Centers for Medicare & Medicaid Services

Center for Medicare and Medicaid Innovation

Seamless Care Models Group

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

Request for Applications

State Medicaid Agency

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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 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 state Medicaid agencies and outlines model design elements, model eligibility criteria, and additional model details. State Medicaid agencies that submit a timely and complete response to this RFA may be eligible to participate in this model with CMS, and may, upon execution of a State Agreement (SA), be eligible to become a model participant.

1.1.1 General Approach

The CMS 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 healthy behaviors for beneficiaries. Within this model, CMS will negotiate standard key terms directly with each eligible manufacturer (the Medicaid

[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.

Key Terms). "Medicaid Key Terms" means the central parameters of the agreement negotiated between CMS and a manufacturer, including pricing, rebate calculation and amounts, the duration of the agreement, and any options or variations, that will form the basis for individual agreements between the manufacturer and participating states. The Medicaid Key Terms may include provisions regarding guaranteed rebates and manufacturer-provided lifestyle support.

Upon agreement on the Medicaid 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 communicate the agreed-upon standardized Key Terms to all states and Part D plan sponsors (hereinafter "model participants" in addition to participating manufacturers), who may, at their option, execute an SA) or Part D Contract Addendum (CA) with CMS, thus becoming participants in the model. Participating states will adopt the Medicaid Key Terms through a supplemental rebate agreement (SRA) with each participating manufacturer.[4]

CMS will support implementation of the model through responsibilities such as monitoring, reconciling, and evaluating financial and clinical outcomes. The CMS 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 care 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 SAs for the model.

The CMS Innovation Center is testing this model beginning on May 1, 2026, for participating States and January 1, 2027, for participating Part D sponsors. The model will run through December 2031.

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 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

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

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.[5]

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 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, eliminate 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 or SA. 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 Part D 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, Medicaid and Medicare coverage of model drugs for weight

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

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 state's application to join the model. The application template is attached to this RFA as Appendix A.

The model is voluntary for all eligible participants. While this RFA only applies to states, information regarding manufacturer participation is included within this document for reference and to aid states in responding to this RFA.

2.2 Manufacturer Participation

Manufacturer requirements for participation in the model are as follows:

1) Participation in negotiations with CMS during the model pre-implementation period. Manufacturers that submitted a timely and complete application in response to the Manufacturer RFA, released on December 23, 2025, were eligible to participate in the model pre-implementation period. The model pre-implementation period began January 12, 2026, and ended on February 05, 2026. During the model pre-implementation period, CMS negotiated the Medicaid Key Terms with each eligible manufacturer;
2) Agreement with CMS to enter into a PA following the conclusion of the pre-implementation period;
3) Compliance with the PA;
4) Agreement with CMS not to exclude any state that elects to participate. The manufacturer must agree to offer the Medicaid Key Terms, as agreed to by the manufacturer and CMS, each year to model participants for the duration of the PA as a term of model participation; and
5) Marketing, or the expectation to market by January 1, 2027, an eligible product.

An eligible product must meet all of the following criteria:

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);

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 products that meet the criteria above are described in the Appendix B (hereinafter "model drugs"). Participating manufacturers of these model drugs must offer the Medicaid Key

Terms to all states. The manufacturer must agree to offer the Medicaid Key Terms, as agreed by the manufacturer and CMS, to model participants 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 Medicaid Drug Rebate Program (MDRP).

States will be eligible to sign a State Agreement (SA) if the State submits a timely and complete application in response to this RFA, and CMS accepts the State's application. Upon signing a SA, a state becomes a model participant. States will participate in the model by responding to this state RFA by no later than July 31, 2026, and executing a SA with CMS by January 1, 2027.

In 2026 and 2027, States will be required to adopt the Medicaid Key Terms, or any CMS-approved variations, for all model drugs from all participating manufacturers. States must execute SRAs with each participating manufacturer that reflect the negotiated Medicaid Key Terms for the model drugs. Additional flexibility may be available in subsequent years, based on manufacturer negotiations.

Variation in Medicaid Key Terms may be permitted upon agreement with manufacturer and must be approved by CMS. The state must submit any proposed variations in writing to CMS for review and approval and must provide a copy to the relevant participating manufacturer. If, after a state submits their application, the state seeks to vary the Medicaid Key Terms, the state must submit proposed variations to CMS for approval at least 90 days in advance of implementing the proposed variation. CMS will review and approve, deny, or require modifications to the proposed variations within 30 days of receipt.

The state must have included in its approved state plan the authorization to enter into a SRAs with manufacturers that reflect the parameters of this model. CMS will provide technical assistance to support states in developing and submitting any necessary State Plan Amendments (SPAs). CMS will inform the participating manufacturer(s) upon acceptance of a new state participant.

States that do not join the model by January 1, 2027, may be allowed to participate in the model at CMS discretion. For example, CMS could allow a state to join a model later if their state plan submission approval process to obtain the necessary supplemental rebate authorizations takes an extended period of time.

State obligations will be detailed in the SA and are described in Section 2.4 of this RFA. If a state has an existing SRA with a participating manufacturer concerning a model drug, it must either terminate that existing SRA or amend that SRA to become a model SRA. A state may enter into additional SRAs on model drugs to offer broader coverage than agreed upon criteria, that is, to provide coverage for non-model beneficiaries (such as beneficiaries who cannot receive coverage for the model drugs under the negotiated prior authorization criteria). CMS will

offer direct technical assistance to all state participants in the model to support them in implementing these model requirements.

2.4 Operational Requirements

State participants must comply with the following legal, policy, operational, and system requirements to support the model:

1) Have, or obtain, the necessary authority for states to participate in the model, including CMS approval of a SPA to enter into an SRA;
2) Establish a model drug access policy consistent with the CMS-manufacturer negotiated Medicaid Key Terms, or any CMS-approved variations;
3) Ensure that applicable Medicaid plan policies align with model requirements for both fee-for-service (FFS) and Managed Care;
4) Execute a CMS-authorized model SRA incorporating the CMS-manufacturer negotiated Medicaid Key Terms;
5) Meet minimum requirements as specified in the SA; and.
6) Submit reports to CMS on model implementation and overall model operations, as required.

2.4.1 Legal Authority for States to Participate in the Model

State participants must have an approved SPA allowing them to enter into SRAs for both FFS and Managed Care drug claims (if applicable). States are welcome to contact CMS to discuss state-specific program requirements.

In the application submitted in response to this RFA, state applicants must indicate whether they will need a SPA, or other program waiver or demonstration approval to implement the model (see Application Item 5a). If a SPA is necessary to allow a state to participate in the model, the state should meet with the Center for Medicaid & CHIP Services (CMCS) as early as possible to begin the approval process. States do not need to wait until submitting a model application or becoming model participants to apply for any necessary SPA authority. In the application submitted in response to this RFA, the state must also indicate whether the state would need to enact new state legislation or establish new regulations to participate in the model and describe the anticipated timeline for doing so (see Application Item 5b). By the earliest date by which the state intends to include both FFS and managed care beneficiaries in the model for a model drug, the state participant must submit documentation showing that any necessary state laws or regulations are in effect.

Information included in the model application will be used solely for the purpose of application review and does not represent a formal request for a SPA, waiver, or demonstration approval on the part of the state, nor a commitment to approval on the part of CMS. Rather, the identification of current and planned Medicaid authorities will help support state and federal planning and

communication efforts related to the model and the potential submission of requests for new or revised SPAs.

2.4.2 Standardized Access Policy

For each model drug, a standardized access policy will be described in the Medicaid Key Terms and will include prior authorization policies, any utilization management processes, and patient eligibility criteria for the model drug. The aim of the access policy described in the Medicaid Key Terms is to standardize access to model drugs across all participating states for the model drugs unless variations are necessary and approved by CMS. State participants must establish an access policy for the model drug(s) that is consistent with the standardized access policy described in the Medicaid Key Terms negotiated with the manufacturer. States may create additional criteria and policies within their access policy as approved by CMS. CMS will not approve any variation that disadvantages one model drug relative to other model drugs in terms of the coverage criteria applied; provided; however, that changes in coverage criteria that correspond to differences in the FDA-approved label for model drugs shall not be considered disadvantaging. State criteria and policies must be uniform across all beneficiaries enrolled in FFS Medicaid and Medicaid managed care plans within the state. The prior authorization criteria applied must be: (i) no more burdensome than the criteria listed in Section 2.7.3; (ii) without step therapy that is more burdensome than the applicable model drug's FDA-approved label (and no such step therapy or utilization may include step therapy related to lifestyle or similar requirements); and (iii) for FDA-approved indications only.

2.4.3 Managed Care Alignment

For model drugs, state participants must ensure that applicable Medicaid managed care plan policies are consistent with model requirements, such that the Medicaid Key Terms apply equally to FFS Medicaid and Medicaid managed care beneficiaries (e.g., coverage criteria). For example, states must require that managed care plans apply the standardized access policy described in the Medicaid Key Terms, including any additional related criteria and policies created by the state. State participants must submit an explanation of how the Medicaid Key Terms are being applied in Medicaid managed care, and, as necessary, submit documentation showing that applicable Medicaid managed care plan policies align with model requirements (for example, managed care contracts/rates, memoranda of understanding, or communications with managed care plans). States are encouraged to meet with CMCS as early as possible for technical assistance.

Some states have existing policies in which they exclude certain drugs from applicable Medicaid managed care contracts while providing coverage for these drugs via the FFS delivery system instead. Prior to a state beginning implementation of any model SRA, state participants must inform CMS as to whether they have excluded any model drug(s) from managed care contracts, and if so, describe their process for coordinating prior authorization for managed care beneficiaries' drug(s) that are excluded from managed care contracts. States must ensure that their managed care plans are applying the Medicaid Key Terms.

Participating state Medicaid agencies have until January 1, 2027, to include all of their Medicaid populations in the model. To allow additional time for aligning managed care policies, state Medicaid agencies may choose to begin participation with only their FFS populations (i.e., Medicaid beneficiaries that receive all services through the FFS delivery system) and bring their managed care populations (i.e. Medicaid beneficiaries that receive some or all services through a managed care delivery system) into the agreement at a later time so long as all populations are live by January 1, 2027. When a state includes managed care populations in the model, the Medicaid managed care plans must have policies consistent with the model requirements, such as the Medicaid Key Terms (e.g., coverage criteria).

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.[6]

2.6 Legal Agreements

This model will include a partnership among CMS, participating manufacturers, and participating States to effectuate the model pricing in Medicaid. This partnership will be executed through multiple legal and contractual mechanisms. These include:

- CMS and manufacturer: Manufacturer Participation in Model (Manufacturer PA),
- Manufacturer and state: SRAs to effectuate Medicaid Key Terms (herein after referred to as "Model SRA", and
- CMS and state: State Participation in Model Agreement (SA)

2.7 Medicaid Key Terms

Manufacturers that submitted a timely and complete response to the BALANCE Model Manufacturer RFA were eligible to participate in negotiations with CMS to determine the Key Terms of the model.

The following Medicaid Key Terms are effective through December 31, 2027. Upon renegotiation, updated Medicaid Key Terms will be disclosed to states in a confidential manner. At which point, a participating state could choose to adopt the updated Medicaid Key Terms and amend their model SRA or terminate its participation.

2.7.1 Model Supplemental Rebate Agreement Administration

A. Model SRA Execution and Effectuation

1. The Model SRA shall specify the Model SRA start date, which shall be a date of the participating state's choosing between May 1, 2026, and January 1, 2027. If a

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

state chooses to begin with only their FFS beneficiaries, in accordance with 2.4.3 of this RFA, the Model SRA will specify both the FFS start date and managed care start date.

2. The participating state may access supplemental rebates according to the available GLP-1 Discounted Price for the Model Drug on the Model SRA start date. The "GLP-1 Discounted Price" means the net price the participating manufacturer agrees to offer all participating states, as specified in Appendix B for the Model Drugs.
3. Model SRAs for a Model Drug must either supersede any SRAs previously executed with any participating state for that Model Drug or may not take effect until any previous SRA for that Model Drug has terminated or been amended to comply with the requirements for a Model SRA.

B. Model SRA Term and Renewal

1. The manufacturer and participating state may agree to a GLP-1 Discounted Price for multiple years, so long as that offer is extended to all participating states equally, and the BALANCE model is active.
2. Following the conclusion of the Model SRA, a participating state may renew the Model SRA or agree to a new Model SRA to access a GLP-1 Discounted Price on that new or renewed Model SRA start date.
3. Participating states may continue to enter into Model SRAs with the manufacturer as long as the manufacturer continues to participate in the Model.

C. Updates to GLP-1 Discounted Pricing and Coverage Criteria

A. If a change to GLP-1 Discounted Pricing or Coverage Criteria for a Model Drug were to take effect during the term of a Model SRA, the state may either:

a. Opt to amend that Model SRA to reflect the updated GLP-1 Discounted Pricing or Coverage Criteria; or

b. Maintain the GLP-1 Discounted Pricing or Coverage Criteria from the Model SRA until the expiration of the Model SRA or terminate the Model SRA in accordance with the policies established in the SA.

2.7.2 Pricing on Model Drugs

Information regarding GLP-1 Discounted Pricing is available in Appendix B. Appendix B will be distributed to states through a confidential Box folder.

2.7.3 Coverage Criteria

A. The Model SRA will reflect that the participating state must adopt the following Coverage Criteria for both fee-for-service (FFS) and managed care beneficiaries without step therapy that is more burdensome than the applicable Model Drug's label (and no such step therapy or utilization management may include step therapy related to lifestyle or similar requirements); and with any prior authorization criteria being no more burdensome than those set forth below, provided that the model drugs are prescribed solely for indications approved by FDA.

1. 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), (c) has obstructive sleep apnea (OSA), or (d) is currently on and will continue lifestyle modification (as clinically appropriate) and one or more of the following:
2. The patient is at least eighteen (18) years of age and has a Body Mass Index ("BMI") greater than or equal to thirty-five (≥35) at the time of initiation of therapy, or
3. The patient is at least eighteen (18) years of age and has a BMI greater than or equal to thirty (≥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) F2/F3 stage will be confirmed using one guideline-supported test, including: Fib-4, Ultrasound, ELF, Fibroscan, MRE/MRI, or Fibrosure, or
4. The patient is at least eighteen (18) years of age and has a BMI greater than or equal to twenty-seven (≥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.

B. The participating state may choose to adopt Coverage Criteria that are less restrictive at their discretion, provided the criteria remain within the FDA approved label.

C. With respect to a Model Drug, the participating state will include such Model Drug on its Preferred Drug List, (PDL), as applicable, without disadvantaging relative to competitor products.

D. For the purposes of this Model, a participating state will not be considered to be engaged in disadvantaging activities if the only differences in prior authorization criteria between Model Drugs and competitor products correspond to differences in the approved FDA labels of these products.

E. All references to therapeutic class refer to the category in which the applicable Model Drug is placed on the participating state's own PDL as defined by that participating state.

2.7.4 Lifestyle Support Program

Drug Manufacturer will provide access at no cost to a lifestyle support program that empowers patients who have been prescribed Model Drugs to reach health goals through the provision of educational materials, health and lifestyle coaching, and recommendations for exercise and diet modification. 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.

2.7.5 CMS Responsibilities

CMS responsibilities will be specified in the Medicaid Key Terms and in the PAs and SAs. At a minimum, CMS will be responsible for compiling, monitoring, and analyzing data necessary to support the model, including utilization data, claims data, and clinical records.

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.

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 PAs and SAs. CMS retains the right to terminate the model.

2.8.1 Modification of Medicaid Key Terms

CMS and participating manufacturers shall have the option to mutually renegotiate on annual basis the following elements: the list of model drugs, the GLP-1 Discounted Pricing, the Clinical Criteria, the obligations of model participation for participating Medicare Part D plans and states, and the parameters of the lifestyle support program. CMS and participating manufacturers shall also have the option to enter into renegotiations regarding the list of Model Drugs and the Clinical Criteria if the FDA-approved label for model drugs changes to include additional safety risks or if a previously covered indication is excluded from the scope of the label. If renegotiation between CMS and the manufacturer results in prospective change to the Medicaid Key Terms, participating states would have an opportunity to execute new SRAs with any participating manufacturer or terminate model participation with respect to future performance years.

2.8.2 Termination

The SA resulting from this RFA shall commence no later than January 1, 2027, and continue until the end of the model on December 31, 2031, subject to earlier termination as provided for in the SA. CMS reserves the right to terminate a participating state's SA at any point during the model for reasons associated with poor performance, program integrity issues, non-compliance with the terms and conditions of the applicable SA, or as otherwise specified in the SA or required by section 1115A(b)(3)(B) of the Act. A participating state may voluntarily terminate its SA and participation in the model, subject to terms that will be outlined in the SA.

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 CMS Innovation Center reserves the right to monitor and validate information and data submitted by model participants to the CMS 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 if there is evidence that participation in the model is adversely impacting enrollee quality of care or that the participant has failed to provide required information and to 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 states, 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 monitoring of the model.

In certain situations, participating states 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. 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

States seeking to participate in the model must complete and submit the application and any supporting documentation via provided Qualtrics link by no later than 11:59 PMPM EDT on July 31, 2026. CMS will acknowledge receipt of the application to the Primary Application Contact (see Appendix A)

To participate in the model, a state will be required to execute a SA with CMS by January 1, 2027. States that do not join the model by January 1, 2027, will not be allowed to participate in the model except at CMS discretion as discussed in Section 2.3. CMS encourages states to engage with CMS as early as possible regarding potential participation in the model. States may contact the BALANCE Model at BALANCEModel@cms.hhs.gov.

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 Information

Information required by CMS in response to this RFA regarding the Medicaid Key Terms and parameters of model participation is included in Appendix A. While Appendix A includes the minimum information required per this RFA, states 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:

Model Announcement	**December 23, 2025**	
State Request for Application	March 9, 2026	Due: No later than July 31, 2026, by 11:59 PM
Model Launch for State Medicaid Agencies (Window for Execution of State Agreement)	May 1, 2026	Jan 1, 2027

5.5 Withdrawal of Application

Prior to signing a State Agreement, a state that submitted an application in response to this RFA may withdraw its application by submitting a written request on the state's letterhead that is signed by one of the following: (1) the State Governor, (2) the State Secretary of Health, or official in equivalent position, (3) the State Medicaid Director, or (4) an individual with the directly delegated authority to perform the certification of the application on behalf of one of the individuals mentioned in (1) through (3). To submit a withdrawal request, the state applicant 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 states with a Qualtrics link where the completed application template and supporting documents must be submitted.

States seeking to participate in the model must submit the completed application via the Qualtrics link, including uploading any supporting documents in PDF or Microsoft Word format by no later than 11:59pm EDT on July 31, 2026.

Questions about the application for the model should be directed to BALANCEModel@cms.hhs.gov.

BALANCE MODEL APPLICATION TEMPLATE

APPLICANT INFORMATION

Please provide the following information:

Name of State, District, or Territory:	
Name of Agency:	
Mailing Address:	
Primary Contact: *Name:* *Title/Position:* *Business Phone Number:* *Email Address:*	**Secondary Contact:** *Name:* *Title/Position:* *Business Phone Number:* *Email Address:*

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

SECTION I: ADOPTION OF MEDICAID KEY TERMS

a. Based on the information currently available, will the state need to vary any of the Medicaid Key Terms described in this RFA to comport with state laws and regulations? If so, please identify those terms and the source of the state level

conflict. Also indicate whether the state will propose changes to any conflicting state laws and regulations.

b. At this time, will the state seek to vary any of the Medicaid Key Terms described in this RFA for a reason other than conflicts with state laws and regulations? If so, please state which terms and the reasoning. If the state does not know at this time whether they plan to seek a variation to the Medicaid Key Terms, please explain the process and timing for such a decision.

SECTION II: LEGAL AUTHORITY

a. Will the state need to obtain a state plan amendment (SPA) or other program waiver to implement the model? Please specify whether the state has already submitted a SPA or met with Center for Medicaid & CHIP Services (CMCS) to discuss a request for a SPA/demonstration/waiver.

b. Will the state need new state law or regulations to implement the model? If yes, please describe the type of changes that are needed and the anticipated timeline for implementing them.

SECTION III: ANTICIPATED START DATE

a. Given states may choose to execute a State Agreement and begin participation between May 1, 2026, and January 1, 2027, what is your state's desired start date?

b. Does your state intend to have different start dates for FFS and Medicaid managed care? If so, what is your state's intended managed care start date?

SECTION IV: MANAGED CARE ALIGNMENT

Are any model drugs currently excluded from managed care contracts? If so, please describe your process for coordinating prior authorization for managed care beneficiaries' drug(s) that are excluded from managed care contracts

SECTION V: OPTIONAL ADDITIONAL INFORMATION

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

SIGNATURE

An individual eligible to certify this submission on behalf of the state must be one of the following: (1) the State Governor, (2) the State Secretary of Health, or official in equivalent position, (3) the State Medicaid Director, 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]