosure of private and sensitive data of specific model participants.

#### **5. Application**

##### **5.1 Application Process and Selection**

Through this RFA, CMS is soliciting applications from eligible Part D plan sponsors to participate in the model. The application process and selection for the model are non-competitive. A Part D plan sponsor's participation in the model is contingent upon its execution of an approved contract to participate in the Part D program for CY 2027.

Participation in the model is at the parent organization level. At the time of the application, parent organizations will need to specify the PBPs to be included in the model. As part of the application process, applicants will provide the parent organization information, including Part D plan sponsor contract number, PBP number(s), as well as names, titles, and contact information

as well as a proposed crosswalk to 2027 enrollment by PBP to support the calculation of the participation threshold.

Part D plan sponsor applicants will attest that by applying, they agree to be part of the model for the specific PBP(s) they indicate for participation. Part D plan sponsor applicants will submit to CMS, by 11:59 p.m. PDT on April 20, 2026, the proposed contract(s), PBP(s), and segments included in the model via instructions found on the model's website.

CMS will confirm eligibility for the contracts and PBP(s) that Part D plan sponsors submit. Once confirmed, Part D plan sponsors will indicate their intended participation in the model in HPMS by 11:59 p.m. PDT on June 1, 2026. In addition, as part of the Part D bid, Part D plan sponsor model applicants with participating EGWPs will attest their participation via HPMS.

CMS will formally obligate participants to the terms of the model for CY 2027 via a model-specific supplemental CA to their CY 2027 agreement with CMS for participation in Part D. That CA will incorporate the requirements of the model, as well as any policy documents issued by CMS to govern the model test. CMS expects to finalize and execute the CAs in September 2026, concurrently with the signing of other Part D contract documents.

Participating Part D plan sponsors will execute a CA that will include terms and conditions that vary from standard Part D requirements, and these terms and conditions will include, but are not limited to, the following:

- Applicability of specific program and payment waivers of statutory or regulatory requirements, and any limitations to such program and payment waivers; and
- Requirements for participation in CMS monitoring and evaluation activities.

Any fraud and abuse waivers will be issued separately.

## **5.2 Rights in Data and Intellectual Property**

CMS may use any data obtained pursuant to the model to evaluate the model and to disseminate quantitative results to model participants and to the public. Data to be disseminated may include savings information, results of beneficiary experience of care and quality of life surveys, as well as measures based upon claims. Model participants will be permitted to comment on evaluation reports for factual accuracy, where appropriate, but may not edit conclusions or control the dissemination of reports.

## **5.3 Submission of Information**

Information required by CMS in response to this RFA regarding the parameters of model participation is included in Appendix A. While Appendix A includes the minimum information required per this RFA, model applicants may, at their discretion, include additional information they wish to present to CMS.

#### 5.4 Model Timeline

A summary of the model's timeline is provided below:

<b>Date</b>	<b>Milestone</b>
March 9, 2026	CMS releases Request for Applications (RFA) for Part D Parent Organizations
April 20, 2026	Deadline for Part D Parent Organizations to apply (at 11:59 pm PDT)
April 30, 2026	Target date for notification of Part D Participation Threshold in Model
May 18, 2026	Conditional Approvals are sent to Part D Parent Organizations
June 1, 2026	Part D bid deadline for CY 2027. Part D plan sponsor's bid reflects its intended participation in the Model
September 2026	CY 2027 Model Contract Addendum executed BALANCE Model Part D Participants Announced
January 1, 2027	Plan year begins

## **5.5 Withdrawal of Application**

Given the participation threshold, described in Section 2.5, which is calculated based on applications received from plans, CMS expects that Part D plan sponsors applying to participate will not withdraw applications, barring unforeseen circumstances. A completed application expresses an intent to participate in the BALANCE Model, and CMS discourages Part D plan sponsors from withdrawing applications.

Part D plan sponsor applicants seeking to withdraw an entire application or modify the scope of a pending application must send their requests prior to conditional approvals for participation in the model. Any withdrawal requests should be submitted by May 11<sup>th</sup>, 2026, and include a written request on the Part D plan sponsor's letterhead that is signed by the primary point of contact named in the application submission.

The following information must be included in the letter:

- Legal Name of the Parent Organization
- Address
- Point of Contact information, including the person and their title named in the application
- Description of the Nature of the Withdrawal (e.g., Withdrawal of entire application or change in scope of a pending application)
- Justification for Withdrawal

To submit a request to withdraw participation, the Part D plan sponsor must send the request in a PDF format by email to [BalanceModel@cms.hhs.gov](mailto:BalanceModel@cms.hhs.gov).

## **5.6 Amendment of RFA**

CMS may modify the terms of the model or cancel it entirely in response to stakeholder comments or other factors. Questions regarding the model or application process may be sent by email to [BalanceModel@cms.hhs.gov](mailto:BalanceModel@cms.hhs.gov). While CMS will not attribute any question to its author, CMS may publicly share responses to questions on the CMS Innovation Center website to ensure that all applicants have access to clarifying information regarding the model and the application process.

## **Appendix A: Application Template**

CMS will safeguard the information provided in submitted applications in accordance with the Privacy Act of 1974, as amended (5 U.S.C. § 552a).

CMS provides no opinion on the legality of any contractual or financial arrangement that the applicant may disclose, propose, or document in this application. The receipt by CMS of any such information during the application process or otherwise shall not be construed as a waiver or modification of any applicable laws, rules, or regulations, and will not preclude CMS, the Department of Health and Human Services (HHS), the HHS Office of Inspector General, a law enforcement agency, or any other federal or state agency from enforcing any and all applicable laws, rules, and regulations.

***Part D parent organizations seeking to participate in the model must submit the completed application template 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) with the proposed subject Line: “Parent Organization Name” BALANCE Model Application***

***Applications must be submitted by the Part D parent organization.*** While the application template includes the minimum information required per this RFA, model applicants may, at their discretion, include additional information they wish to present to CMS. Questions about the application for the model should be directed to [BalanceModel@cms.hhs.gov](mailto:BalanceModel@cms.hhs.gov).

## Appendix B: DEFINITIONS

“**Drug Manufacturer**” or “**Manufacturer**” means pharmaceutical manufacturers of eligible GLP-1s under BALANCE Model.

“**GLP-1 Product**” means all eligible formulations of semaglutide, tirzepatide, and orforglipron as specified in Appendix C. Additional products may be added as GLP-1 Products subject to this Agreement upon the mutual agreement of the Parties, who agree to engage in good faith discussions and not unreasonably withhold, condition, or delay such agreement.

“**National Drug Code**” or “**NDC**” means the 11-digit numerical code maintained by the FDA that includes the labeler code, product code, and package code. A set of NDCs with the same 9-digit labeler and product code are referred to as an “**NDC-9**”.

“**RXCUIs**” means the RxNorm Concept Unique Identifiers (RxCUIs) which are unique, machine-readable numbers assigned by the National Library of Medicine to normalized drug names, including active ingredients, strengths, and dosage forms.

“**GLP-1 Discounted Price**” means the price the participating manufacturer agrees to offer to all participating Part D plan sponsors net of all applicable discounts, rebates, and other price concessions.

**Appendix C: Model Drugs for CY 2027**

<b>Drug Manufacturer</b>	<b>GLP-1 Product</b>	<b>Included Formulations</b>	<b>Included National Drug Code (NDC)s</b>	<b>Included RXCUIs</b>	<b>GLP-1 Net Price</b>
<b>Eli Lilly</b>	Zepbound®	KwikPen® presentations	0002-3566-11	TBD	\$245 per month supply
			0002-3555-11		
			0002-3544-11		
			0002-3533-11		
			0002-3522-11		
	0002-3511-11				
	Mounjaro®	All presentations	0002-1495-80	2601746	
			0002-1484-80	2601785	
			0002-1471-80	2601770	
0002-1460-80			2601776		
0002-1457-80			2601758		
0002-1506-80	2601764				
Orforglipron* <i>pending FDA approval</i>	Tablets	0002-4178-31	TBD		
		0002-4503-31			
		0002-4794-31			
		0002-4803-31			
		0002-4839-31			
0002-4953-31					
<b>Novo Nordisk Inc.</b>	Ozempic®	All presentations	0169-4181-13	2619154	
			0169-4130-13	2398842	
			0169-4772-12	2599365	
	Rybelsus®	All presentations	0169-4314-30	2200650	
			0169-4303-30	2200654	
			0169-4307-30	2200658	
	Wegovy®	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				

## Appendix D: Narrowed Risk Corridor Triggering Event Methodology

Participating parent organizations may elect whether they want all of their eligible Plan Benefit Packages (PBPs) in the BALANCE Model to be potentially eligible for a narrowed first risk corridor threshold at the time of application. Eligibility for this enhanced risk protection is determined by a triggering event based on model drug utilization patterns and EGWP status (as EGWPs are not eligible for the narrowed risk corridor). A participating PBP in the model can qualify for the narrowed risk corridor if its plan-level model drug utilization rate exceeds one standard deviation above the mean for its plan type among all eligible participating plans that have opted for the narrowed risk corridor. This eligibility determination is independent of the total number of plans participating in the BALANCE Model. The narrowed risk corridor option provides additional financial protection for PBPs with higher-than-average enrollment of beneficiaries utilizing model drugs.

### CY2027 Risk Corridor Structure

#### Standard Part D Risk Corridor:

Cost Variance	Plan Responsibility	CMS Responsibility
±0-5%	100%	0%
±5-10%	50%	50%
±10% and beyond	20%	80%

#### Narrowed Risk Corridor under BALANCE (for eligible plans who meet the triggering event):

Cost Variance	Plan Responsibility	CMS Responsibility
±0-2.5%	100%	0%
±2.5-10%	50%	50%
±10% and beyond	20%	80%

### Triggering Event Definition

For purposes of the BALANCE Model, the triggering event is defined as utilization of model drugs that exceeds the threshold specified in the eligibility criteria above. This provision applies to all participating Part D sponsor organizations that opt in to the narrowed risk corridor option for their eligible PBPs. Employer Group Waiver Plans (EGWPs) are excluded from this option.

### Methodology

#### 1. Identify and categorize all Model-eligible plans opting into the narrowed risk corridor

- CMMI would generate a list of model eligible plans in each contract year. Each plan will be identified and categorized as either a C-SNP, I-SNP, D-SNP, MA-PD or PDP plan.

- b. CMMI then will confirm the list of plans approved for model participation who also opted into the narrowed risk corridor via application to the model and on HPMS.
  - c. EGWPs are not eligible to participate in this incentive.
- 2. *Identify all beneficiaries enrolled in all plans opting into the narrowed risk corridor during the Calendar Year***
- a. All beneficiaries enrolled in December in each of the plans on the plan list generated in step 1 would be identified.
  - b. For this set of beneficiaries, each would be flagged as being a model drug utilizer in the event they have a single PDE for a model drug during the calendar year in eligible Part D plans.
- 3. *Calculate the plan-level Model-drug utilization rate for plans opting into the narrowed risk corridor***
- a. This rate is calculated as the number of all beneficiaries enrolled in December in the plan with a model drug PDE (as identified in step 2) divided by the total enrollment in the plan in the same CY.
- 4. *Calculate the average and standard deviation of model-drug utilization rates for each plan type across all plans opting into the narrowed risk corridor***
- a. This is calculated as the simple arithmetic mean and standard deviation of plan-level utilization rates (as described in step 3) for each of the plan types.
- 5. *Compare plan-level utilization to the average for the appropriate plan type***
- a. Participating plans that opted-in (see Step 1 above) that experience a model-drug utilization rate greater than one standard deviation above the mean for their plan type are eligible for a narrowed risk corridor.