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

Manufacturer

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Contents

1. Background and General Information

1.1 Model Scope

The CMS Innovation Center (CMMI), under statutory authority in section 1115A of the Social Security Act, is proposing a voluntary Medicaid and Medicare Part D payment model starting in May 2026 for Medicaid and January 2027 for Medicare Part D that tests whether an approach where CMS (acting on behalf of state Medicaid agencies and Part D sponsors) negotiates expanded coverage of medications for weight management, paired with beneficiary access to healthy lifestyle supports, preserves or enhances quality of care (including improved cardiometabolic health) for beneficiaries while reducing or maintaining program expenditures.

The Better Approaches to Lifestyle and Nutrition for Comprehensive hEalth (BALANCE) Model (the model) aims to test this approach by:

- Incentivizing coverage of GLP-1 medications[1] to improve metabolic health and weight management;
- Negotiating reduced net prices in Medicaid and 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.

This request for applications (RFA) is for pharmaceutical manufacturers that market U.S. Food & Drug Administration (FDA)-approved GLP-1 receptor agonist drugs (hereinafter, "Manufacturers") and outlines model design elements, model eligibility criteria, and additional model details. Manufacturers who submit a timely and complete response to this RFA may be eligible to participate in negotiation under this model with CMS, and may, upon conclusion of negotiation, be eligible to become a model participant.

1.1.1 General Approach

The Innovation Center is testing the impact of a voluntary model wherein CMS facilitates the development and implementation of negotiated pricing agreements between state Medicaid agencies,[2] Medicare Part D plan sponsors,[3] and manufacturers that includes selected evidence-based lifestyle interventions to promote health behaviors for beneficiaries. Within this model,

[1] 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, dual GIP/GLP-1 receptor agonists, such as tirzepatide, and similar pipeline products.

[2] "State" means any state, the District of Columbia, and any U.S. territory that participates in the Medicaid Drug Rebate Program (MDRP).

[3] See 42 CFR 423.4 for definition of Part D plan sponsor.

CMS will negotiate standard key terms[4] directly with each eligible manufacturer. These pricing agreements may include guaranteed rebates and manufacturer-provided lifestyle support.

Upon agreement regarding the standard key terms between CMS and the manufacturer, the manufacturer will enter into a Participation Agreement (PA) with CMS and formally become a participant in the model. CMS will then communicate the agreed-upon standardized key terms to all states and Part D plan sponsors (hereinafter eligible "model participants" in addition to participating manufacturers), who may, at their option, execute a State Agreement (SA) or Part D Contract Addendum (CA) with CMS, thus also becoming participants in the model. Participating states will adopt the key terms through a supplemental rebate agreement (SRA) with each participating manufacturer(s).[5] Likewise, participating Part D sponsors will adopt the key terms as outlined in the Contract Addendum.[6]

CMS will support implementation of the model through responsibilities such as monitoring, reconciling, and evaluating the financial and clinical outcomes specified in the key terms. The Innovation Center will conduct a robust model evaluation through an independent contractor. CMS will conduct monitoring activities to ensure compliance with all aspects of the model by all participants, and other relevant entities. These activities will include a focus on the quality of services provided, beneficiary experience, and appropriate access to care. 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 applicable agreement with the model participant. CMS may modify the terms of the model or cancel it entirely. The terms set forth in this RFA may differ from the terms set forth in the finalized PAs for the model.

The Innovation Center is testing this model beginning on May 1, 2026, for participating States and January 1, 2027, for participating Part D sponsors. This RFA is limited to manufacturers of products that meet the following criteria:

Eligible manufacturers for the initial negotiations are 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 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);

[4] "Key Terms" means 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.

[5] The State-specific contracts will comport with applicable laws and regulations.

[6] Agreements between manufacturers and Part D Plan sponsors will comport with applicable laws and regulations. Participating Part D sponsors would incorporate the cost sharing limits for model drugs within the Part D benefit.

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.

These products are hereinafter referred to as "model drugs."

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

The 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.[7]

1.3 Waiver Authority

Under section 1115A(d)(1) of the Act, the Department of Health and Human Services (or 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 sponsor participants in the model.

Programmatic waivers under consideration are the following:

- Section 1860D-2(e) of the Act to the extent necessary to allow Part D coverage of statutory excluded drugs, specifically agents when used for weight loss.

[7] Social Security Act § 1115A [42 U.S.C. § 1315a], "Center for Medicare and Medicaid Innovation."

- 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 sponsors to offer model-specific cost-sharing on model drugs.
- 42 C.F.R. § 423.578(a) to the extent necessary to permit model-participating Part D 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.
- Section 1860D-11(b) of the Act, to the extent necessary solely to permit Part D 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 sponsors as they negotiate within the bounds of the model.
- Section 1860D-4(a)(1) of the Act and 42 C.F.R. § 423.128 waived to the extent necessary for a Part D sponsor to comply with the model test design's unique marketing requirements; and
- 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 permit CMS to waive the requirements regarding the application of the Maximum Fair Price to drugs selected for participation in the Drug Price 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 manufacturers to provide rebates associated with Model pricing for a Model drug in the alternative to the Maximum Fair Price requirements of the Negotiation Program.

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.

1.4 CMS-Sponsored Model Safe Harbor

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 Section 2.2, as well as the regulatory requirements of 42 CFR § 1001.952(*ii*). The CMS 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 model PA. 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 Participation

Under the model, CMS will negotiate on behalf of states and plans agreements with the manufacturers of GLP-1 therapies to permit coverage of the drugs for improved metabolic health. Participation in the model will be voluntary for GLP-1 drug manufacturers, state Medicaid programs, and Medicare Advantage prescription drug (MA-PD) plans and standalone prescription drug plans (PDPs). The CMS Innovation Center will support model participants in implementing, monitoring, and evaluating usage of the medications for the model-covered purpose.

The model is expected to expand access to critical supportive services that are likely to increase beneficiary uptake of and adherence to the model drugs in order to improve health outcomes. This includes, but is not limited to, improvements in state reimbursement methods, Medicaid and Medicare coverage of model drugs for weight loss, and access to robust lifestyle support programs. Finally, CMS will take a central role in data collection and monitoring to facilitate the implementation of agreements among model participants and related monitoring, helping to relieve participants of some of that burden.

The purpose of this RFA is to outline the elements that must be included in a manufacturer's application to join the model. The application template is attached to this RFA as Appendix A. Eligible respondents to this RFA will be invited by CMS to participate in the model pre-implementation period (outlined below), including negotiation of key terms. While this RFA may result in subsequent negotiation, a response to this RFA constitutes a formal offer to CMS regarding all aspects of the model described herein. Responding to this RFA does not obligate the manufacturer to become a model participant.

The model is voluntary to all participants. While this RFA only applies to manufacturers, information regarding state and Part D plan sponsor participation is included within this document for the reference of manufacturers and to aid in responses to this RFA.

2.2 Manufacturer Participation

Manufacturers that satisfy the above requirements in Section 1.1 and submit a timely and complete application in response to this RFA will be eligible to participate in the model pre-implementation period.

The model pre-implementation period begins January 12, 2026, and is expected to end on February 05, 2026. During the model pre-implementation period, CMS will negotiate the standard key terms with each eligible manufacturer. If an agreement between parties is reached,

then the manufacturer must execute a PA with CMS following the conclusion of the pre-implementation period. See Section 5.4 for more details about the model timeline, including the dates for submission of applications in response to this RFA.

A manufacturer that participates in the model pre-implementation period and signs a PA by February 28, 2026, with CMS is considered a model participant.

Manufacturer requirements for participation in the model are as follows:

1) Participated in negotiations with CMS during the model pre-implementation period;
2) Entered into a PA with CMS following the conclusion of the pre-implementation period; and
3) Maintains compliance with the PA.

Participating manufacturers must offer the standard negotiated key terms to all States and Part D plan sponsors. Variation in key terms will only be permitted as necessary to comport with State laws and regulations and must be approved by CMS. A process for disclosure of variation in key terms by model participants and approval, as necessary will be specified in the State and Part D plan sponsor RFAs. A participating manufacturer may not exclude any State or Part D plan sponsor that elects to participate. The manufacturer must agree to offer the key terms, as agreed by the manufacturer and CMS, each year to model participant for the duration of the PA as a term of model participation.

2.3 State Participation

Model participation is open to all states, the District of Columbia, and all U.S. territories that participate in the MDRP. State participants will be required to execute SRAs with all manufacturer participants.

States will participate in the model by responding to a State Request for Applications and executing an SA with CMS. Additional information regarding State obligations will be included in the SA. . States will be required to adopt the Key Terms for all model drugs from all participating manufacturers. States must execute SRAs with each participating manufacturer(s) that reflect the negotiated key terms for the model drug(s).). CMS will provide technical assistance to support states in developing and submitting any necessary State Plan Amendments. CMS will inform the participating manufacturer(s) upon acceptance of a new state participant.

2.4 Medicare Part D Plan Sponsor Participation

Part D sponsors in all states and territories will be eligible to participate in the model, through 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 Special Needs Plans (SNPs) and all employer/union group waiver plans (EGWPs) that offer Part D.

Private fee-for-service plans, section 1876 cost contract plans, section 1833 health care prepayment plans, PACE organizations, LI-NET Sponsor, fallback plans, and religious fraternal

benefit plans will not be eligible to participate. Part D 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.

Incentives for Participation

The model's voluntary nature requires strong incentives for Part D plan participation. To ensure robust participation of Part D sponsors, including both PDPs and MA-PD plans, the CMS Innovation Center intends to explore several options for incentives. Options may include adjustment of capitated payment rates for obesity and increasing the government reinsurance for model drug fills.

CMMI will also consider requiring that a minimum threshold of participation be reached for the model to go into effect. The threshold will be determined on a Part D parent organization level and by a percentage of beneficiaries among eligible plan types. Final participation incentives and flexibilities will be determined ahead of the Part D bid process.

Part D Application

Part D plan sponsors who seek to participate in the model may respond to a Part D Plan Sponsor Request for Applications and once accepted, will be required to execute a Part D Contract Addendum (CA) with CMS. Additional information regarding Part D plan sponsor obligations will be included in the CA.. Part D plan sponsors that apply and are approved to participate in the model will be required to provide all model drugs to eligible beneficiaries. Part D plan sponsors will be required to apply to participate in the model each plan year. CMS will inform the participating manufacturer(s) of any changes in Part D plan sponsor participation.

2.5 Model Population

Model beneficiaries are beneficiaries in the model population who are deemed eligible for (i.e., are clinically eligible for and meet all negotiated prior authorization criteria) and receive a model drug that is covered and paid for by either (1) a participating State Medicaid program as a covered outpatient drug where Medicaid is the primary payor, or (2) a participating Part D plan.[8]

2.6 Legal Agreements

This model will include a partnership among CMS, participating manufacturers, participating States, and participating Part D sponsors. This partnership will be executed through multiple legal and contractual mechanisms. CMMI expects to execute, at a minimum, the manufacturer PA, state SRAs, state PAs, Part D sponsor CA, and any applicable waivers.

2.7 Key Terms

Manufacturers that submit a timely and complete response to this RFA will be eligible to participate in negotiations with CMS to determine the key terms of the model. Key terms mean

[8] Model beneficiaries receiving a model drug for the expanded weight management indication must be 18 years and older in Medicare and Medicaid.

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 SMA and Part D plan sponsors. In its application to this RFA, the manufacturer must include proposals related to each of these key terms. The manufacturer should not consider the list below as being exhaustive and may propose additional key terms as an attachment to their model application. The full application template for this RFA is included as Appendix A.

The negotiations between CMS and manufacturers will seek to reach alignment on:

Cost: Agreement on a guaranteed, lowered net price on model drugs on a National Drug Code (NDC) level for all approved medically accepted indications including weight management.

For Medicare Part D, CMS would be negotiating a set cost sharing limit (copayment or coinsurance) in the initial coverage phase. Deductible applicability will be the subject of model-specific negotiations with manufacturers.

Access Policy: Agreement on a standardized set of coverage criteria for the model target population in both Medicaid and Medicare Part D, including clinical eligibility criteria, prior authorization requirements, and a cost-sharing limit (copayment or coinsurance) on model drugs when coverage is under the basic Part D benefit. Coverage of drugs for weight management through the model does not meet the definition of a supplemental benefit and therefore does not satisfy enhanced alternative coverage requirement. Part D sponsors participating in the model would be expected to cover all medically accepted indications covered under Part D for model drugs in addition to weight management and to apply the same cost-sharing limit to all indications.

Lifestyle Supports: Agreement on beneficiary support for healthy lifestyle. This will initially be implemented by manufacturers. The exact parameters of the final arrangements are subject to negotiations and may evolve over time as capabilities for additional integration become more available. Additional information about the lifestyle support requirements may be found in Section 2.7.3.

2.7.1 Pricing on Model Drugs and Cost-Sharing

State Medicaid Agency Coverage

Price reductions on model drugs for state Medicaid agencies would occur under supplemental rebate agreements between participating State Medicaid agencies and manufacturers that reflect the negotiated key terms. CMS-authorized supplemental rebate agreements, under MDRP, are rebate agreements wherein states and manufacturers mutually elect for higher rebate level than what states would receive under the statutory rebate.[9]

[9] 42 C.F.R. 447.502.

Part D Coverage

CMMI intends to waive 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.

Part D Benefit Structure

Under the model, coverage would be provided as part of the basic benefit structure with established model cost sharing limits for beneficiaries. The model test will provide coverage at the NDC level, applying cost-sharing maximums to all indications including medically accepted indications including weight management, with required coverage of all negotiated drugs from all participating manufacturers for participating Part D sponsors.

Part D Effectuation of Model Key Terms

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 Manufacturer Discount Program (MDP) payments for applicable discounts, the net price of the drug would equal the price negotiated under the model. The base for the calculation of CMS and plan liability would be the gross drug costs.

Due to implications for federal savings, the CMS Innovation Center is pursuing a rebate option under which manufacturers of drugs that are subject to Maximum Fair Prices (MFPs) will be exempt from MFP effectuation through the Medicare Transaction Facilitator (MTF) for claims filled by beneficiaries enrolled in plans participating in the model. The CMS Innovation Center will explore statutory and program instruction waivers to implement the approach and will raise issues as appropriate with the relevant components of CMS and leadership.

Part D plans would incorporate the agreed-upon cost sharing limits for model drugs within the Part D offering.

2.7.2 Coverage Criteria

Model beneficiaries will be those enrolled in a participating plan or state, meeting the coverage criteria requirements resulting from the negotiations, and receiving a covered GLP-1 product. CMS Innovation Center is interested in standardizing access via a set of coverage criteria for patients that meet a BMI threshold and/or have additional evidence of metabolic dysfunction (e.g., heart failure, uncontrolled hypertension, pre-diabetes), and who meet FDA-approved label specifications.

The manufacturer must describe in detail proposed policies for State and Part D plan coverage in their response to this RFA. This response should include proposed prior authorization policies for the model drug(s), , and eligibility for the model drug. The coverage criteria may differ between Medicaid and Medicare markets but would be standardized within each market.

2.7.3 Lifestyle Support Program

CMS is interested in negotiating as part of the key terms manufacturer-provided lifestyle support. The lifestyle support program will support medication adherence and augment GLP-1 effectiveness. The lifestyle support program will be provided to all model beneficiaries by participating manufacturers. CMS expects to revisit these requirements annually based on model performance and available program supports. All lifestyle supports provided to model beneficiaries should be based on evidence-based practices and designed to aid beneficiaries in reducing gastrointestinal side effects and understanding how to incorporate a nutrient-dense reduced calorie diet and increased physical activity into their daily living.

In their response to this RFA, manufacturers should include information on proposed lifestyle support programs, including:

How the program meets the requirements below, details on how a model beneficiary can access the lifestyle support program (e.g., via an app or online platform), any accessibility considerations, the evidence base the program is based upon, any additional functionality, and how data from the platform would be collected and shared with CMS.

Lifestyle Program Requirements

Program Component	Program Component
Diet & Nutrition	Encourage healthy eating habits and goal setting, including strategies for reducing gastrointestinal side-effects, avoidance of nutritional deficiencies, and maintenance of muscle and bone strength, through educational or financial interventions.
Physical Activity	Encourage increased physical activity, either through offering improved access to services and/or counseling including goal setting.
Medication Adherence	Support medication adherence through medication reminders, prompts encouraging beneficiaries to speak to their prescribers about mitigating side-effects, and guidance on rotating injection sites for injectable medications.
Recurrence	Are delivered on a recurrent basis for patients receiving GLP-1 treatment. Beneficiaries should be able to engage with the program regularly to log weight, review goals, and engage in asynchronous education (if available). Beneficiaries should also be able to engage with the core supports (e.g., synchronous or incrementally released asynchronous education, coaching) at a regular cadence. The program should have the functionality to demonstrate and validate timely engagement.
Scale & Accessibility	Available to all patients receiving GLP-1s for weight management, including patients requiring offline (e.g., telephone, in-person) supports due to limited digital access or fluency. Any digital support would be expected to meet established HHS IT standards.

2.7.4 CMS Responsibilities

CMS' responsibilities will be specified in the key terms and in the PAs, SAs, and CAs. At a minimum, CMS will be responsible for compiling, monitoring, and analyzing data necessary to support the model, including utilization data, claims data, clinical records, and patient reported measures.

Sources of data utilized by CMS may include, but are not limited to:

- The Transformed Medicaid Statistical Information System (T-MSIS) for utilization and claims information.
- Part D Prescription Drug Event (PDE) data
- Patient-reported data for information on the impact of lifestyle support programs.

2.7.5 Rebate Documentation & Reconciliation

The key terms must clearly specify, for each type of rebate, what is required for acceptable Rebate Documentation, and the deadline by which Rebate Documentation must be provided to the manufacturer from CMS. The manufacturer must describe, for each rebate proposed in its RFA response, what is necessary for Rebate Documentation. CMS will have the responsibility to establish, through its review of data as described in the key terms, whether thresholds have been met for an applicable performance assessment and will be responsible for the transmission of Rebate Documentation to the manufacturer on behalf of participating States.

The PA resulting from this RFA will include language finalizing the interim and final reconciliation processes.

2.8 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 PA, SAs, and CAs.

2.8.1 Modification of Key Terms

CMS and manufacturers will negotiate standard language regarding termination and renewals of the key terms, and the manufacturer may propose such terms in their response to this RFA. The manufacturer will agree to offer the key terms to model participants.

The key terms will specify the circumstances in which renegotiation would occur (e.g., changes in the FDA labeling, new clinical evidence, new products launched). If renegotiation between CMS and the manufacturer results in prospective change to the key terms, participating States and Part D sponsors would have an opportunity to execute new SRAs and CAs, respectively, with any participating manufacturer or terminate model participation with respect to future performance years.

2.8.2 Termination

The PA resulting from this RFA shall commence on May 1, 2026 for Medicaid and January 1, 2027 for Medicare, and continue until the end of the model on December 31, 2031, subject to earlier termination as provided for in the PA. CMS reserves the right to terminate a participating manufacturer's PA at any point during the model for reasons associated with poor performance, new safety or efficacy data regarding the model Drug, program integrity issues, non-compliance with the terms and conditions of the applicable PA, or as otherwise specified in the PA or required by section 1115A(b)(3)(B) of the Act. A participating manufacturer may voluntarily terminate their PA and participation in the model, subject to terms that will be outlined in the PA.

3. Quality and Performance Monitoring

As part of both model implementation and evaluation, CMS will monitor the impacts of the model on Medicare and Medicaid program spending 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 and will not be tied to the model-negotiated SRAs or CAs. The Innovation Center reserves the right to monitor and validate information and data submitted by model participants to the Innovation Center for the purposes of either model implementation or model evaluation. Model participants will be required to comply with all monitoring activities and validation efforts as part of their model participation. The monitoring and evaluation requirements of model participation will be detailed in full in the PAs, SAs, and CAs.

3.1 Enrollee Protections and Oversight

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 participating manufacturers or model participants, particularly in the event that CMS receives a high number of complaints or other indicators of poor performance. CMS expects participating manufacturers 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 or participating manufacturer 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 manufacturers 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 manufacturers 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, only aggregated results would be reported. CMS does not anticipate that confidential, commercially valuable information will be used in the evaluation.

5. Application

5.1 Application Process and Selection

Manufacturers seeking to participate in the model must complete and submit the application template in Appendix A in either PDF or Word format by 11:59 pm EDT on January 6th, 2026, according to the instructions provided in Appendix A. CMS will acknowledge receipt of the application to the Primary Application Contact (see Appendix A) and will respond to the manufacturer with a request for an initial meeting and, if applicable, an initial counterproposal to the key terms submitted by the manufacturer. All eligible manufacturers that submit a response to this RFA will be individually invited to participate in Key Term negotiations with CMS, and, if, upon conclusion of negotiation an agreement is reached, will be selected as a model participant. If an agreement is reached with a manufacturer, CMS will enter into a PA with the manufacturer and a fully executed PA must be completed on or before February 28th, 2026.

If additional manufacturers receive FDA approval for a GLP-1 after the conclusion of the pre-implementation period, CMS may open a new application cycle to allow eligible manufacturers to participate in negotiation with CMS.

5.1.1 Meetings between CMS and Manufacturers

Representatives of CMS and manufacturers may meet as needed, subject to agreement between parties, between the submission of the manufacturer's response to this RFA and the conclusion of the pre-implementation negotiation period, to discuss the manufacturer's application or subsequent offers provided by either CMS or the manufacturer.

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 and medical records. Model participants and participating manufacturers will be permitted to comment on evaluation reports for factual accuracy, where appropriate, but may not edit conclusions or control the dissemination of reports.

All proprietary trade secret information and technology of the manufacturer is, and shall remain, the sole property of the manufacturer and, except as required by federal law, shall not be released by CMS without express written consent. The regulation at 48 CFR § 52.227-14, "Rights in Data-General" is hereby incorporated by reference into this RFA. CMS does not acquire by license or otherwise, whether express or implied, any intellectual property rights or other rights to the manufacturer's proprietary information or technology. Such protections will be provided for in agreements effectuated between CMS and the manufacturers.

If the manufacturer maintains any information that should not be publicly disclosed because the manufacturer considers such information to be proprietary and confidential, the manufacturer should submit to CMS a form, using either the template attached as Appendix B, or a form substantially the same as Appendix B, identifying specific examples of information the manufacturer considers to be proprietary and confidential. The manufacturer must notify CMS, in a form and manner to be specified by CMS, of any updates to this form. If the participating manufacturer does not submit such a form, it will be deemed to be confirmed that the

manufacturer has no information in its response to this RFA it considers proprietary and confidential.

5.3 Submission Information

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

5.4 Model Timeline

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

Model Announcement: December 19, 2025
Manufacturer Request for Application: December 19, 2025, due Jan 8, 2026 by 11:59 PM
Pre-Implementation Period: Jan 12, 2026 through Feb 5, 2026
Model Launch for State Medicaid Agencies: May 1, 2026
Model Launch for Part D Sponsors: Jan 1, 2027

5.5 Withdrawal of Application

Prior to 11:59 pm EDT January 8th, 2026 , a manufacturer that submitted an application may withdraw from participating in the pre-implementation period by submitting a written request on the organization's letterhead that is signed by one of the following: (1) the chief executive officer (CEO) of the manufacturer, (2) the chief financial officer (CFO) of the manufacturer, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

To submit a withdrawal request, the manufacturer must send the request in a PDF format by email to 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. 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.

CMS will provide manufacturers with a secure platform where the completed application template and supporting documents must be submitted. Manufacturers must contact CMS at BalanceModel@cms.hhs.gov to receive instructions regarding accessing the secure application platform and may do so at any time following the release of this RFA.

Manufacturers seeking to participate in the model must submit the completed application template and any supporting documents in PDF or Microsoft Word format by 11:59pm EDT on January 8th. Text responses in the application template are limited to no more than 1,000 words for each response.

Direct questions about the application for the model to BalanceModel@cms.hhs.gov.

BALANCE MODEL
MANUFACTURER APPLICATION FOR PARTICIPATION

APPLICANT INFORMATION

Please provide the following information:

Manufacturer Name:
Manufacturer Mailing Address:
Primary Contact Name:
Primary Contact Title/Position:
Primary Contact Business Phone Number:
Primary Contact Email Address:
Secondary Contact Name:
Secondary Contact Title/Position:
Secondary Contact Business Phone Number:
Secondary Contact Email Address:

Please provide product information below and attach supporting documents demonstrating that the drug meets the criteria outlined in Section 1.1 of the RFA.
Proprietary Name of Model Drug:
NDC(s):

The following sections are required for your application to be considered.

SECTION I: DEFINITIONS

Please use the definitions provided in the Request for Applications (RFA) to the fullest extent possible in your application. If you would like to suggest additional or revised definitions, please provide them below:

SECTION II: MODEL DRUGS AND GUARANTEED REBATE

a. Please provide the following information on eligible model drugs for both Medicare and Medicaid coverage. Respondents may use the attached excel template in addition to the following space:
   - *Complete list of eligible drugs identified by 11-digit NDCs*
   - *Drug names (brand and generic)*
   - *First quarter 2026 pricing information by 11-digit NDC. This should be the average standardized fill for one-month supply. This should also be weighted net prices from the Medicaid perspective (average net price paid in states inclusive of all statutory and supplemental rebates where such product is covered) and separately for Medicare Part D perspective (inclusive of PDPs and MA-PDs). Provide both the pricing information and the number of fills on which it is based.*
   - *Any special considerations or restrictions*

b. **Medicaid:** For each unit (NDC-9 or NDC-11) of the model drug utilized by a model Beneficiary during the Administration Period, Manufacturer agrees to pay a Guaranteed Rebate beyond the rebate owed under the MDRP or any other state supplemental rebate. The amounts will be determined as follows:
   - *Calculation Type: GNUP*
   - *Supplemental Rebate Per Unit:*
   - *Net price to government (including beneficiary out-of-pocket) per fill:*

c. **Medicaid Conditions for Guaranteed Rebates:** In the space below, please provide any additional conditions relevant to the provision of Guaranteed Rebates under these key terms. This may include, but is not limited to, data reporting requirements, timing requirements, or state invoicing specifications.

d. **Medicare:** For each unit (NDC-11) of the model drug utilized by a model Beneficiary during the Administration Period, Manufacturer agrees to pay a Guaranteed Rebate beyond 2027 net prices in Medicare. The amounts will be determined as follows:
   - *Calculation Type (specify whether it is based on WAC, AMP, or other):*
   - *[Additional] Rebate Per Unit (NDC-11):*
   - *Net price to PDP and MA-PD plans (including beneficiary out-of-pocket) per fill:*

e. **Medicare Conditions for Guaranteed Rebates:** In the space below, please provide any additional conditions relevant to the provision of Guaranteed Rebates under these key terms. This may include, but is not limited to, data reporting requirements, timing requirements, or state invoicing specifications.

SECTION III: ADDITIONAL REBATES

In the space below, please describe any additional rebate proposals not otherwise included in the application.

SECTION IV: COVERAGE CRITERIA

a. **Access Policy for Model Participants:** In the space below, please describe your proposed access policy that participating states and Part D plan sponsors would adopt as part of the model. Please include criteria for eligibility for the model drug, any utilization management processes, provider qualifications,

or other terms for prior authorization. *CMS is interested in access policies focused on cardiometabolic risk rather than body mass index alone.*

b. **Access Policy Justification:** If the proposed access policy differs between participating states and Part D sponsors, please include additional justification in the different coverage criteria in the space below.

SECTION V: MANUFACTURER-PROVIDED LIFESTYLE SUPPORT

Please describe your proposed lifestyle support program and how it meets the requirements below. For each Program Component below, please provide a description of Service/Intervention:

- *Modality:*
- *Diet & Nutrition:*
- *Physical Activity:*
- *Recurrence:*
- *Scale & Accessibility:*

SECTION VI: ADDITIONAL KEY TERMS

If desired, please describe below any additional key terms that you would like to propose to CMS for consideration. Additional key terms are not to exceed more than 10 pages.

SECTION VII: SUPPLEMENTAL INFORMATION

Please submit additional materials, including but not limited to clinical trial data, white papers, and patient or provider testimonials, that you believe support your proposal. Supplemental information is not to exceed 50 pages.

SIGNATURE

An individual eligible to certify this submission on behalf of the Manufacturer must be one of the following: (1) the chief executive officer (CEO) of the Manufacturer, (2) the chief financial officer (CFO) of the Manufacturer, (3) an individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO, or (4) an individual with the directly delegated authority to perform the certification on behalf of one of the individuals mentioned in (1) through (3).

I hereby certify, to the best of my knowledge, that the information being sent to CMS in this submission is complete and accurate, and the submission was prepared in good faith and after reasonable efforts. I reviewed the submission and made a reasonable inquiry regarding its content. I also certify that I will timely notify CMS if I become aware that any of the information submitted in this form has changed. I also understand that any misrepresentations may also give rise to liability, including under the False Claims Act.

Yes [ ]
No [ ]

[DATE]
[Signature block]

Appendix B: Manufacturer Proprietary and Confidential Information

The following are specific examples, without limitation, of what the Manufacturer considers proprietary and confidential information currently maintained by the Manufacturer that should not be publicly disclosed:

1)

2)

3)

In accordance with Section 5.2 of the RFA, this information shall remain the sole property of the Manufacturer and, except as required by federal law, shall not be released by CMS without the express written consent of the Manufacturer.

Appendix C: Excel File Submission Template

Respondents may use the attached excel template labeled *BALANCE Model Manufacturer RFA Appendix_v1* to provide the requested information on eligible model drugs for both Medicare and Medicaid coverage. Any materials submitted in response to the RFA must be included in the initial submission.