



U.S. Department of Health & Human Services

Centers for Medicare & Medicaid Services

[Center for Medicare & Medicaid Innovation](#)

[Seamless Care Models Group](#)

7500 Security Boulevard

Baltimore, MD 21244

[Cell & Gene Therapy Access Model](#)

Request for Applications for States

1. Background and General Information	4
1.1 Model Scope.....	4
1.1.1 <i>General Approach</i>	4
1.1.2 <i>Sickle Cell Disease</i>	5
1.2 Statutory Authority.....	7
1.3 Waiver Authority	7
1.4 CMS-Sponsored Model Safe Harbor.....	8
2. Description of Model.....	9
2.1 Purpose and Concept	9
2.2 Model Participation.....	10
2.2.1 <i>Manufacturer Participation</i>	10
2.2.2 <i>State Participation</i>	11
2.3 Model Population	13
2.3.1 <i>Children’s Health Insurance Program (CHIP)</i>	13
2.4 Performance Period.....	13
2.5 Legal Agreements	15
2.6 Key Terms	19
2.6.1 <i>Adoption of Key Terms</i>	21
2.7 Changes to Model Design in Current or Future Model Years	22
2.7.1 <i>Modification of Key Terms</i>	22
2.7.2 <i>Termination</i>	22
3. Requirements for State Participation	24
3.1 Operational Requirements.....	24
3.1.1 <i>Legal Authority</i>	24
3.1.2 <i>Standardized Access Policy</i>	25
3.1.3 <i>Model Drug Carveout</i>	25
3.1.4 <i>Provider Reimbursement Requirements</i>	26
3.1.5 <i>Permissible State Expenses</i>	27
3.1.6 <i>Managed Care Alignment</i>	27
3.2 Agreements with Manufacturers	28
3.2.1 <i>VBP SRA for Medicaid Beneficiaries</i>	28
3.2.2 <i>Optional VBP Agreement for Separate CHIP Beneficiaries</i>	28
3.3 Beneficiary Access to Care.....	29
3.3.1 <i>Provider Network Adequacy</i>	29
3.3.2 <i>Beneficiary Transportation</i>	30
3.4 Data and Reporting.....	31
3.4.1 <i>Data Submissions</i>	31

3.4.2 Reporting.....	32
4. CMS Support	35
4.1 Learning System	35
5. Quality and Performance Monitoring.....	37
5.1 Enrollee Protections and Oversight.....	37
6. Evaluation	38
6.1 Rights in Data and Intellectual Property	38
7. Application	39
7.1 Application Process and Selection.....	39
7.1.1 State Engagement During Model Pre-Implementation	39
7.2 Submission Information	39
7.3 Model Timeline.....	40
7.4 Withdrawal of Application.....	41
Appendix A: Application Template	42

1. Background and General Information

1.1 Model Scope

The Centers for Medicare & Medicaid Services (CMS) is seeking applications for a voluntary Model (the Cell and Gene Therapy Access Model, or “the Model”) that tests whether a CMS-led approach to developing and administering outcomes-based agreements (OBAs) for cell and gene therapies (CGTs) improves Medicaid beneficiary access to innovative treatment, improves health outcomes for Medicaid beneficiaries, and reduces health care expenditures. While the Model is focused at this time on participation by state Medicaid programs, depending on state and manufacturer interest, the Model could also include beneficiaries in separate Children’s Health Insurance Programs (CHIP).¹

This request for applications (RFA) is for any state, the District of Columbia, and any U.S. territory that participates in the Medicaid Drug Rebate program (MDRP)² (hereinafter, “States”)³ and outlines Model design elements, Model eligibility criteria, and additional Model details. States that submit an approved application in response to this RFA will be eligible to become Model participants.

The Model was selected by the Secretary of Health and Human Services (HHS) for testing by the CMS Center for Medicare and Medicaid Innovation (the Innovation Center) in response to Executive Order 14087, “Lowering Prescription Drug Prices for Americans.”⁴ The Model was announced by the Innovation Center on January 30, 2024. The Innovation Center is conducting the Model under section 1115A of the Social Security Act.

1.1.1 General Approach

The Innovation Center is testing the impact of a voluntary Model wherein CMS facilitates the development and implementation of OBAs between States and Manufacturers.⁵ Within this Model, CMS will negotiate standard Key Terms⁶ directly with the Manufacturer. These OBAs may include outcomes-based rebates, volume-based rebates, and guaranteed rebate components.

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. The agreed-upon standardized Key Terms will then be communicated to all

¹ Inclusion of the separate CHIP population would be under a value-based purchasing arrangement.

² Under section 1927 of the Social Security Act. As of the date of publication of this RFA, Puerto Rico is the only U.S. territory that participates in the MDRP.

³ The specific State entity that may apply to the Model (and ultimately enter into a State Agreement) may be a state Medicaid agency, state health department, or other state agency with appropriate authority over the state Medicaid program (and CHIP, if applicable).

⁴ Becerra, X. “A Report in Response to the Executive Order on Lowering Prescription Drug Costs for Americans.” Department of Health and Human Services, 2023, available [here](#).

⁵ “Manufacturer” means an entity that holds the New Drug Application(s) (NDA(s)) / Biologics License Application(s) (BLA(s)) of a gene therapy with an FDA approved indication for the treatment of sickle cell disease.

⁶ “Key Terms” means the central parameters of the agreement negotiated with CMS, including rebate calculation and amounts, the duration of the agreement, data sharing arrangements, and any options or variations, that will form the basis for individual Supplemental Rebate Agreements between the Manufacturer and participating States.

States, who may, at their option, execute a State Agreement (SA) with CMS, thus also becoming participants in the Model. Participating States will adopt the Key Terms through a supplemental rebate agreement (SRA) with a participating Manufacturer.⁷ (See Section 2.5 for a description of the legal relationships between CMS, Manufacturers, and States. See Section 2.3.1 for additional details regarding required variation in the optional participation of separate CHIPs.)

CMS will support implementation of the Model through responsibilities such as implementing, monitoring, reconciling, and evaluating the financial and clinical outcomes specified in the Key Terms. In addition, the Innovation Center will conduct a robust model evaluation by an independent contractor. CMS will also conduct monitoring activities to ensure compliance with all aspects of the Model by States, Manufacturers, 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 (as described in Section 2.7). 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 test.

The Innovation Center anticipates testing this Model for 11 performance years, beginning on January 1, 2025. The Model, at this time, is limited to gene therapies approved or licensed by the FDA for the treatment of sickle cell disease (SCD) that are covered outpatient drugs under the MDRP (hereinafter, “Model Drugs”). Additional information regarding the Model timeline is set forth in Section 7.3.

1.1.2 Sickle Cell Disease

SCD is an inherited, genetic blood disorder that causes blood cells to become rigid and irregularly, abnormally shaped due to an abnormality in hemoglobin – the protein that carries oxygen throughout the body – resulting in blood flow obstruction, painful vaso-occlusive crises (VOCs), anemia, and serious complications including acute chest syndrome, stroke, and bacterial infections. This condition is the most prevalent genetic blood disorder in the nation, affecting more than 100,000 people in the United States, the vast majority of whom are African American.⁸

The Model is currently focused on gene therapies for SCD for several reasons:

- Medicaid is a disproportionate payer for individuals with SCD. SCD is a costly condition, particularly for the Medicaid program, as approximately 50-60% of people with SCD are enrolled in Medicaid.⁹ The total cost to the health system of SCD is estimated at \$2.98 billion per year in the United States.¹⁰ This estimation does not take into account the social costs of the disease, including lost time at school or work for both patients and, in many cases, caregivers.

⁷ The State-specific contracts will comport with applicable laws and regulations.

⁸ “About Sickle Cell Disease.” National Human Genome Research Institute, 2020, available [here](#).

⁹ Andelson, E., et al. “Medicaid Access & Landscape Review for Prescription Drugs Treating Sickle Cell Disease: Opportunities to Improve Access for Sickle Cell Disease Therapies.” Sick Cells & Avalere Health, 2022, available [here](#).

¹⁰ Huo, J., et al. “The Economic Burden of Sickle Cell Disease in the United States.” Value in Health, 2018, available [here](#).

- Historic health disparities and inequities experienced by the SCD population means that this Model may have a significant positive impact on access to care in this population. Though SCD affects all racial and ethnic groups, Black and Hispanic populations are disproportionately impacted.¹¹ People living with SCD regularly experience systemic health care disparities and racial bias in health care settings.^{12,13} Racial bias and treatment disparities in accessing health care among racial and ethnic minorities in the United States are well established, and individuals with SCD have inadequate access to specialized care and existing treatments, exacerbating the poor health outcomes and low life expectancy associated with SCD.¹⁴

In December 2023, the FDA approved two gene therapies for the treatment of SCD. Exagamglogene autotemcel (“Casgevy” or “exa-cel,” Vertex Pharmaceuticals and CRISPR Therapeutics) is approved for the treatment of patients 12 years of age and older with SCD and recurrent VOCs.¹⁵ Casgevy is manufactured by altering a person’s stem cells to induce the production of fetal hemoglobin, which is a form of oxygen-carrying hemoglobin that is naturally present during fetal development but generally ceases after birth.¹⁶ Lovotibeglogene autotemcel (“Lyfgenia” or “lovo-cel,” bluebird bio) is approved for the treatment of patients 12 years of age and older with SCD and a history of vaso-occlusive events (VOEs).¹⁷ Lyfgenia is manufactured by adding a functional copy of a modified globin gene into a patient’s stem cells.¹⁸ After FDA approval, the manufacturer of Casgevy set the list price at \$2.2 million per dose and the manufacturer of Lyfgenia set the list price at \$3.1 million per dose.¹⁹ The manufacturers have not publicly disclosed price concessions that they may offer.²⁰ The treatment process to receive these gene therapies is complex, similar to a bone marrow transplant, spanning months of outpatient and inpatient care. The major milestones in the patient care journey include:

- Patient identification for gene therapy; duration varies (outpatient).
- Disease management by a hematologist that specializes in SCD; duration varies (outpatient).

¹¹ Wilson-Frederick, S., et al. “Medicaid and CHIP Sickle Cell Disease Report, T-MSIS Analytic Files (TAF) 2017.” Centers for Medicare and Medicaid Services, 2021, available [here](#).

¹² “Data & Statistics on Sickle Cell Disease.” Centers for Disease Control and Prevention, 2024, available [here](#).

¹³ Assistant Secretary for Health. “Sickle Cell Disease.” Department of Health and Human Services, 2020, available [here](#).

¹⁴ Lee, L., et al. “Reducing Healthcare Disparities in Sickle Cell Disease: A Review.” Public Health Reports, 2019, available [here](#).

¹⁵ “Package Insert - CASGEVY (exagamglogene autotemcel), suspension for intravenous infusion.” Vertex Pharmaceuticals Incorporated, 2024, available [here](#).

¹⁶ “Vertex and CRISPR Therapeutics Present New Data on More Patients With Longer Follow-Up Treated With exagamglogene autotemcel (exa-cel) at the 2022 European Hematology Association (EHA) Congress.” CRISPR Therapeutics, 2022, available [here](#).

¹⁷ “Package Insert - LYFGENIA® (lovotibeglogene autotemcel) suspension for intravenous infusion.” bluebird bio, Inc., 2023, available [here](#).

¹⁸ Kanter, J., et al. “Biologic and Clinical Efficacy of LentiGlobin for Sickle Cell Disease.” New England Journal of Medicine, 2022, available [here](#).

¹⁹ Satija, B. “Vertex/CRISPR price sickle cell disease gene therapy at \$2.2 mln.” Reuters, 2023, available [here](#).

²⁰ These products may be covered outpatient drugs under the Medicaid Drug Rebate Program. As such, States would receive rebates mandated under section 1927 of the Social Security Act, and may pursue SRAs to obtain greater rebates.

- Evaluation for and patient education about gene therapy; lasts approximately 30 days (outpatient).
- Weaning off hydroxyurea and beginning chronic transfusion therapy; 2-3 months (outpatient).
- Cell harvesting that takes 3-9 days (inpatient).
- Modification of stem cells in a lab, during which time a patient waits at home over a period of 6-16 weeks.
- Optional fertility preservation; typically takes place while a patient is waiting for their cells to be modified, prior to chemotherapy (outpatient).
- Chemotherapy, which typically results in patient infertility, requires a stay of 7-9 days (inpatient).
- Modified stem cell product infusion, requiring a stay of 35-45 days (inpatient).
- Follow-up care for 15 years (outpatient). A typical follow-up would consist of weekly visits to the transplant center for the first month or two after discharge, then monthly for the next year, and then annually for 15 years.

Potential care delivery gaps and access barriers can arise at each step in the care journey. The CGT Access Model aims to address these gaps and barriers to maximize equitable access to gene therapies for eligible individuals. Through a separate Notice of Funding Opportunity (NOFO), CMS will outline optional activities related to equitable access to care for which Model funding will be available to States under a Cooperative Agreement.

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-centered criteria) and changes in federal spending in each model. The Secretary of HHS is authorized to expand the scope and duration of successful models, through rulemaking, that reduce spending without reducing quality of care, or that improve the quality of patient care without increasing spending.²¹

1.3 Waiver Authority

Under section 1115A(d)(1) of the Act, the Secretary of HHS may waive such requirements of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), and 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 testing models. In general, CMS believes such waivers are not necessary to test the Model for the Medicaid population. However, to the extent that Manufacturers and States execute value-based purchasing arrangements under the Model that include Model Drugs that are administered to beneficiaries under separate CHIPs,

²¹ Social Security Act § 1115A [42 U.S.C. § 1315a], "Center for Medicare and Medicaid Innovation."

the Model could affect Manufacturers' calculations of average sales price (ASP) for Model Drugs in a manner that could disincentivize Manufacturer participation with respect to the separate CHIP population and impede the Innovation Center's ability to observe the impacts of the Model. To help avoid such disincentivizing effects and ensure the Innovation Center may observe and measure Model impacts, under the authority in section 1115A(d)(1) of the Act, CMS will issue a Model-specific waiver of requirements of 1847A(c) to the extent necessary to exclude from the calculation of the Manufacturers' ASP units of Model drugs administered to participating separate CHIP beneficiaries, thereby avoiding impacts on a Manufacturer's calculation of ASP for a Model Drug. Consistent with section 1847A(c)(5) of the Act, CMS will issue program instructions to further describe how the waiver will impact a Manufacturers' calculation of ASP for a Model Drug. For example, CMS envisions that Manufacturers will take reasonable steps and make reasonable assumptions to exclude applicable units from this calculation. Notwithstanding such a waiver, Manufacturers must continue to comply with all other applicable ASP reporting requirements. For example, Manufacturers who misrepresent or fail to report Model Drug ASP data would remain subject to civil monetary penalties, as applicable and described in sections 1847A and 1927(b) of the Act and codified in regulations at 42 CFR § 414.806.

1.4 CMS-Sponsored Model Safe Harbor

Manufacturers will be required to financially support a defined scope of fertility preservation services at no cost to beneficiaries who receive treatment within the Model or to other payers. In doing so, CMMI seeks to test whether manufacturer payment, rather than beneficiary or Medicaid payment, for fertility preservation services (defined further in the [Manufacturer Request for Applications](#) published on March 7, 2024) would improve health outcomes, by reducing long-term health care utilization for patients with SCD, and produce savings for the federal government and states. Specifically, Manufacturer payment for fertility preservation services may yield learning that could inform state Medicaid agencies' future decision-making regarding coverage for fertility preservation services in connection with gene therapy and the potential for contracting arrangements with Manufacturers to fund the cost of treating adverse outcomes related to use of the manufacturer's therapy.

To be eligible to qualify for protection under the "CMS-sponsored model" safe harbor at 42 CFR § 1001.952(ii), Manufacturers must meet program requirements, as outlined in the Manufacturer RFA, 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.²² CMS may detail additional safeguards and reporting requirements regarding these activities in the Manufacturer 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 Cell & Gene Therapy Access Model and could differ in scope or design from waivers and safe harbor protections in other situations, including other programs or models.

²² OIG, HHS Office of Inspector General Fact Sheet, Final Rule: Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements (November 2020), available [here](#).

2. Description of Model

2.1 Purpose and Concept

Gene therapies are a rapidly growing class of transformative, potentially one-time, medicines designed to treat previously intractable diseases.^{23,24} Through these novel technologies, it may be possible to correct the underlying causes of a disease, restore functionality, or halt the progression of devastating illnesses, such as SCD. However, the combination of a) the relative novelty of these products; b) the rare indications on which most gene therapies focus; and c) limited utilization and outcomes data to date, means the long-term curative potential of these therapies remains uncertain. In addition, the typically high cost of these therapies may present affordability and financial predictability challenges for state Medicaid programs and other payers, despite potential downstream savings that may result from avoided progression of these diseases and ongoing treatment costs. In response to these pressures, some payers, including state Medicaid agencies, are using cost containment and utilization management strategies, as legally permissible, that can have the effect of limiting access to gene therapies.²⁵

One way to capture the positive potential of novel therapies, while addressing the uncertainty regarding their clinical outcomes, is by using an OBA, wherein a payer's spending for a gene therapy varies based on whether a pre-specified clinical outcome(s) is achieved over a defined period of time. There are a number of possible structures for an OBA, but in its simplest form, a payer and a manufacturer enter into a contract that defines Outcome Measures²⁶ (clinical values, patient-reported outcome (PRO) measures, or utilization of care measures) and a Measurement Period.²⁷ Over the course of the Measurement Period, an entity (such as the payer) tracks the agreed-upon Outcome Measures applicable to an individual beneficiary or population. If pre-defined thresholds for the Outcome Measures are not met, then rebates may be due to the payer, from the manufacturer, at agreed-upon intervals. A retrospective analysis and reconciliation of rebates (i.e., final settlement of the rebate amounts owed and paid) occurs following the conclusion of the Measurement Period.

State Medicaid agencies today can, and do, independently negotiate rebates through SRAs permitted under CMS-authorized State Plan Amendments (SPAs). Specifically, states may enter into SRAs as long as the agreements result in rebates equal to or greater than the federal statutory rebate states receive from the MDRP.²⁸ A number of states have received authorization from CMS to enter specifically into Value-Based Purchasing SRAs (VBP SRAs), which allow them to operate or enter into OBAs. However, States have reported that their ability to pursue OBAs for gene therapies is curtailed by the complexity in negotiating endpoints and thresholds with manufacturers, the States' lack of leverage stemming from

²³ "Advancing Health Equity." Centers for Disease Control and Prevention, 2022, available [here](#); Nowogrodzki, A. "No adult left behind: bridge the health-care gap for sickle-cell disease." *Nature*, 2021, available [here](#).

²⁴ Cell and gene therapy represent overlapping fields of biomedical research with similar therapeutic goals, which target DNA or RNA inside or outside the body. Gene therapy involves making changes to a patient's genetic material, or DNA, whereas cell therapy involves the infusion or transplantation of whole cells into a patient.

²⁵ "Chapter 1: Addressing High-Cost Specialty Drugs." June 2021 Report to Congress on Medicaid and CHIP. Medicaid and CHIP Payment and Access Commission, 2021, available [here](#).

²⁶ "Outcome Measures" mean the agreed-upon clinical or utilization-based factors that are linked to rebates.

²⁷ "Measurement Period" means the time period following administration of the drug during which Outcome Measures will be monitored.

²⁸ 42 CFR § 447.502 (defining "CMS-authorized supplemental rebate agreement").

the lack of alternative treatments and statutory coverage obligations, as well as the burden of data collection and continuous level of effort for evaluation over multiple years.²⁹

Through the Model, the Innovation Center will test whether a partnership among CMS, Manufacturers and States related to gene therapies could offer better and more equitable access to treatment for beneficiaries with rare and severe diseases, including those in underserved communities, and how that access may translate into improved quality and health outcomes.

For State participants, the Model aims to reduce the burden of negotiating and implementing OBAs for gene therapies and potentially facilitate the adoption of OBAs in more states. This Model could also facilitate savings to, and improve stability for, States due to financial predictability, greater rebates, and long-term reductions in health expenditures. Through a standardized policy across participating States, this Model also may ease burdens on beneficiaries and providers by improving efficiency in navigating utilization management in the patient's care journey.

In addition, the Model is expected to expand access to critical supportive services that may remove barriers for beneficiaries for whom the Model Drug is clinically appropriate and would improve health outcomes. This includes, but is not limited to, care coordination, access to SCD specialists, access to behavioral health providers and fertility preservation services. Finally, CMS will take a central role in data collection and monitoring to facilitate the adoption and implementation of OBAs and related monitoring, helping to relieve participants, both Manufacturers and States, of some of that burden. Overall, the Model aims to reduce the burden to States and Manufacturers of operating an OBA, while maximizing access to novel and transformative therapies for beneficiaries.

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. Eligible respondents to this RFA will execute a State Agreement with CMS to become a Model participant. Responding to this RFA does not obligate the State to become a Model participant.

At this time, the Model is exclusively soliciting applications from States to participate in the Model with respect to gene therapies for SCD. In future years, this Model may solicit applications with respect to CGTs indicated to treat other conditions.

2.2 Model Participation

The Cell & Gene Therapy Access Model is voluntary to all participants. While this RFA only applies to States, information regarding Manufacturer participation is included within this document for the reference of States and to aid in the responses to this RFA. The legal agreements described throughout this Section are outlined in Section 2.5.

2.2.1 Manufacturer Participation

In a separate [Manufacturer RFA](#), released on March 7, 2024, CMS invited eligible manufacturers of SCD gene therapies to apply to participate in the Model. Eligible Manufacturer respondents were invited to participate in the Model pre-implementation period.

²⁹ Becerra, X. "A Report in Response to the Executive Order on Lowering Prescription Drug Costs for Americans." Department of Health and Human Services, 2023, available [here](#).

The Model pre-implementation period began May 1, 2024 and ends November 29, 2024. During the Model pre-implementation period, CMS and Manufacturers will negotiate the standard Key Terms. If an agreement between parties is reached, then the Manufacturer must execute a PA with CMS before the conclusion of the pre-implementation period. See Section 7 for more details about the Model timeline.

A Manufacturer that participates in the Model pre-implementation period and signs a PA by November 29, 2024 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 before 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. If a State accepts the Key Terms, the Participating Manufacturer must enter into a VBP SRA incorporating the Key Terms with that State. Variation in Key Terms will only be permitted as necessary to comport with State laws and regulations and must be approved by CMS. A Participating Manufacturer may not exclude any States that elect to participate.

If additional Manufacturers receive FDA approval for gene therapies for SCD after May 1, 2024, CMS may open a new application cycle to allow eligible Manufacturers to participate in negotiation with CMS. In the future, CMS may release an additional RFA pertaining to other conditions for manufacturers that market FDA-approved gene therapies for such conditions. Additional manufacturers may be eligible to participate in negotiation under this Model with CMS and join the Model at that time.

2.2.2 State Participation

Model participation is open to all states, the District of Columbia, and all U.S. territories that participate in the MDRP. States may respond to this RFA even if they did not submit a preliminary non-binding [Letter of Intent](#) in response to the Model announcement.

CMS encourages States to engage with CMS as early as possible regarding potential participation in the Model. Prior to the application deadline, CMS will host a webinar to provide details about the Model and answer questions from potential State applicants. Information about the webinar will be provided to the National Association of Medicaid Directors and will be posted on the Innovation Center [Model website](#). States may contact CGTModel@cms.hhs.gov with questions about the Model.

States will apply to participate in the Model after the Key Terms have been negotiated and at least one Manufacturer becomes a Model participant (i.e., executes a PA prior to November 29, 2024). In order to participate in the Model, States must respond to this RFA by no later than February 28, 2025 and execute a State Agreement (SA) with CMS by no later than June 1, 2025. State obligations in the SA are described in detail in Section 3. Upon signing an SA, a State becomes a Model participant.

State participants must then begin performance in the Model on a pre-selected date of their choosing from January 1, 2025 to January 1, 2026 (their “Performance Period Start Date,” see Section 2.4). By the Performance Period Start Date, State participants must adopt the Key Terms (i.e., have an active VBP SRA with the Manufacturer that reflects the Key Terms, and implement the Key Terms in accordance with Model requirements in Section 3) for at least one Model Drug (see Section 2.6.1). States must

include beneficiaries enrolled in fee-for-service (FFS) Medicaid by the beginning of their Performance Period and beneficiaries enrolled in Medicaid managed care plans³⁰ by no later than January 1, 2026. This means that a State can either begin performance in the Model with both FFS and managed care beneficiaries at the same time, or begin performance with only its FFS beneficiaries and add its managed care beneficiaries at a later date that is no later than January 1, 2026.

To facilitate model implementation, State applicants must respond to this RFA at least 10 business days prior to their Performance Period Start Date, but no later than February 28, 2025. States that do not sign an SA by June 1, 2025 will not be allowed to participate in the Model, except at CMS discretion. CMS may allow States to join the Model at a later date in cases such as, but not limited to, the following:

- If a Manufacturer of a new gene therapy for SCD joins during the course of the Model (as described in Section 2.2.1), CMS may open a new application cycle to allow non-participating States to join the Model. States that join the Model during this application cycle will be eligible to adopt only the Key Terms negotiated with the new participating Manufacturer.
- If a territory does not participate in the MDRP as of February 28, 2025, but joins the MDRP during the course of the Model, CMS may open a new application cycle to allow the newly eligible territory to participate in the Model. Territories that join the Model during this application cycle will be eligible to adopt Key Terms negotiated with any participating Manufacturer.

CMS will inform participating Manufacturer(s) upon acceptance of a new State participant. States that participate in this Model may not alter or make additions to the Key Terms except as necessary to comport with State laws and regulations and as approved by CMS.

States that respond to this RFA may also choose to apply for optional Model funding from CMS through a State Notice of Funding Opportunity (NOFO). The funding opportunity will be non-competitive, meaning that all States that participate in the Model and can meet the State requirements for Model funding will be able to receive funding. Two types of funding for State participants will be available under the Model, pending the availability of funds:

- 1) Implementation Funding.** States may use implementation funding to support required and optional Model planning and implementation activities, such as staff time and infrastructure costs. For states that choose to partner with community-based/non-profit organizations to carry out optional Model activities (which will be listed in the State NOFO), states may also use implementation funding to pay for costs to such entities.
- 2) Milestone Funding.** Milestone funding will be available to States that achieve performance milestones related to increasing equitable access to SCD gene therapy and promoting multi-disciplinary, comprehensive care for beneficiaries who are considering or receiving SCD gene therapy.

More details will be provided in the NOFO later this summer. To be considered for funding under the NOFO, the State must apply to both this State RFA and the NOFO. States may apply for funding by

³⁰ Medicaid managed care plans include Medicaid managed care organizations (MCOs) as well as prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs) as defined in 42 CFR § 438.2.

responding to the NOFO by no later than February 28, 2025. States awarded funding under the NOFO will execute a Cooperative Agreement with CMS. The Cooperative Agreement will start as early as June or July 2025.

2.3 Model Population

The Model population includes Medicaid and Medicaid expansion CHIP beneficiaries in fee-for-service and Medicaid managed care who do not have other coverage that is the primary payer for a Model Drug (hereinafter, “Medicaid beneficiaries”). Manufacturers and States will have the option to include separate CHIP beneficiaries alongside Medicaid beneficiaries. See Section 2.3.1 for more information on the optional inclusion of separate CHIP beneficiaries in the Model.

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 payer, or (2) if the Manufacturer and State engage in a separate VBP arrangement for separate CHIP beneficiaries, a separate CHIP that participates in the Model.

2.3.1 Children’s Health Insurance Program (CHIP)

Inclusion of beneficiaries in Title XXI-funded Medicaid expansion CHIPs (that is, CHIPs in which the State receives Title XXI funding to expand Medicaid eligibility to optional targeted low-income children) is required. All requirements for Medicaid beneficiaries in this RFA apply to both Title XIX-funded Medicaid and Title XXI-funded Medicaid expansion CHIPs.

Inclusion of beneficiaries in separate CHIPs is optional for Manufacturers and States. CMS and the Manufacturers may, during Key Term negotiation, structure supplemental Key Terms that constitute a VBP arrangement that meets the definition of such an arrangement at 42 CFR § 447.502 (hereinafter, “separate CHIP Key Terms”). The separate CHIP Key Terms would be distinct from the Key Terms for Medicaid program supplemental rebates and would satisfy requirements under CMS’s existing “multiple best price” reporting framework.

Negotiated Key Terms regarding volume rebates or guaranteed rebates, as distinct from outcomes-based rebates, will not qualify under the “multiple best price” reporting framework and may be excluded in the agreement reached for separate CHIP beneficiaries. Unless explicitly noted (or otherwise not permissible by law), all requirements regarding the Key Terms discussed throughout this RFA must apply to any agreement reached for the separate CHIP population.

See Section 1.3 for a discussion of Model-specific waivers related to exclusion from the calculation of ASP units of Model Drugs administered to participating separate CHIP beneficiaries.

In response to this RFA, State applicants must indicate whether they intend to include separate CHIP beneficiaries in the Model (see [Application Item 3a](#)).

2.4 Performance Period

The Model is expected to consist of eleven Performance Years (PYs). For each State, the Model Performance Period will begin on a date of the State’s choosing from January 1, 2025 to January 1, 2026. In other words, States may choose whether to begin performance during PY1 (January 1, 2025 –

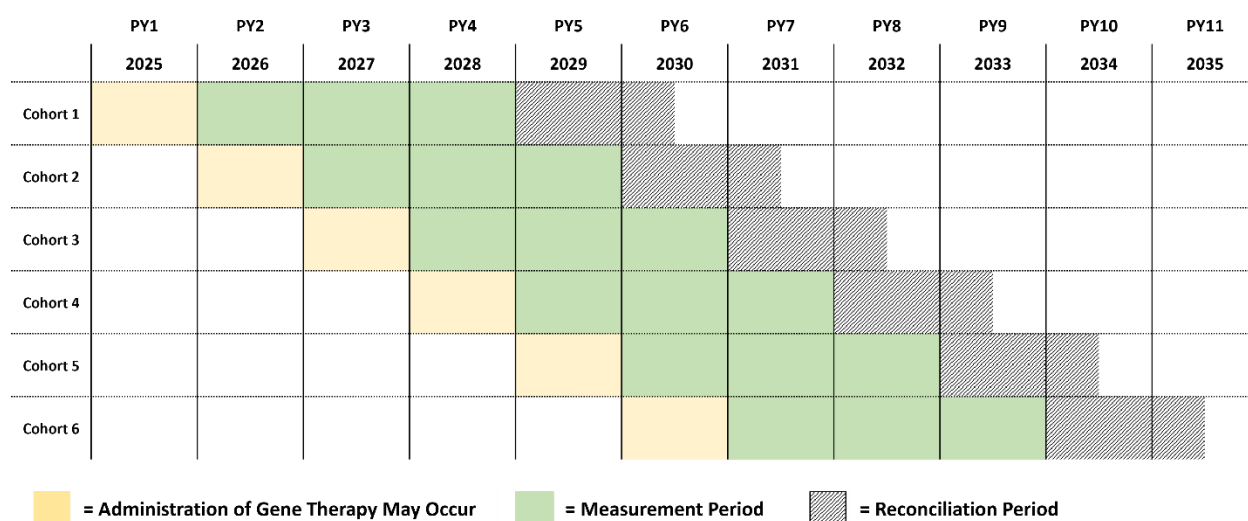
December 31, 2025), but must begin performance by the start of PY2 (January 1, 2026). For all participating States, the Model Performance Period is anticipated to conclude at the end of PY11 on December 31, 2035, unless the State’s participation in the Model is terminated earlier (see Section 2.7.2).

Depending on the CMS-Manufacturer negotiated Key Terms, the OBA Term may be as long as PYs 1-6.³¹ Some state obligations will only apply for the duration of the OBA Term, and other state obligations extend for the duration of the Model, as described in Section 3.

An example that illustrates how periods for gene therapy administration, measurement, and reconciliation specified in the Key Terms may overlap throughout the Model Performance Period is included below and in Figure 1.

- Example:** Administration of gene therapy would occur during PYs 1-6, and beneficiaries who receive a Model Drug in each PY would represent a different cohort. For each cohort, measurement of outcomes would begin the year following administration of gene therapy, and final reconciliation of rebates would follow the measurement period.

Figure 1: Example Model Performance Period



If States begin performance during PY1 (January 1, 2025 – December 31, 2025), States must include in the Model, at a minimum, Medicaid beneficiaries enrolled in fee-for-service (FFS) Medicaid. States may also choose to include Medicaid beneficiaries enrolled in Medicaid managed care plans and/or separate CHIP beneficiaries. To enable interested States to join the Model as early as possible, some Model requirements will not apply during PY1, as described throughout Section 3. If a state begins performance after January 1, 2025 but before January 1, 2026, PY1 will be less than a full calendar year.

³¹ "OBA Term" means the time period for which the Key Terms are applicable. In other words, the OBA term is the period of time during which State financial arrangements with the Manufacturer governed by the OBA apply for beneficiaries who receive the Model Drug. The OBA Term is expected to be no more than 6 years, and no related obligations are expected to extend beyond 2035.

All participating States must begin performance no later than the start of PY2 (January 1, 2026).

Starting in PY2, States must include in the Model all Medicaid beneficiaries (both FFS and managed care). If States choose to include separate CHIP beneficiaries in the Model, they must be included by the start of PY2. PY2 and all subsequent PYs will be full calendar years.

In its response to this RFA, the State applicant must specify the following three Start Dates:

- **Performance Period Start Date** – The date by which the State commits to begin performance in the Model. By this date, the State must include beneficiaries enrolled in fee-for-service Medicaid in the Model. The State may select a date from January 1, 2025 to January 1, 2026. States should note that their application in response to this RFA must be submitted at least 10 business days prior to their requested Performance Period Start Date. (See [Application Item 2a.](#))
- **Managed Care Start Date** – The date by which the State commits to include beneficiaries enrolled in Medicaid managed care plans in the Model.³² The State may select a date from January 1, 2025 to January 1, 2026. The Managed Care Start Date may be the same or later than the Performance Period Start Date. (See [Application Item 2b.](#))
- **Separate CHIP Start Date (if applicable)** – The date by which the State commits to include separate CHIP beneficiaries in the Model, if the State chooses to do so (provided that CMS-Manufacturer negotiated separate CHIP Key Terms are available for the State-Selected Model Drug(s)). The State may select a date from January 1, 2025 to January 1, 2026. The separate CHIP Start Date may be the same or later than the Performance Period Start Date. (See [Application Item 3a.](#))

If a State participant anticipates that it will not be able to fulfill participation requirements by a specified Start Date, the State must promptly notify CMS and may request to modify the specified Start Date.

2.5 Legal Agreements

This Model will include a partnership among CMS, participating Manufacturers, and participating States. This partnership will be executed through multiple legal and contractual mechanisms. Legal relationships are enumerated in both Figure 2 and Table 1.

³² A beneficiary must be included in the Model by the Managed Care Start Date if a Medicaid managed care plan is responsible for providing medical services related to the State-Selected Model Drug(s) (defined in Section 2.6.1) for that beneficiary, even if a State chooses to carve the State-Selected Model Drug(s) itself out of the managed care contract.

Figure 2: Legal Agreements

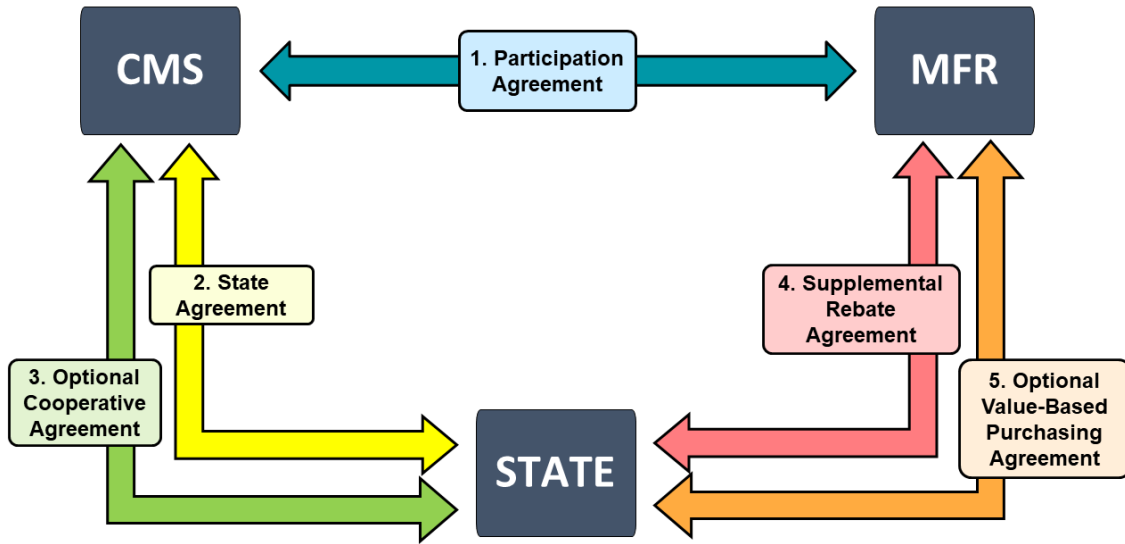


Table 1: Legal Agreements

1. CMS and Manufacturer: Manufacturer Participation in Model (Participation Agreement)
<p>Anticipated Effective Dates: No later than January 1, 2025 – December 31, 2035</p> <p>Description:</p> <ol style="list-style-type: none"> 1) Formalizes Manufacturer Participation in the Model. 2) Specifies “Key Terms” negotiated with CMS, which will be included in the OBAs established with participating States. Key Terms may address, but are not limited to: <ol style="list-style-type: none"> a. Duration of OBA Term, Measurement Period, Volume Accrual Period, and Reconciliation Period b. Pricing related to Outcome-Based Rebates, Guaranteed Rebates, Volume-Based Rebates c. Outcome Measures and Outcome Measure Benchmarks d. Fertility Preservation Services e. Access Policy f. CMS Responsibilities g. Rebate Documentation h. Termination, Renewals, Renegotiation or Alterations i. Coverage Shifts 3) Specifies terms of CMS and Manufacturer data exchange. 4) Specifies terms of potential Model renewal.

2. CMS and State: State Participation in Model (State Agreement)

Anticipated Effective Dates: January 1, 2025*** – December 31, 2035

Description:

- 1) Formalizes the terms of State participation in the Model.
- 2) Requires States to include Medicaid beneficiaries in the Model when Medicaid is the primary payer for a Model Drug. Beneficiaries enrolled in fee-for-service Medicaid must be included by the beginning of the Performance Period. Beneficiaries enrolled in Medicaid managed care plans must be included by no later than January 1, 2026.
- 3) Allows States to include separate CHIP beneficiaries in the Model by no later than January 1, 2026, subject to separate, optional agreement with Manufacturers.
- 4) Establishes State requirements for Model participation. For instance, States must:
 - a. Have or obtain the necessary authority to implement the Model, including CMS approval of a SPA to enter into a VBP SRA.
 - b. Establish a standardized Model Drug access policy consistent with the CMS-Manufacturer negotiated Key Terms.
 - c. Carve Model Drugs out of an inpatient payment bundle, if necessary, and pay for the Model Drugs in a manner such that rebates under the MDRP apply.
 - d. Require providers to follow Model-specific requirements related to registry participation and claims submission.
 - e. Ensure that applicable Medicaid managed care plan policies align with Model requirements.
 - f. Execute a VBP SRA with a participating Manufacturer that incorporates the CMS-Manufacturer negotiated Key Terms.
 - g. If applicable, execute a VBP agreement for separate CHIP beneficiaries with a participating Manufacturer that incorporates the CMS-Manufacturer negotiated separate CHIP Key Terms.
 - h. Attest that included beneficiaries will have access to gene therapy care with at least one qualified SCD gene therapy provider within the state or in another state.
 - i. Attest that the State will ensure necessary transportation and related travel expenses to Model beneficiaries (and their caregivers, as applicable).
 - j. Meet minimum data requirements and conduct data quality activities.
 - k. Submit reports to CMS on Model implementation.

*** States will sign SAs on a rolling basis following CMS acceptance of their applications (which may be submitted between December 2024 and February 2025).

3. (Optional) CMS and State: Model Funding (Cooperative Agreement Award)

Anticipated Effective Dates: June/July 2025 – December 31, 2035

Description:

- 1) Outlines funding for activities related to Model implementation (e.g., data collection, coordination with managed care plans and out-of-state providers, partnerships with community-based organizations, etc.).
- 2) Describes performance milestones for which states may receive funding related to increasing equitable access to SCD gene therapy and promoting multi-disciplinary, comprehensive care for beneficiaries who are considering or receiving SCD gene therapy.

4. Manufacturer and State: Outcomes-Based Agreement (Value-Based Purchasing Supplemental Rebate Agreement)

Anticipated Effective Dates: January 1, 2025* – December 31, 2030**

Description:

- 1) Formalizes all supplemental rebates as negotiated by CMS and the Manufacturer.
- 2) Specifies “Key Terms” negotiated by CMS and the Manufacturer. Key Terms may include, but are not limited to:
 - a. Duration of OBA Term, Measurement Period, Volume Accrual Period, and Reconciliation Period
 - b. Pricing related to Outcome-Based Rebates, Guaranteed Rebates, Volume-Based Rebates
 - c. Outcome Measures and Outcome Measure Benchmarks
 - d. Fertility Preservation Services
 - e. Access Policy
 - f. CMS Responsibilities
 - g. Rebate Documentation
 - h. Termination, Renewals, Renegotiation or Alterations
 - i. Coverage Shifts

* May begin on a date of the State's choosing from January 1, 2025, to January 1, 2026.

** Ends at the conclusion of the OBA Term, which will be part of the Key Terms subject to CMS-Manufacturer negotiation.

5. (Optional) Manufacturer and State: Inclusion of separate CHIP Population (Value-Based Purchasing Agreement)

Anticipated Effective Dates: January 1, 2025* – December 31, 2030**

Description:

- 1) Formalizes the rebates related to the OBA as negotiated by CMS.
- 2) Specifies “separate CHIP Key Terms” negotiated by CMS and the Manufacturer. Separate CHIP Key Terms may include, but are not limited to:
 - a. Duration of OBA Term, Measurement Period, and Reconciliation Period
 - b. Pricing related to Outcome-Based Rebates
 - c. Outcome Measures and Outcome Measure Benchmarks
 - d. Fertility Preservation Services
 - e. Access Policy
 - f. CMS Responsibilities
 - g. Rebate Documentation
 - h. Termination, Renewals, Renegotiation or Alterations
 - i. Coverage Shifts

* May begin on a date of the State's choosing from January 1, 2025 to January 1, 2026.

** Ends at the conclusion of the OBA Term, which will be part of the Key Terms subject to CMS-Manufacturer negotiation.

2.6 Key Terms

CMS will negotiate with Manufacturers to determine the “Key Terms” of the Model. Key Terms means the central parameters of the agreement negotiated with CMS, including rebate calculation and amounts, the duration of the agreement, data sharing arrangements, and any options or variations, that will form the basis for individual SRAs between the Manufacturer and participating States.

The negotiated Key Terms will be disclosed to States in December 2024. Separate CHIP Key Terms that CMS and Manufacturers have negotiated for separate CHIP beneficiaries will also be disclosed, if applicable (see Section 2.3.1). After the Key Terms have been disclosed, States may submit an application to participate in the Model in response to this RFA.

The Key Terms may include the following (Table 2), but States should not consider the list below as being complete or binding. States may refer to the [Manufacturer RFA](#) published on March 7, 2024 for more details about the potential Key Terms.

Table 2: Key Terms

Key Term	Description
<i>Access Policy</i>	The State coverage policy for the Model Drug, including utilization management policies, such as prior authorization criteria. Such access policies would be standardized across all participating States’ Medicaid fee-for-service and Medicaid managed care beneficiaries unless necessary to diverge to

	comply with state law. ³³ States may create their own criteria and policies so long as they are no more restrictive than the standardized access policy.
<i>CMS Responsibilities</i>	CMS’s role in operationalizing the Key Terms. This includes, but is not limited to, supporting States and Manufacturers with the implementation of the Model and the OBA. CMS will be responsible for gathering, aggregating, and analyzing data, as well as assessing whether the Outcome Measure Benchmarks are met. CMS will determine the resulting financial obligations and share reports with States and Manufacturers.
<i>Coverage Shifts</i>	How to consider patients who have a change in healthcare coverage after receiving the Model Drug but before the collection of all data relevant to Outcome Measures.
<i>Fertility Preservation Services</i>	CMS will require participating Manufacturers to provide payment for certain fertility preservation services for individuals who receive a Model Drug.
<i>Guaranteed Rebates</i>	Rebates provided for the Model Drug that are applied to all units, regardless of outcomes or volume. These guaranteed rebates are specific to the Model and are in addition to the existing statutory rebates required under the MDRP.
<i>Measurement Period</i>	The time period following administration of the Model Drug during which Outcome Measures for an individual or cohort will be monitored.
<i>OBA Term</i>	The time period for which the Key Terms are applicable. In other words, the OBA term is the period of time during which State financial arrangements with the Manufacturer governed by the OBA apply for beneficiaries who receive the Model Drug. The OBA Term is expected to be no more than 6 years, and no related obligations are expected to extend beyond 2035.
<i>Outcome Measure Benchmarks</i>	The measurable thresholds at which the Outcome Measure performance will result in a rebate. Outcome Measure Benchmarks will be assessed at agreed upon performance assessments throughout the Measurement Period. The number and timing of performance assessments are encompassed within this Key Term.

³³ Manufacturers and States will have the option of including their separate CHIP beneficiaries in the OBA, discussed further in Section 2.3.1.

<i>Outcome Measures</i>	The agreed-upon measures that are linked to rebates. If certain outcomes following treatment with a gene therapy are not achieved, then the outcomes-based rebate is triggered.
<i>Outcome-Based Rebates</i>	The rebate amount paid by the Manufacturer due to failure to reach an Outcome Measure Benchmark. Can be a calculation based on pricing.
<i>Rebate Documentation</i>	The materials and data required to confirm that an outcome-based or volume-based rebate is owed to the State.
<i>Reconciliation Period</i>	The time period following the conclusion of the Measurement Period in which final performance measurement, financial settlement and payment of rebates will occur. The Reconciliation Period may include interim and final calculation and payment of rebates.
<i>Termination, Renewals, Renegotiation or Alterations</i>	How to proceed with any termination, renewals, alterations, or renegotiations of the Key Terms throughout the duration of the Model. This includes processes for Manufacturer or State withdrawal from Model participation.
<i>Volume Accrual Period</i>	The time period in which additional units of the Model Drug count towards the volume-based rebate before resetting to baseline.
<i>Volume-Based Rebates</i>	The amount paid by Manufacturer based on the number of eligible units of the Model Drug counted during the Volume Accrual Period.

2.6.1 Adoption of Key Terms

To participate in the Model, States must select at least one Model Drug from a participating Manufacturer (hereinafter, “State-Selected Model Drug(s)”). States must then adopt the applicable Key Terms (i.e., have an active VBP SRA with the Manufacturer(s) of the State-Selected Model Drug(s) that reflects the Key Terms, and implement the Key Terms in accordance with Model requirements in Section 3). In response to this RFA, State applicants must specify the State-Selected Model Drug(s) (see [Application Item 4a](#)). States should note that the Model does not waive a State’s obligation to cover non-selected Model Drug(s) under the MDRP, subject to MDRP formulary requirements as described in Section 1927(d) of the Social Security Act.

CMS and participating Manufacturer(s) may negotiate Key Terms applicable to States that choose the Manufacturer’s Model Drug as the only preferred drug (e.g., additional pricing concessions associated with preferred status or reduced pricing concessions associated with non-preferred status). Additionally, CMS and participating Manufacturers may negotiate additional Key Terms applicable to States that do not grant preferential status for one Model Drug over another. In response to this RFA, State applicants

must indicate whether the State intends to grant preferred status to any of the State-Selected Model Drug(s) (see [Application Item 4b](#)).

State participants may change their State-Selected Model Drug(s) at annual renewals of the VBP SRA during the course of the Model, so long as they continue to meet the participation requirements with respect to at least one Model Drug at all times. If a State participant wishes to change the State-Selected Model Drug(s), the State must notify CMS and submit applicable information to CMS for approval. The State must continue all data collection and rebate reconciliation activities for beneficiaries who received the previous State-Selected Model Drug(s).

Variation in Key Terms are only permitted as necessary to comport with State laws and regulations and must be approved by CMS. In response to this RFA, State applicants may propose any such variation to the Key Terms (see [Application Item 4c](#)). During the course of the Model, if a State participant requires variation in Key Terms to comport with changes to State laws or regulations, the State must submit proposed changes to CMS for approval.

2.7 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 and SAs.

2.7.1 Modification of Key Terms

CMS understands that participating States may have nuanced and individualized contracting processes that may require, among other accommodations, annual renewals for the VBP SRA. These annual renewals are allowable under the Model, as long as the Key Terms are adopted at each renewal. The Manufacturer must agree to offer the Key Terms, as agreed by the Manufacturer and CMS, each year to States for the duration of the OBA Term as a term of Model participation.

CMS and Manufacturers will negotiate standard language regarding termination and renewals of the Key Terms. The Manufacturer will agree to offer the Key Terms to States, subject to annual VBP SRA renewals, during the OBA Term. A participating State may include additional language regarding termination and renewals in their VBP SRA as required by State laws or regulations.

The Key Terms will specify the circumstances in which renegotiation would occur (e.g., changes in the FDA labeling, new clinical evidence, or the approval of a new gene therapy for the treatment of SCD). If renegotiation between CMS and the Manufacturer results in prospective change to the Key Terms, States would have an opportunity to execute new VBP SRAs with any participating Manufacturer or terminate Model participation with respect to future PYs.

2.7.2 Termination

The State Agreement (SA) resulting from an approved response to this RFA shall commence no later than January 1, 2026 and continue until the end of the Model (anticipated to be December 31, 2035), subject to earlier termination as provided in the SA. CMS reserves the right to terminate a 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 SA, or as otherwise specified in the SA or required

by Section 1115A(b)(3)(B) of the Social Security Act. A State may voluntarily terminate their SA with CMS and participation in the Model, subject to terms that will be outlined in the SA.

3. Requirements for State Participation

Requirements for State participation will be established in the State Agreement (SA). A State must execute an SA with CMS by no later than June 1, 2025 to become a participant in the Model. States will be eligible to sign an SA if the State submits a timely and complete application in response to this RFA, and CMS accepts the State's application. Upon signing an SA, a State becomes a Model participant.

State obligations in the SA are described in this section. CMS will offer direct technical assistance to all State participants participating to support them in implementing these Model requirements. Additionally, States may choose to apply for funding for activities related to Model implementation (among other things) through the NOFO. State participants that are awarded funding will execute a separate Cooperative Agreement with CMS governing optional Model funding (see Section 2.5.3). In the case of any conflict between the State Agreement and the Cooperative Agreement, the State Agreement shall govern. The State must notify CMS of the potential conflict, and CMS will work with the State to resolve the conflict to the extent possible.

Requirements in Sections 3.1 to 3.2 will apply for the duration of the OBA Term (in the example in Figure 1, PYs 1-6). Requirements in Section 3.3 will apply for the duration of the OBA Term plus the duration of the Measurement Period (combined, in the example in Figure 1, PYs 1-9). Requirements in Section 3.4 will apply for the duration of the Model (in the example in Figure 1, PYs 1-11).

3.1 Operational Requirements

State participants must implement legal/policy, operational, and system requirements to support the Model. These may include the following:

3.1.1 Legal Authority

Have, or obtain, the necessary authority to implement the Model, including CMS approval of a State Plan Amendment (SPA) to enter into a VBP SRA.

CMS does not anticipate that States will *require* new federal authority to participate in this Model. However, State participants must have an approved State Plan Amendment (SPA) allowing them to enter value-based purchasing (VBP) supplemental rebate agreements (SRAs). Depending on State Medicaid program design, States may also need other program waivers or state-level legislative changes to implement the Model. States should consider any impact on existing section 1115 demonstrations prior to entering the Model. States are welcome to contact CMS to discuss State-specific program requirements.

In response to this RFA, State applicants must indicate whether they will need a SPA, Medicaid section 1115 demonstration authority, or other program waiver to implement the Model (see [Application Item 5a](#)). 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/section 1115 demonstration authorities.

If a SPA or Medicaid section 1115 demonstration authority 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 or Medicaid section 1115 demonstration authority. In response to this RFA, State applicants must include an anticipated timeline for SPA/Medicaid section 1115 demonstration authority approval as applicable (see [Application Item 5a](#)). By the Performance Period Start Date, State participants must submit documentation of approved SPAs or Medicaid section 1115 demonstration authorities necessary to implement the Model.

In response to this RFA, State applicants must also indicate whether the State would need to enact new state legislation or establish new regulations to implement the Model and describe the anticipated timeline for doing so (see [Application Item 5b](#)). By the Performance Period Start Date, State participants must submit documentation showing that any necessary state laws or regulations are in effect.

3.1.2 Standardized Access Policy

Establish a standardized Model Drug access policy consistent with the CMS-Manufacturer negotiated Key Terms.

For each Model Drug, a standardized access policy will be described in the Key Terms and will include prior authorization policies, any utilization management processes, provider qualifications, and patient eligibility criteria for the Model Drug. The aim of the access policy described in the Key Terms is to standardize access to Model Drugs across all participating States unless variations are necessary to comply with state law.

By the Performance Period Start Date, State participants must establish an access policy for the State-Selected Model Drug(s) that is consistent with the standardized access policy described in the Key Terms. States may create additional criteria and policies within their access policy so long as they are no more restrictive than the standardized access policy described in the Key Terms. State criteria and policies must be uniform across all beneficiaries enrolled in FFS Medicaid and Medicaid managed care plans within the State.

For States beginning performance during PY1 (January 1, 2025, to December 31, 2025), the access policy must apply, at a minimum, to beneficiaries enrolled in FFS Medicaid. By the State's Managed Care Start Date, the same access policy must also apply to beneficiaries enrolled in Medicaid managed care plans.

By the State's separate CHIP Start Date, if applicable, the State must also establish an access policy for separate CHIP beneficiaries that is consistent with the standardized access policy described in the separate CHIP Key Terms.

State participants must submit documentation of their access policy(ies) to CMS by each specified Start Date.

3.1.3 Model Drug Carveout

Carve Model Drugs out of an inpatient payment bundle, if necessary, and make payment for the Model Drugs in a manner such that rebates under the MDRP apply.

State participants must make payments to providers (e.g., hospitals, treatment centers, or specialty pharmacies) for State-Selected Model Drug(s) in the form of direct reimbursement, not as part of a

bundled inpatient or outpatient service. If a State reimburses drugs administered in an inpatient setting as part of an inpatient payment bundle (using a reimbursement method that bundles multiple services during a single inpatient encounter into a single payment, such as payments based on Diagnosis-Related Groups (DRGs) or Ambulatory Payment Classifications (APCs)), the State must ensure the State-Selected Model Drug(s) is directly reimbursed. If the State-Selected Model Drug(s) otherwise would be included in a bundled payment where it is not separately reimbursed, the State must carve State-Selected Model Drug(s) out of the inpatient payment bundle by the Performance Period Start Date. This enables the State-Selected Model Drug to be considered a “covered outpatient drug” and be part of the MDRP.³⁴ State participants must make payment to a provider for a State-Selected Model Drug according to the applicable reimbursement methodology, which does not result in the provider being reimbursed less than the provider’s actual acquisition cost.

By the Performance Period Start Date, State participants must submit to CMS its payment methodology or other documentation showing that the State reimburses providers for the State-Selected Model Drug(s) in a way that the reimbursement is not less than the actual acquisition cost.

3.1.4 Provider Reimbursement Requirements

Require providers to follow Model-specific requirements related to registry participation and claims submission.

State participants must require providers administering State-Selected Model Drug(s) to follow Model-specific requirements for registry participation and claims submission and must condition payment for State-Selected Model Drugs and administration of State-Selected Model Drugs on ongoing adherence to these Model requirements. These requirements include:

- A provider who submits a claim for administration of a State-Selected Model Drug must be a member of the CMS-designated patient registry for the Model and seek patient consent for a CMS-specified study. CMS plans to contract with a patient registry to gather clinically based patient-level information that is not captured in claims data. This requirement should be reflected in the State’s access policy for State-Selected Model Drug(s) (see Section 3.1.2).
- A provider who submits a claim for a State-Selected Model Drug must adhere to the State’s billing instructions. States must inform providers administering State-Selected Model Drug(s) how to properly submit claims and ensure provider compliance with the billing instructions. CMS will provide States with billing instruction guidance, including specific instructions on which billing codes, diagnosis codes and claim types providers must use, business rules that the State must support within its claims processing, and template provider communication materials. State participants must submit their provider billing instructions to CMS by their Performance Period Start Date.

³⁴ See the definition of “covered outpatient drug” at 42 CFR § 447.502. For further clarification, see *also* Centers for Medicare and Medicaid Services, “Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program,” 88 Fed. Reg. 34238 (May 26, 2023).

3.1.5 Permissible State Expenses

As part of the Model, CMS will require participating Manufacturers to provide payment for certain fertility preservation services for individuals who receive a Model Drug (for more information, see the [Manufacturer RFA](#) published on March 7, 2024). State participants must not claim any costs for services paid for by a Manufacturer as State expenses for purposes of federal financial participation (FFP).

As a condition of the Model, State participants will certify that the non-Federal share for services provided under the CGT Model is obtained from permissible State and/or local funds that are not funds provided by the Manufacturer to providers. In addition, CMS reserves the right to prohibit the use of any sources of non-Federal share funding that it determines impermissible.

3.1.6 Managed Care Alignment

Ensure that applicable Medicaid managed care plan policies align with Model requirements.

By the specified Managed Care Start Date, State participants must ensure that applicable Medicaid managed care plan policies are consistent with Model requirements, such that the Key Terms apply equally to FFS and managed care members. For example, managed care plans must apply the standardized access policy described in the Key Terms, including any additional related criteria and policies created by the State (see Section 3.1.2), and must make any payments to providers for State-Selected Model Drug(s) in the form of direct reimbursement (see Section 3.1.3). If necessary, State participants must submit state-directed payment preprint(s) and amend their applicable Medicaid managed care contracts and corresponding rates to ensure alignment with Model requirements. By the Managed Care Start Date, State participants must submit documentation showing that applicable Medicaid managed care plan policies align with Model requirements (e.g., managed care contracts/rates, memoranda of understanding, communications with managed care plans). States are encouraged to meet with CMCS as early as possible for technical assistance.

State participants must ensure continuity of care for Model beneficiaries that switch between FFS and managed care coverage or among Medicaid managed care plans within the State. The State must ensure that the new plan honors prior authorizations for SCD gene therapy-related care and prescriptions that were authorized by the previous plan in accordance with the standardized access policy. States must ensure that Model beneficiaries continue to have access to their same SCD gene therapy providers until at least one year after receiving their gene therapy infusion.

States may choose to carve State-Selected Model Drug(s) out of applicable Medicaid managed care contracts. If a State participant carves the State-Selected Model Drug(s) out of the managed care contract and the managed care plan retains responsibility for providing other services for beneficiaries receiving Model Drugs, the State must ensure that the managed care plan covers services in accordance with the access policy in the Key Terms. State participants must ensure that applicable Medicaid managed care plans pay for and cover inpatient and outpatient services and transportation for Model beneficiaries to at least the same extent that the State would pay for those services for FFS beneficiaries (see Section 3.3.2). States must coordinate with Medicaid managed care plans on requests for a prior authorization or single case agreement for beneficiaries receiving both the Model Drug paid by the State and other services paid by the managed care plan. By the Managed Care Start Date, State participants must inform CMS as to whether they have carved State-Selected Model Drug(s) out of managed care

contracts, and if so, describe their process for coordinating prior authorization and single case agreements for managed care beneficiaries.

3.2 Agreements with Manufacturers

State participants must submit documentation of the following signed agreement(s) with Manufacturer(s) by each specified Start Date:

3.2.1 VBP SRA for Medicaid Beneficiaries

Execute a value-based purchasing (VBP) Supplemental Rebate Agreement (SRA) with a participating Manufacturer that reflects the CMS-Manufacturer negotiated Key Terms.

State participants must execute a VBP SRA with the Manufacturer(s) of the State-Selected Model Drug(s) that takes effect on the Performance Period Start Date. The VBP SRA must reflect the Key Terms as negotiated by CMS with the Manufacturer, except as necessary to comport with State laws and regulations and as approved by CMS. State participants must renew their VBP SRAs as necessary to ensure that State-Selected Model Drug(s) are governed by the Key Terms for the duration of the OBA Term. If CMS and a participating Manufacturer revise the negotiated Key Terms, State participants must revise their VBP SRAs to reflect the revised Key Terms (for more information on State options to change their State-Selected Model Drug or terminate their VBP SRA, see Sections 2.6.1 and 2.7).

The VBP SRA must apply the Key Terms to all Medicaid beneficiaries who do not have other coverage that is the primary payer for a Model Drug. This includes beneficiaries in FFS Medicaid, as well as beneficiaries in Medicaid managed care plans. However, during PY1 (January 1, 2025, to December 31, 2025), States may choose to execute VBP SRAs that apply the Key Terms only to their FFS beneficiaries. By the Managed Care Start Date, States must have in effect VBP SRAs that apply the Key Terms to both FFS and managed care beneficiaries. Once its Model VBP SRA takes effect, a State participant may not have any additional SRAs for the State-Selected Model Drug(s) applicable to Medicaid beneficiaries during the OBA Term.³⁵

3.2.2 Optional VBP Agreement for Separate CHIP Beneficiaries

If applicable, execute a VBP agreement for separate CHIP beneficiaries with a participating Manufacturer that reflects the CMS-Manufacturer negotiated separate CHIP Key Terms.

If CMS and a Manufacturer have also negotiated separate CHIP Key Terms that apply to separate CHIP beneficiaries (see Section 2.3.1), States may choose to execute a VBP agreement with a participating Manufacturer that reflects those separate CHIP Key Terms. If a State chooses to include separate CHIP beneficiaries in the Model, it must execute a VBP agreement that takes effect on the specified separate CHIP Start Date. State participants that choose to include separate CHIP beneficiaries in the Model must renew and/or revise their VBP agreements as necessary to ensure that State-Selected Model Drug(s) are governed by the separate CHIP Key Terms for the duration of the OBA Term. Once its Model VBP agreement for separate CHIP beneficiaries takes effect, a State participant that chooses to include

³⁵ However, during PY1, if the State executes a VBP SRA that applies the Key Terms only to their FFS beneficiaries, the State is permitted to have a separate non-Model SRA applicable to managed care beneficiaries before the Managed Care Start Date.

separate CHIP beneficiaries in the Model may not have any additional VBP agreements for the State-Selected Model Drug(s) applicable to separate CHIP beneficiaries during the OBA Term.

3.3 Beneficiary Access to Care

The patient care journey for SCD gene therapy is long (see Section 1.1.2) and certain steps may only be available at a select number of treatment centers around the country. Thus, States should keep in mind requirements to ensure beneficiary access to care. These may include the following:

3.3.1 Provider Network Adequacy

Attest that included beneficiaries will have access to gene therapy care with at least one qualified SCD gene therapy provider within the State or in another State.

CMS anticipates gene therapy for SCD to only be administered at a select number of treatment centers, due to the significant resources and specialties required to appropriately administer gene therapies for SCD. If a State does not have an in-state SCD gene therapy provider, the State must pay for services from an out-of-state provider, in accordance with 42 CFR § 431.52.

In response to this RFA, State applicants must attest that Model beneficiaries will have access to gene therapy care (including preparation and follow-up care) with at least one SCD gene therapy provider qualified to administer each State-Selected Model Drug within the State or in another State³⁶ (see [Application Item 6a](#)). Provider qualification criteria may be part of the access policy specified in the Key Terms. Throughout the course of the Model, CMS will provide States with contact information for treatment centers that administer Model Drugs. For assistance with out-of-state provider enrollment questions, States may contact the Center for Program Integrity at MedicaidProviderEnrollment@cms.hhs.gov.

Throughout the course of the Model, States must monitor beneficiary wait times and network adequacy. Starting in PY2 (January 1, 2026) and continuing throughout the OBA Term, State participants must:

- Maintain a contract with at least one treatment center qualified to administer each State-Selected Model Drug. The contract must establish reimbursement rates for services associated with SCD gene therapy care. Acceptable contracts include, but are not limited to, a Medicaid provider enrollment agreement or a memorandum of understanding (MOU) with an out-of-state treatment center. CMS may provide a suggested template MOU to aid States in contracting with out-of-state treatment centers.
- Ensure that at least one qualified SCD gene therapy provider in each contracted treatment center is enrolled in the State Medicaid program. If there is evidence that a State participant's network of SCD gene therapy providers qualified to administer State-Selected Model Drugs is not sufficient to meet capacity, CMS may require the State to contract with additional treatment centers and/or enroll additional SCD gene therapy providers.
- Ensure that managed care plans maintain an adequate network of providers qualified to administer the State-Selected Model Drug(s).

³⁶ Qualified SCD gene therapy providers must be a member of the CMS-designated patient registry for the Model (see Section 3.1.4).

Continuing throughout the Measurement Period, States must ensure that Model beneficiaries who remain enrolled in the State Medicaid program (or CHIP, if applicable) continue to have access to follow-up care at a treatment center that is qualified to administer Model Drugs and is a member of the CMS-designated patient registry for the Model.

Streamlined communication between States and SCD gene therapy providers may reduce delays in care. Thus, by the Performance Period Start Date, State participants must also:

- Publish the coverage criteria or utilization management policy for the State-Selected Model Drug(s) in a manner that is accessible by both enrolled and non-enrolled providers.
- Identify a primary and secondary point of contact for providers regarding single case agreements (SCAs), prior authorization, and provider enrollment; and make the contact information available to all licensed SCD gene therapy providers. States must respond to questions and requests for SCAs and provider enrollment within 5 business days and must render decisions within 14 days. States must comply with existing requirements for responding to prior authorization requests for Model Drugs³⁷ and associated medical services.³⁸
- Submit to CMS a template SCA for SCD gene therapy. In developing their template SCAs, States should identify which services are provided in-state and out-of-state, taking into account the entire care journey described in Section 1.1.2, including a) initial consultation to determine whether the beneficiary is eligible for the State-Selected Model Drug, b) cell harvesting, d) chemotherapy, e) gene therapy infusion, f) ancillary care (e.g., fertility preservation, behavioral health services), and g) return visits for long-term follow-up care.

CMS encourages States to take further steps to streamline care from out-of-state providers. For example, States may wish to consider entering into agreements with other states to facilitate cross-state Medicaid provider enrollment and payment terms. States may also rely on provider screening performed by another state's Medicaid Program or by Medicare, pursuant to 42 CFR § 455.410(c) and as detailed in the Medicaid Provider Enrollment Compendium.³⁹ For more information, CMS encourages States to review relevant guidance from CMCS on coordinating care provided by out-of-state providers.⁴⁰

3.3.2 Beneficiary Transportation

Attest that the State will ensure necessary transportation and related travel expenses to Model beneficiaries (and their caregivers, as applicable).

Due to the relatively small number of gene therapy providers nationwide, CMS anticipates that many beneficiaries may have to travel long distances to receive gene therapy for SCD.

Medicaid's assurance of transportation⁴¹ requires States to ensure that every Medicaid beneficiary who has no other means of transportation has access to transportation needed to receive covered services.

³⁷ See Social Security Act § 1927(d)(5).

³⁸ See 42 CFR § 440.230(e)(1); 42 CFR § 457.495(d); 42 CFR § 438.210(d); 42 CFR § 457.1230(d).

³⁹ "Medicaid Provider Enrollment Compendium." Center for Program Integrity (Mar. 2021), available [here](#).

⁴⁰ "CMCS Informational Bulletin: Guidance on Coordinating Care Provided by Out-of-State Providers for Children with Medically Complex Conditions." Center for Medicaid & CHIP Services (Oct. 2021), available [here](#).

⁴¹ Social Security Act § 1902(a)(4)(A); see also 42 CFR § 431.53.

Transportation also includes travel-related expenses determined to be necessary by the agency to secure services. Related travel expenses include the cost of meals, lodging, and the cost of a transportation attendant when necessary. States should review the Medicaid Transportation Coverage Guide for more information on requirements and flexibilities regarding Medicaid’s transportation assurance.⁴²

In response to this RFA, State applicants must attest that the State will ensure timely non-emergency medical transportation services and related travel expenses to beneficiaries eligible for Model Drugs (and their caregivers, as applicable). State applicants must describe how they will communicate these services to beneficiaries and make them accessible in a timely manner (see [Application Item 6b](#)).

3.4 Data and Reporting

Throughout the course of the Model, State participants and CMS will exchange data and reports. States will be required to ensure appropriate technical, administrative, and related safeguards, which will be specified in the State Agreement. Data and reporting requirements may include the following:

3.4.1 Data Submissions

Meet minimum data requirements and conduct data quality activities.

State participants must continue to submit Medicaid claims data to CMS throughout the course of the Model. Medicaid claims data, along with other data sources like patient registries, will be used for the administration of the OBA, as well as for monitoring and evaluating Model performance. For example, these data will be used to identify payments for Model Drugs, beneficiaries who receive Model Drugs, and other services these beneficiaries receive pre- and post-therapy. State participants will submit claims data through the Transformed Medicaid Statistical Information System (T-MSIS), with potential other pathways for state-submitted claims data if necessary. CMS will work with State participants to establish acceptable alternative data reporting processes on a case-by-case basis.

Starting in PY2 (January 1, 2026) and continuing throughout the course of the Model, State participants must meet (or have a plan in place to meet) the data quality expectations specified in the T-MSIS Outcomes Based Assessment methodology.⁴³ States are expected to meet or exceed the targets for all three T-MSIS Outcomes-Based Assessment criteria: critical priority issues, high priority issues, and expenditures.⁴⁴

If a State participant does not meet the T-MSIS Outcomes Based Assessment data quality targets, the State must submit for CMS approval an action plan and expected timeline to meet the targets. The action plan must describe current and planned future improvements, where necessary, related to T-MSIS quality, completeness, lag time, and other issues.

⁴² SMD #23-006 “Re: Assurance of Transportation: A Medicaid Transportation Coverage Guide.” Center for Medicaid & CHIP Services (Sept. 2023), available [here](#).

⁴³ “Transformed Medicaid Statistical Information System (T-MSIS).” Centers for Medicare and Medicaid Services (Nov. 2023), available [here](#).

⁴⁴ States that currently meet the T-MSIS Outcomes Based Assessment data quality targets are indicated in blue on the map at “Transformed Medicaid Statistical Information System (T-MSIS).” Centers for Medicare and Medicaid Services, available [here](#). States can check the T-MSIS Operations Dashboard for their most up-to-date data.

State participants must conduct data quality activities as necessary to maintain data quality targets or comply with data quality action plans. States can check for and address potential T-MSIS data submission errors and data quality issues through the T-MSIS Operations Dashboard available on the CMS Enterprise Portal. In addition, CMS provides States with data quality technical assistance to monitor and address specific data quality issues.

In response to this RFA, State applicants must either a) attest that the State will meet the T-MSIS Outcomes Based Assessment data quality targets by January 1, 2026; or b) if the State will be unable to meet the T-MSIS Outcomes Based Assessment data quality targets by January 1, 2026, describe the State’s action plan and expected timeline to meet the targets (see [Application Item 7](#)).

Additionally, CMS may require that States address additional T-MSIS data quality issues during the course of the Model. If CMS identifies an issue with a State participant’s T-MSIS data that is relevant to the operation of the Model, the State must cooperate with CMS to resolve the issue and may be required to use an alternative data reporting process.

3.4.2 Reporting

Submit reports to CMS on Model implementation.

Each State participant must submit documentation to CMS to verify that the State has met the requirements for Model participation. Documentation will be submitted through a participant portal or other manner specified by CMS. Table 3 describes the documentation that must be submitted and associated due dates. CMS may also require additional documentation. If any of the required documentation is revised or renewed, State participants must submit an updated version no later than the quarter following the revision or renewal.

Table 3: Required Documentation

Relevant Requirements	Documentation	Due
3.1.1 Legal Authority	SPA for VBP SRAs approved by CMCS	Performance Period Start Date
3.1.1 Legal Authority	Any section 1115 demonstration authority or other program waiver from CMCS necessary to implement the Model	Performance Period Start Date
3.1.1 Legal Authority	Documentation of state legal authority to implement the Model	Performance Period Start Date
3.1.2 Standardized Access Policy	Published coverage policy or utilization management policy for the State-Selected Model Drug(s), along with an attestation that the State has implemented a standardized access policy consistent with the Key Terms	Performance Period Start Date

3.1.2 Standardized Access Policy	Documentation showing that all managed care plans have implemented the standardized access policy consistent with the Key Terms	Managed Care Start Date
3.1.2 Standardized Access Policy	<i>If the State has chosen to include separate CHIP beneficiaries in the Model, published coverage policy or utilization management policy for the State-Selected Model Drug(s) for separate CHIP beneficiaries, along with an attestation that the State has implemented a standardized access policy consistent with the separate CHIP Key Terms</i>	Separate CHIP Start Date
3.1.3 Model Drug Carveout	Payment methodology or other documentation	Performance Period Start Date
3.1.4 Provider Reimbursement Requirements	Provider billing instructions	Performance Period Start Date
3.1.6 Managed Care Alignment	Documentation showing that applicable Medicaid managed care policies align with Model requirements (e.g., managed care contracts, State directed payment preprints (if applicable), rate development documentation, memoranda of understanding, communications with managed care plans)	Managed Care Start Date
3.2.1 VBP SRA for Medicaid Beneficiaries	Either: <ul style="list-style-type: none"> - the VBP SRA signed by the State and Manufacturer, or - an excerpt of the VBP SRA reflecting the Key Terms, combined with an attestation that the VBP SRA has been signed by the State and Manufacturer 	Performance Period Start Date *If initial version only applied to FFS beneficiaries, updated version due by Managed Care Start Date
3.2.2 Optional VBP Agreement for Separate CHIP Beneficiaries	<i>If the State has chosen to include separate CHIP beneficiaries in the Model, either:</i> <ul style="list-style-type: none"> - the separate CHIP VBP agreement signed by the State and Manufacturer, or - an excerpt of the separate CHIP VBP agreement reflecting the Separate CHIP Key Terms, combined with an attestation that the separate CHIP VBP agreement has been signed by the State and Manufacturer 	Separate CHIP Start Date

3.3.1 Provider Network Adequacy	Documentation showing that the State has contracted with at least one treatment center qualified to administer the State-Selected Model Drug(s)	Start of PY2 (January 1, 2026)
3.3.1 Provider Network Adequacy	Template SCA for SCD gene therapy	Performance Period Start Date

State participants must submit quarterly reports on Model implementation and performance. CMS will provide State participants with a standard report template no later than 90 days before each report is due. In each quarterly report, States must, for example:

- Provide data on the amounts of supplemental rebates owed to and paid to the State by participating Manufacturers under the OBA
- Provide information about gene therapy provider network (e.g., number of gene therapy providers enrolled; response and decision times for enrollment requests)
- Provide information about beneficiaries seeking SCD gene therapy (e.g., number of prior authorization requests and their status; response and decision times for prior authorization and SCA requests)
- Identify updates to any of the documentation required above, and attest that the most recent versions have been submitted to the participant portal.
- Disclose any updates to State law or program policies that are relevant to the Model or will result in any meaningful changes to the operation of the Model and discuss how the State will continue to achieve the objectives of the Model.

CMS may also request additional reporting items. For example, States may be required to notify CMS upon approval of a prior authorization for the State-Selected Model Drug(s) and provide additional information in a form and manner to be specified by CMS.

Throughout the course of the Model, State participants must also cooperate with CMS efforts to conduct monitoring (see Section 5) and evaluation (see Section 6).

4. CMS Support

In addition to negotiating Key Terms with the Manufacturer, CMS will support States in operationalizing the Key Terms. This includes, but is not limited to, supporting States and Manufacturers with the implementation of the Model and the OBA. CMS will be responsible for gathering, aggregating, and analyzing data, as well as assessing whether the Outcome Measure Benchmarks are met. CMS will determine the resulting financial obligations and share reports with States and Manufacturers.

CMS' responsibilities will be specified in the Key Terms and in the CMS-Manufacturer PA and CMS-State SAs. At a minimum, CMS will be responsible for compiling, auditing, and analyzing data necessary to support the Model, including utilization data, claims data, clinical records, and patient-reported outcome measures (PROMs). Sources of data utilized by CMS will include, but are not limited to:

- T-MSIS for utilization and claims information.
- Patient registries, such as the Center for International Bone Marrow Transplant and Research (CIBMTR), for clinical information that is not captured on patient claims.
- Patient-level data provided by participating Manufacturers, such as the name of the beneficiary, the date the Model Drug was shipped to the treatment center, and the date of administration.

CMS may share data with State participants. Requirements for data safeguards/security and disposition of data will be specified in the State Agreement.

Further, CMS will offer direct technical assistance to all State participants to support them in implementing the Model requirements described in Section 3. States may also apply for optional Model funding through the NOFO (see Section 2.2.2).

4.1 Learning System

State participants will have the opportunity to participate in a learning system designed to support their success in the achieving the aims of the model. The primary functions of the learning system will be to:

1. Connect States so they can learn from each other how to effectively increase access and outcomes for individuals living with SCD through the exchange of ideas, knowledge, tools, and resources;
2. Provide access to data feedback that can guide States in their learning and improvement activities; and
3. Share emergent and data-driven learnings on what States have done that has worked to achieve improved access and outcomes.

State participants will be able to:

1. Participate in convenings with other States to facilitate peer-to-peer learning.
2. Participate in the identification and dissemination of promising practices and lessons learned.
3. Respond to CMS and its contractors and staff when using various mechanisms such as surveys or interviews to identify recipient learning needs and lessons learned.

CMS will also provide learning opportunities for community-based organizations (CBOs) that are partnering with participating States and/or gene therapy providers in the participating State, to connect with each other on how to effectively increase awareness and demand for cell and gene therapies and

on how to address the health-related social needs that have been barriers to accessing care. This learning will be systematically captured and shared with States in addition to participating CBOs. While providers are not direct participants of this model, CMS will seek to provide virtual and/or in-person meetings through existing stakeholder groups that already support these providers in caring for individuals living with SCD, so that there is a forum to consider changes to care delivery that meets increased demand and improves patient outcomes.

5. Quality and Performance Monitoring

As part of both Model implementation and evaluation, CMS will monitor the impacts of the Model on the Medicaid program and separate CHIP (as applicable) 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.

CMS will collect additional information regarding beneficiary claims, clinical outcomes, and PROMs beyond what is necessary to monitor Outcome Measures throughout the Model. This information will be used to monitor and evaluate the performance of the Model and will not be tied to the OBAs. The CMS Innovation Center reserves the right to monitor and validate information and data submitted by Model participants for the purposes of either Model implementation or Model evaluation. Model participants will be required to comply with any and all monitoring activities and validation efforts as part of their Model participation. The data sharing requirements of Model participation will be detailed in full in the PAs and SAs.

5.1 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 Model participants, particularly in the event that CMS receives a high number of complaints or other indicators of poor performance. CMS expects Model participants to cooperate to the fullest extent possible in requests for relevant data and information. CMS will closely monitor Model implementation to ensure that performance is consistent with Model parameters. CMS will also monitor the impact the Model has on other CMS initiatives. CMS reserves the right to investigate a participating State 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 a corrective action plan or potential termination from the Model.

6. 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 Medicaid program and CHIP spending and the quality of care. All Model participants 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, Model participants will be required to cooperate with primary data collection activities, which may include participation in surveys, interviews, site visits, 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.

6.1 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 States 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. Participating States 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.

7. Application

7.1 Application Process and Selection

States may submit applications to participate in the Model after the negotiated Key Terms have been communicated to States in December 2024. The application portal will be open from December 2024 through February 28, 2025. This RFA is made available prior to December to allow potential State applicants as much time as possible to review the requirements for Model participation before applications are due.

States seeking to participate in the Model must complete and submit the application (see Appendix A) according to the instructions provided in the application portal. States must submit applications at least 10 business days prior to their requested Performance Period Start Date. For example, if a State wishes to begin performance on January 1, 2025, its application must be submitted no later than December 16, 2024. Applications must be submitted at the latest by 11:59pm EST on February 28, 2025. (Please note that optional applications in response to the NOFO will be due at the same time through a separate submission process; see the NOFO for details).

CMS will acknowledge receipt of the application to the Primary Application Contact (see Appendix A) and will review the application within 10 business days. CMS will review applications and work with States to execute State Agreements on a rolling basis.

States that do not sign an SA by June 1, 2025 will not be allowed to participate in the Model except at CMS discretion.

7.1.1 State Engagement During Model Pre-Implementation

CMS encourages States to engage with CMS as early as possible regarding potential participation in the Model. Prior to the application deadline, CMS will host a webinar to provide details about the Model and answer questions from potential State applicants. Information about the webinar will be provided to the National Association of Medicaid Directors and posted on the [CGT Access Model website](#).

States may contact CGTModel@cms.hhs.gov with questions about the Model.

7.2 Submission Information

Information required by CMS in response to this RFA is included in Appendix A.

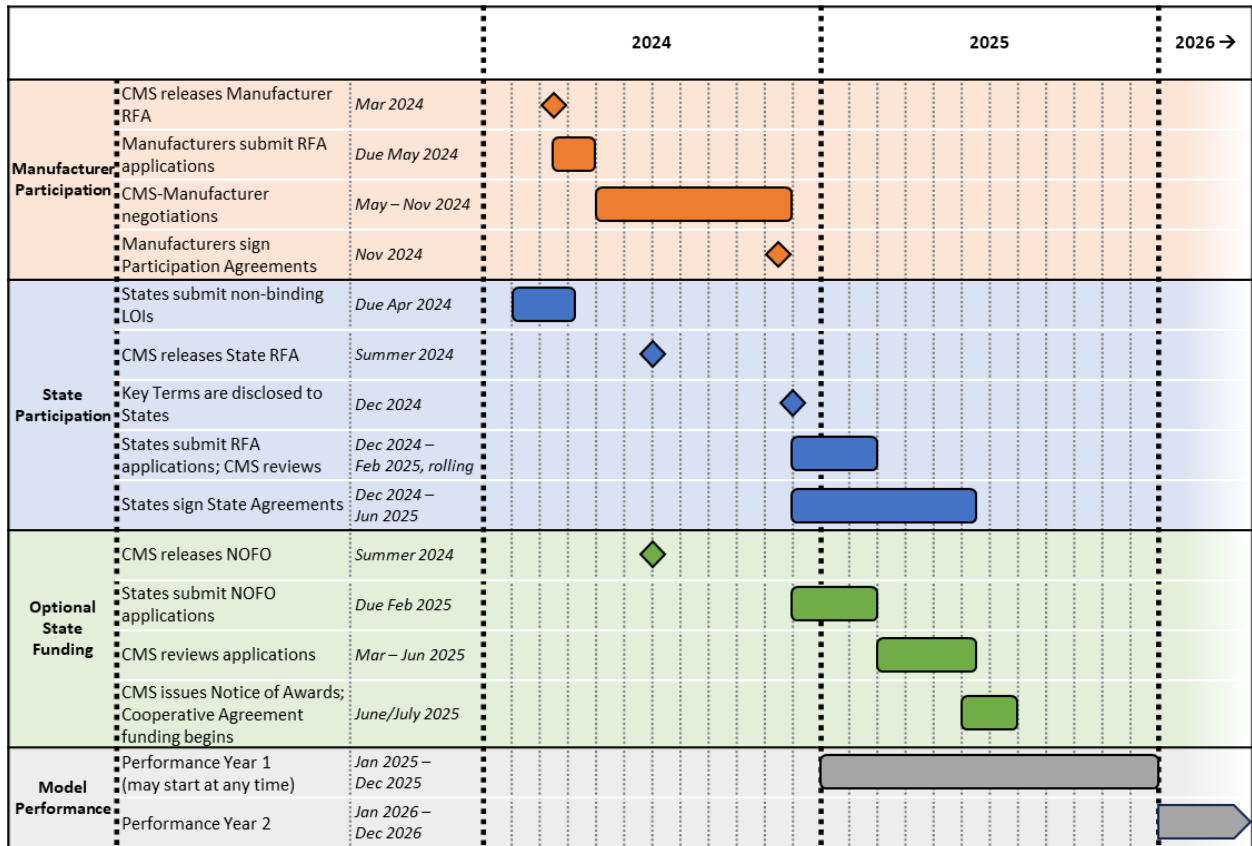
7.3 Model Timeline

A summary of the Model’s timeline is provided below in Table 4 and Figure 3.

Table 4: Key Model Dates

Milestone	Target Date
Release of State Letter of Intent Template (LOI)	January 30, 2024
Release of Manufacturer Request for Applications (RFA)	March 7, 2024
State LOIs due (optional, non-binding)	April 12, 2024 (extended from April 1, 2024)
Manufacturer Applications due	May 1, 2024
CMS—Manufacturer Negotiations Ongoing	May 2, 2024 – November 29, 2024
Release of State RFA and Notice of Funding Opportunity (NOFO)	Summer 2024
CMS Acceptance/Rejection of Manufacturer Final Offers (PA is signed)	November 29, 2024
Announcement of Participating Manufacturers & Disclosure of CMS-Manufacturer Negotiated Key Terms to States	December 2024 (no later than)
OBA Term begins	January 1, 2025
State RFA Applications due	February 28, 2025 (rolling)
State NOFO Applications due	February 28, 2025
State Agreements (SAs) signed	June 1, 2025 (no later than)
Cooperative Agreement Funding begins	June or July 2025
Publication of First Public Evaluation Report	Q2 of 2027 (Negotiation Report)
Latest Date of OBA Term	December 31, 2030 (anticipated)
End of Model Evaluation Period	No later than Q3 2035 (anticipated)

Figure 3: Timeline of Model Launch



7.4 Withdrawal of Application

Prior to signing an SA, a State that submitted an RFA application 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 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 CGTModel@cms.hhs.gov.

Appendix A: Application Template

The Centers for Medicare & Medicaid Services (CMS) is seeking applications for a voluntary Model (the Cell and Gene Therapy Access Model, or “the Model”) that tests whether a CMS-led approach to developing and administering outcomes-based agreements (OBAs) for cell and gene therapies improves Medicaid beneficiary access to innovative treatment, improves health outcomes for Medicaid beneficiaries, and reduces health care expenditures.

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 will provide States with a secure platform where the completed application and supporting documents must be submitted. The application portal will be open from December 2024 through February 28, 2025. CMS provides this appendix as a reference for the questions to be asked in the application portal, and all applications must be submitted through the application portal.

States seeking to participate in the Model must submit a complete application and any supporting documents by 11:59pm EST on February 28, 2025. Text responses in the application template are limited to no more than 1,000 words for each response.

Questions about the application for the Model should be directed to CGTModel@cms.hhs.gov.

1. **BACKGROUND INFORMATION**

a. **Applicant Information**

Please provide the following information regarding your state Medicaid agency.

FIELD	RESPONSE FORMAT
<i>Name of state, D.C., or territory:</i>	<i>Text</i>
<i>Name of state agency:</i>	<i>Text</i>
MAILING ADDRESS:	
<i>Street Address:</i>	<i>Text</i>
<i>City:</i>	<i>Text</i>
<i>State:</i>	<i>Text</i>
<i>ZIP Code:</i>	<i>Text</i>

b. **Contact Information**

Please include information for the Primary Application Contact and Secondary Application Contact. CMS will contact these two individuals to confirm receipt, direct follow up questions, and schedule meetings regarding the Model. The primary means of communication will be via E-mail.

For Primary Application Contact

FIELD	RESPONSE FORMAT
<i>Full Name:</i>	<i>Text</i>
<i>Title/Position:</i>	<i>Text</i>
<i>Business Phone Number:</i>	<i>Text</i>
<i>Business Phone Number Extension:</i>	<i>Text</i>
<i>Alternate Phone Number:</i>	<i>Text</i>
<i>Business Email Address:</i>	<i>Text</i>

For Secondary Application Contact

FIELD	RESPONSE FORMAT
<i>Full Name:</i>	<i>Text</i>
<i>Title/Position:</i>	<i>Text</i>
<i>Business Phone Number:</i>	<i>Text</i>
<i>Business Phone Number Extension:</i>	<i>Text</i>
<i>Alternate Phone Number:</i>	<i>Text</i>
<i>Business Email Address:</i>	<i>Text</i>

2. START OF MODEL PERFORMANCE

- a. Please specify the Performance Period Start Date – the date (no later than January 1, 2026) by which the State intends to begin performance in the Model. (Please see the RFA Section 3 for the requirements the State must fulfill on or before the start of its Performance Period.)

RESPONSE FORMAT
<i>Date</i>

- b. Please specify the Managed Care Start Date – the date (no later than January 1, 2026) by which the State intends to include enrollees in Medicaid managed care plans in the Model.

RESPONSE FORMAT
<i>Date</i>

3. OPTIONAL SEPARATE CHIP PARTICIPATION

- a. Does the State intend to include separate Children’s Health Insurance Program beneficiaries in the Model? If yes, please specify the separate CHIP Start Date – the date (no later than January 1, 2026) by which the State intends to include separate CHIP beneficiaries in the Model.

RESPONSE FORMAT
<i>Yes [] No []</i>

RESPONSE FORMAT
<i>Date</i>

4. ADOPTION OF KEY TERMS

- a. Please specify the State-Selected Model Drug(s) – the Model Drug(s) for which the State intends to adopt the CMS-Manufacturer Key Terms.

RESPONSE FORMAT
<i>Text</i>

- b. If the Key Terms include an option for one or more Model Drugs to receive preferential status, does the State intend to grant preferred status to any State-Selected Model Drug(s)? If so, please specify which State-Selected Model Drug(s) the State intends to select as a preferred drug.

RESPONSE FORMAT
<i>Yes [] No []</i>

RESPONSE FORMAT
<i>Text</i>

- c. Will the State need to vary any of the Key Terms to comport with State laws and regulations? If so, please propose any changes.

RESPONSE FORMAT
<i>Yes [] No []</i>

RESPONSE FORMAT
<i>Text</i>

5. LEGAL AUTHORITY

- a. Will the State need to obtain a state plan amendment (SPA), Medicaid section 1115 demonstration authority, or other program waiver to implement the Model? If yes, please specify the type of SPA/demonstration/waiver approval needed and describe the anticipated timeline for approval. Please specify whether the State has already submitted a SPA/demonstration/waiver application or met with CMCS to discuss a request for a SPA/demonstration/waiver.

RESPONSE FORMAT
<i>Yes [] No []</i>

RESPONSE FORMAT
<i>Text</i>

- 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.

RESPONSE FORMAT
<i>Yes [] No []</i>

RESPONSE FORMAT
<i>Text</i>

6. BENEFICIARY ACCESS TO CARE

- a. Please attest that Model beneficiaries will have access to gene therapy care with at least one SCD gene therapy provider qualified to administer each State-Selected Model Drug within the state or in another state.

RESPONSE FORMAT
<i>Yes [] No []</i>

- b. Please attest that the State will ensure necessary transportation and related travel expenses to Model beneficiaries (and their caregivers, as applicable). Please describe how the State will communicate these services to beneficiaries in a timely manner.

RESPONSE FORMAT
<i>Yes [] No []</i>

RESPONSE FORMAT
<i>Text</i>

7. DATA QUALITY

- a. Please attest as to whether the State will meet the T-MSIS Outcomes Based Assessment data quality targets by January 1, 2026.

RESPONSE FORMAT
Yes [] No []

- b. If the State will be unable to meet the T-MSIS Outcomes Based Assessment data quality targets by January 1, 2026, describe the State’s action plan and expected timeline to meet the targets. The action plan must describe current and planned future improvements, where necessary, related to T-MSIS quality, completeness, lag time, and other issues.

RESPONSE FORMAT
Text

8. ADDITIONAL INFORMATION

- a. Please describe payment policies for any SCD gene therapies that are currently in effect or under consideration (i.e., carved out of inpatient bundled payments, carved out of managed care, reinsurance, etc.)?

RESPONSE FORMAT
Text

- b. Disclose whether the State has already, or is considering, signing a supplemental rebate agreement (SRA) with a manufacturer that has an approved gene therapy for SCD, and the period during which the agreement would be in effect (start and end dates).

RESPONSE FORMAT
Text

9. SIGNATURE

- a. 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.

RESPONSE FORMAT
<i>Yes [] No []</i>

[Signature block]