

**U.S. Department of Health and Human Services  
Centers for Medicare & Medicaid Services  
Center for Medicare and Medicaid Innovation**

**Cell and Gene Therapy (CGT) Access Model**

**Notice of Funding Opportunity Type:** New

**Funding Opportunity Award Type:** Cooperative Agreement

**Notice of Funding Opportunity Number:** CMS-2P2-25-001

**Federal Assistance Listings Number (CFDA):** AL 93.885

**Notice of Funding Opportunity Posting Date:** August 15, 2024 (revised as of February 18, 2025<sup>1</sup>)

**Applicable Dates:**

**Letter of Intent to Apply Due Date:** N/A

**Electronic Application Due Date:** March 14, 2025, 11:59 pm EST

**Anticipated Issuance Notice(s) of Award:** July 1, 2025

**Periods of Performance:** There are two periods of performance to be aware of in this Model as detailed below:

- **Model Performance Period (anticipated):** *January 1, 2025-December 31, 2035*
- **Cooperative Agreement Period of Performance (anticipated):** *July 1, 2025-December 31, 2035*

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<sup>1</sup> This update extends the application deadline from February 28, 2025 to March 14, 2025. All other revisions are non-substantive and do not impact any NOFO funding amounts, activities, requirements, policies, or processes.

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## Executive Summary

This Notice of Funding Opportunity (NOFO) announces the opportunity to apply for Cooperative Agreement funding to support States' participation in the Cell and Gene Therapy (CGT) Access Model (the CGT Access Model or "the Model"). Eligible applicants are States, the District of Columbia, and any U.S. territory that participates in the Medicaid Drug Rebate Program (MDRP). A maximum of \$9.55 million may be awarded to each Recipient, depending on the number of States that apply for funding, pending availability of funds.

The CGT Access Model is a voluntary 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. Within this Model, CMS will negotiate standard Key Terms of an OBA directly with manufacturers of gene therapies approved or licensed by the U.S. Food & Drug Administration (FDA) for the treatment of sickle cell disease (SCD). The negotiated Key Terms will be disclosed to all States in December 2024. After the Key Terms have been disclosed, States: (1) may apply to participate in the Model in response to the State Request for Applications (RFA); and (2) may apply for Cooperative Agreement funding in response to this NOFO.

Cooperative Agreement funding is intended to support State Model implementation activities and to support States that take steps to improve access to gene therapy and multi-disciplinary, comprehensive care in conjunction with the model test.

To be considered for Cooperative Agreement funding, a State must apply to both the State RFA and this NOFO. Up to \$9.55 million in Cooperative Agreement award funding is anticipated to be available to each selected award recipient over the course of up to 10.5 years. The Cooperative Agreement and the Model are anticipated to conclude no later than December 31, 2035.

| <b>Table 1: Summary</b>                    |                                                                                                                                              |
|--------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Item</b>                                | <b>Description</b>                                                                                                                           |
| HHS Awarding Agency                        | Centers for Medicare & Medicaid Services (CMS)                                                                                               |
| CMS Awarding Center                        | Center for Medicare & Medicaid Innovation (Innovation Center)                                                                                |
| Notice of Funding Opportunity Title        | Cell and Gene Therapy (CGT) Access Model                                                                                                     |
| Authorization                              | Section 1115A of the Social Security Act (the Act) as added by Section 3021 of the Patient Protection and Affordable Care Act (P.L. 111-148) |
| Federal Assistance Listings Number         | AL 93.885                                                                                                                                    |
| Funding Opportunity Type                   | New                                                                                                                                          |
| Funding Opportunity Number                 | CMS-2P2-25-001                                                                                                                               |
| Type of Award                              | Cooperative Agreement                                                                                                                        |
| Type of Competition                        | Competitive                                                                                                                                  |
| Letter of Intent                           | N/A                                                                                                                                          |
| Application Due Date and Time              | March 14, 2025 by 11:59 pm EST (Baltimore, MD)                                                                                               |
| Anticipated Issuance Notice(s) of Award    | July 1, 2025                                                                                                                                 |
| Period of Performance Start Date           | July 1, 2025                                                                                                                                 |
| Period of Performance End Date             | December 31, 2035 (anticipated)                                                                                                              |
| Anticipated Total Available Funding        | \$95,500,000 (subject to availability of funds)                                                                                              |
| Estimated Maximum Award Amount Per Awardee | \$9,550,000                                                                                                                                  |
| Estimated Maximum Number of Awardees       | 52 (All 50 States, the District of Columbia, and any U.S. territory that participates in the Medicaid Drug Rebate Program (MDRP))            |

## **A. Program Description**

### **A1. Purpose**

This NOFO provides details and instructions on how to apply for funding under the Cell and Gene Therapy (CGT) Access Model (the CGT Access Model or “the Model”).

The Centers for Medicare & Medicaid Services (CMS) is seeking applications from States, the District of Columbia, and any U.S. territory that participates in the Medicaid Drug Rebate Program (MDRP)<sup>2</sup> (hereinafter, “States”) for optional funding under the CGT Access Model. See Section A6.1.1 *State Participation* for more information.

The Model will test 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.

Depending on state and manufacturer interest, the Model may also include beneficiaries in separate Children’s Health Insurance Programs (CHIP).<sup>3</sup>

Through a Cooperative Agreement award, Implementation Funding will be available to States to support required and optional Model implementation activities (see Section A6.8.1 *Implementation Funding*). Additionally, Milestone Funding will be available to States that successfully complete research projects related to increasing access to sickle cell disease (SCD) gene therapy and promoting multi-disciplinary, comprehensive care for beneficiaries with SCD who are considering or receiving SCD gene therapy (see Section A6.8.2 *Milestone Funding*).

### **A2. Authority**

Section 1115A of the Social Security Act (the Act) authorizes the Secretary of the Department of Health and Human Services to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, or CHIP expenditures, while preserving or enhancing quality of care.

### **A3. 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.<sup>4</sup> Within this model, CMS will negotiate standard Key Terms<sup>5</sup> directly with the Manufacturer. These OBAs may include outcomes-based rebates, volume-based rebates, and guaranteed rebate components.

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

<sup>3</sup> Participation with respect to the separate CHIP population would be under a value-based purchasing arrangement.

<sup>4</sup> “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.

<sup>5</sup> “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.

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 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.<sup>6</sup> (See Section A6.3 *Legal Agreements* for a description of the legal relationships between CMS, Manufacturers, and States.) CMS will support implementation of the Model through such responsibilities as implementing, monitoring, reconciling, and evaluating the financial and clinical outcomes specified in the Key Terms. Under the Cooperative Agreement, Implementation Funding is available to help States implement the Model (see Section A6.8.1 *Implementation Funding*); Milestone Funding is available to States who achieve Model milestones (see Section A6.8.2 *Milestone Funding*).

At this time, the Model, along with this NOFO, is limited to gene therapies approved or licensed by the U.S. Food & Drug Administration (FDA) for the treatment of SCD that are covered outpatient drugs under the Medicaid Drug Rebate Program (MDRP) (hereinafter, “Model Drugs”).

#### **A4. Model Performance Period and Cooperative Agreement Period of Performance**

There are two periods of performance to be aware of in this Model:

- The Model Performance Period; and
- The Cooperative Agreement Period of Performance

Model Performance Period: January 1, 2025 - December 31, 2035

The Model is expected to consist of eleven Model Performance Years (PYs).

- The first Model Performance Year (PY1) will run from January 1, 2025-December 31, 2025.
- Each State has the flexibility of joining the Model anytime during Model PY1, or at the start of Model PY2 (January 1, 2026). In other words, States may choose whether to begin performance during Model PY1 but must begin performance by the start of Model PY2 (January 1, 2026).
- States will specify a Model Performance Period Start Date in response to the State RFA.

For all participating States, the Model Performance Period is anticipated to conclude on December 31, 2035, unless the State’s participation in the Model is terminated earlier.

Depending on the CMS-Manufacturer negotiated Key Terms, the OBA Term may be as long as PYs 1-6.<sup>7</sup> Some state obligations will only apply for the duration of the OBA Term, and other state obligations extend for the duration of the Model.

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.

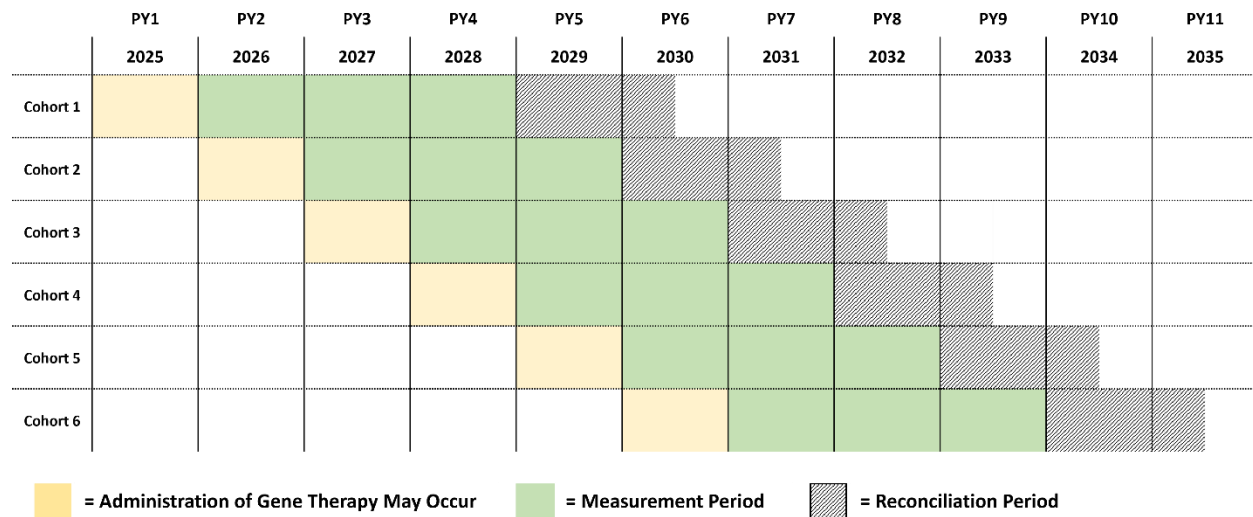
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<sup>6</sup> The State-specific contracts will comport with applicable laws and regulations.

<sup>7</sup> “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.

- **Example:** Administration of gene therapy would occur during Model PYs 1-6, and patients who receive gene therapy in each Model 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**



Cooperative Agreement Period of Performance: July 1, 2025 - December 31, 2035

The Cooperative Agreement period of performance is expected to begin as early as July 1, 2025 and end on December 31, 2035.

- The Cooperative Agreement Period of Performance is further divided into ten Budget Periods (BPs).
- The first Budget Period is 18 months (July 2025 through December 2026) followed by nine 12-month Budget Periods, as shown in Table 2, below.

The relationship between Model PYs, Cooperative Agreement BPs, and Calendar Years are displayed in Table 2. BPs correspond to the release of award funding.

| Table 2. Relationship between Calendar Years, Model Performance Years (PYs) and Cooperative Agreement Budget Periods (BPs) |                                       |                               |      |      |      |      |      |      |      |      |      |      |
|----------------------------------------------------------------------------------------------------------------------------|---------------------------------------|-------------------------------|------|------|------|------|------|------|------|------|------|------|
|                                                                                                                            | 2025                                  |                               | 2026 | 2027 | 2028 | 2029 | 2030 | 2031 | 2032 | 2033 | 2034 | 2035 |
| Model Performance Years (PYs)                                                                                              | PY1<br>(States may start at any time) |                               | PY2  | PY3  | PY4  | PY5  | PY6  | PY7  | PY8  | PY9  | PY10 | PY11 |
| Cooperative Agreement Budget Periods (BPs)                                                                                 | No Funding<br>(Jan - Jun)             | BP1<br>(July 2025 - Dec 2026) |      | BP2  | BP3  | BP4  | BP5  | BP6  | BP7  | BP8  | BP9  | BP10 |

## A5. Background

Gene therapies are a rapidly growing class of transformative, potentially one-time medicines designed to treat previously intractable diseases.<sup>8</sup> 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.<sup>9</sup>

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 Measures<sup>10</sup> (clinical values, patient-reported outcome (PRO) measures, or utilization of care measures) and a Measurement Period.<sup>11</sup> 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 or 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.<sup>12</sup> 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 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.

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

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<sup>8</sup> 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.

<sup>9</sup> "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](#).

<sup>10</sup> "Outcome Measures" mean the agreed-upon clinical or utilization-based factors that are linked to rebates.

<sup>11</sup> "Measurement Period" means the time period following administration of the drug during which Outcome Measures will be monitored.

<sup>12</sup> 42 CFR § 447.502 (defining "CMS-authorized supplemental rebate agreement").

Section A6.3 *Legal Agreements/Cooperative Agreement Award* for more information about the legal relationships that will govern this partnership.)

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.

### **A5.1 Sickle Cell Disease (SCD)**

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.<sup>13</sup>

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.<sup>14</sup> The total cost to the health system of SCD is estimated at \$2.98 billion per year in the United States.<sup>15</sup> 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.

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.<sup>16</sup> 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.<sup>17</sup> 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

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<sup>13</sup> “About Sickle Cell Disease.” National Human Genome Research Institute, 2020, available [here](#).

<sup>14</sup> Andelson, E., at 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](#).

<sup>15</sup> Huo, J., et al. “The Economic Burden of Sickle Cell Disease in the United States.” Value in Health, 2018, available [here](#).

<sup>16</sup> “Package Insert - CASGEVY (exagamglogene autotemcel), suspension for intravenous infusion.” Vertex Pharmaceuticals Incorporated, 2024, available [here](#).

<sup>17</sup> “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](#).

(VOEs).<sup>18</sup> Lyfgenia is manufactured by adding a functional copy of a modified globin gene into a patient's stem cells.<sup>19</sup>

## **A5.2 Illustrative Care Journey for SCD Gene Therapy and Potential Access Barriers<sup>20</sup>**

Table 3 below outlines elements of the illustrative care journey for gene therapy for individuals with SCD, which CMS developed in coordination with clinical experts. Table 3 also describes the set of services and supports a beneficiary may need along that journey, and the potential for gaps in those services and supports. Potential care delivery gaps cited below include services that are not covered by Medicaid (e.g., childcare), optional Medicaid services (e.g., case management, dental care), and mandatory services for which beneficiaries may experience access barriers or delays in services (e.g., access to out-of-state providers). Funding available under this NOFO is designed to help States address some of these potential care delivery gaps. Access barriers may vary from state to state and individual to individual.

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<sup>18</sup> "Package Insert - LYFGENIA® (lovotibeglogene autotemcel) suspension for intravenous infusion." bluebird bio, Inc., 2023, available [here](#).

<sup>19</sup> Kanter, J., et al. "Biologic and Clinical Efficacy of LentiGlobin for Sickle Cell Disease." New England Journal of Medicine, 2022, available [here](#).

<sup>20</sup> Table 3 is intended to provide a high-level overview of the care journey for individuals with SCD undergoing gene therapy, which CMS developed in coordination with clinical experts. This table may aid Applicants in identifying service and support gaps in the beneficiary care journey for gene therapy, and producing a comprehensive response to this NOFO that addresses potential gaps in recommended services and supports in the Applicant State. This table is *not* intended to provide a guide for gene therapy medical providers and is not a CMS recommendation for care or treatment.

Table 3 may aid Applicants in identifying service and support gaps in the beneficiary care journey for gene therapy, and producing a comprehensive response to this NOFO that addresses potential gaps in recommended services and supports in the Applicant State. This table is *not* intended to provide a guide for gene therapy medical providers and is not a CMS recommendation for care or treatment. The CGT Access Model does not limit patient rights to make care decisions in consultation with their clinical providers.

| <b>Table 3. Illustrative Care Journey for Gene Therapy for SCD and Potential Care Delivery Gaps</b>                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                        |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Step in Care Journey</b><br><i>(Length of Time / Care Setting)</i>                                                                                                                                | <b>Description of Step in Care Journey</b>                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Potential Care Delivery Gap(s)</b>                                                                                                                                                                                  |
| <b>1. Patient Identification for Gene Therapy</b><br><i>(Duration will likely vary by patient access to providers and provider type / Outpatient)</i>                                                | <b>Patient is identified as a possible candidate for gene therapy</b> by a health care provider based on clinical needs and product eligibility criteria, or patient approaches their healthcare provider with interest in gene therapy. Health care provider refers patient to a health care provider who specializes in SCD.                                                                                                                                                   | <ul style="list-style-type: none"> <li>• Access to a provider who is knowledgeable about SCD gene therapy</li> <li>• Patient awareness of gene therapy</li> </ul>                                                      |
| <b>2. Disease Management by Hematologist<sup>21</sup> who Specializes in SCD</b><br><i>(Duration of patient management and counseling varies according to the needs of the patient / Outpatient)</i> | <b>Patient is managed by a hematologist who specializes in SCD.<sup>22</sup></b> The hematologist will assess whether the patient’s SCD is being optimally managed (particularly for patients who have not been seen by a hematologist who specializes in SCD), and if not, will begin appropriate disease management, and assess whether gene therapy is the most suitable treatment course for the patient. Patients’ mental health and pain should be addressed at this time. | <ul style="list-style-type: none"> <li>• Access to hematologist who specializes in SCD</li> <li>• Access to mental health providers and health care providers specializing in pain management and addiction</li> </ul> |

<sup>21</sup> It is ideal for patients to be seen by a hematologist who specializes in SCD; however, patients may also be managed by other health care providers who are knowledgeable about SCD.

<sup>22</sup> See, e.g., literature surrounding gaps in access to evidence-based care, including Cronin R., et al., “The Use of FDA-Approved Medications for Preventing Vaso-Occlusive Events in Sickle Cell Disease,” *Blood Advances* (2023), available [here](#). See also “2021 Report to Congress: Sickle Cell Disease Treatment Demonstration Regional Collaboratives Program,” National Institute for Children’s Health Quality (2021), available [here](#), pages 6-18, describing challenges in access to specialty care that aligns with NHLBI promulgated guidelines.

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| <p><b>3. Evaluation for Gene Therapy and Patient Education</b><br/>(~30 days / Outpatient)</p> | <p><b>Patient travels to sickle cell<sup>23</sup> or transplant center and is evaluated for suitability/“fitness” for gene therapy and educated about the care journey.</b><br/>This includes both a diagnostic evaluation (e.g., pulmonary function tests, echocardiogram, brain MRI/MRA, labs, liver MRI, renal assessment, dental evaluation, genetic testing, and social work assessment) and an evaluation of a patient’s ability to adhere to the gene therapy regimen (e.g., compliance with current pain regimen, adequate family/social supports,<sup>24</sup> reliable transportation, and reliable communication methods, among others).<br/>Consultation with transplant physicians, hematologists specializing in SCD, psychologists, psychiatrists, and social workers before, during, and after gene therapy is important to educate the patient about gene therapy, manage pain, reduce opioid dependence, help patients manage depression, and set reasonable expectations of what life will be like during and after therapy.<sup>25</sup> Patients also need access to reproductive health specialist counseling about the likely impact of gene therapy on their ability to have children in the future, and options for fertility preservation.<br/>Peer counseling by individuals with SCD who have participated in a gene therapy clinical trial or undergone a similar procedure (e.g., bone marrow</p> | <ul style="list-style-type: none"> <li>• Access to out-of-state providers, if there is no qualified SCD gene therapy provider (or no capacity) in the state</li> <li>• Access to hematologists and transplant physicians who specialize in SCD</li> <li>• Access to reproductive health specialists</li> <li>• Access to dental care</li> <li>• Beneficiary knowledge of and timely access to non-emergency medical transportation (NEMT)<sup>26</sup></li> <li>• Access barriers,<sup>27</sup> including childcare<sup>28</sup></li> <li>• Access to peer counseling and support</li> <li>• Access to mental health providers and health care providers specializing in pain management and addiction</li> <li>• Access to care coordination/patient navigation/community</li> </ul> |
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<sup>23</sup> There are two principal categorizations of “sickle cell centers.” Under the HRSA Sickle Cell Disease Treatment Demonstration Program, there are 5 awardee regional “hubs,” which have relationships with 51 participating clinical sites. Each of the hubs and participating sites could be considered a sickle cell “center” based on their provision of multidisciplinary sickle cell specialty care, including behavioral health care focused on opioid addiction, pain management, and depression. There is also a National Association of Sickle Cell Centers, started by some of the principal investigators in the HRSA program, which includes over 80 certified Sickle Cell Centers.

<sup>24</sup> Patients may be required to have a caregiver in order to be considered fit for gene therapy.

<sup>25</sup> Individuals with SCD may have behavioral health challenges relevant to their SCD and potential gene therapy, including depression, and opioid dependence, and may have developed an identity as a person living with a debilitating chronic disease. They may also need education to develop realistic expectations of what their life will be like post-therapy.

<sup>26</sup> Many patients will likely need to travel and stay overnight near the center, and some will need to cross state lines to access sickle cell or transplant centers. Many beneficiaries will require assistance with transportation to and from the center, and meals and lodging for themselves and a caregiver while being treated on an outpatient basis at the center.

<sup>27</sup> Throughout this document, access barriers refer to things like transportation, housing, nutrition, and childcare. CMS encourages States to review CMS’ framework of services and supports to address access barriers that CMS considers allowable under specific Medicaid and CHIP authorities. “CMCS Informational Bulletin: Coverage of Services and Supports to Address Health-Related Social Needs in Medicaid and the Children’s Health Insurance Program.” Center for Medicaid & CHIP Services (Nov. 2023), available [here](#).

<sup>28</sup> Patients with children may require childcare during the patient journey. See Ranji U, Rosenzweig C, Gomez I. “Executive Summary: 2017 Kaiser Women’s Health Survey,” Kaiser Family Foundation (2018), available [here](#). Within this survey, 17% of women at less than 200% of FPL reported going without or delaying care due to problems with childcare.

|                                                                                                             |                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
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|                                                                                                             | <p>transplant for SCD) can be very important for patients as they consider whether gene therapy is the right choice for them, as well as during and after the treatment regimen.</p> <p>Patients opting for gene therapy provide their consent to move forward with the treatment regimen.</p> | health worker (CHW) services                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>4. Transition Disease Management to Preparation for Gene Therapy</b><br><i>(60-90 days / Outpatient)</i> | <b>Patient is managed by a hematologist who specializes in SCD.</b> Patient is gradually taken off hydroxyurea and begins chronic transfusion therapy for 2-3 months, while SCD continues to be managed.                                                                                       | <ul style="list-style-type: none"> <li>• Access to a hematologist who specializes in SCD</li> <li>• Timely access to NEMT</li> <li>• Access to care coordination/patient navigation/CHW services</li> </ul>                                                                                                                                                                                                                                                                                                                                                                             |
| <b>5. Apheresis</b><br><i>(3-9 days / Inpatient)</i>                                                        | <b>Patient travels to transplant center for apheresis (harvesting cells).</b> Patients require 1-3 cycles of cell collection, each of which takes 3 days.                                                                                                                                      | <ul style="list-style-type: none"> <li>• Access to out-of-state providers, if there is no qualified SCD gene therapy provider (or no capacity) in the state</li> <li>• Access to hematologists and transplant physicians who specialize in SCD</li> <li>• Timely access to NEMT</li> <li>• Access barriers, including childcare</li> <li>• Access to peer counseling and support</li> <li>• Access to mental health providers and health care providers specializing in pain management and addiction</li> <li>• Access to care coordination/patient navigation/CHW services</li> </ul> |
| <b>6. Stem Cell Modification</b><br><i>(~40-180 days / Home)</i>                                            | <b>Patient returns home while Manufacturer modifies stem cells.</b> Manufacturers can take anywhere from 6-16 weeks to modify the cells and send them to the transplant center. During this time, a hematologist must continue to manage the patient's sickle cell disease.                    | <ul style="list-style-type: none"> <li>• Access to a hematologist who specializes in SCD</li> <li>• Access barriers</li> <li>• Access to peer counseling and support</li> <li>• Access to mental health providers and health care providers specializing in pain management and addiction</li> </ul>                                                                                                                                                                                                                                                                                    |

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|                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <ul style="list-style-type: none"> <li>• Access to care coordination/patient navigation/CHW services</li> </ul>                                                                                                                                                                                                                                                                                                                                     |
| <b>7. Optional Fertility Preservation</b><br><i>(Duration may take several months; typically concurrent with stem cell modification / Outpatient)</i> | <b>Fertility Preservation typically takes place while waiting for the genetically modified cells to be sent back to the transplant center.</b> Fertility Preservation consists of harvesting, freezing, and storing reproductive material. The time required to collect reproductive material differs for males and females, and from individual to individual. Treatment requires coordination between the patient's fertility, transplant, and SCD specialists. | <ul style="list-style-type: none"> <li>• Access to fertility preservation services</li> <li>• Coordination between the patient's fertility, transplant, and SCD specialists</li> <li>• Access barriers</li> <li>• Access to care coordination/patient navigation/CHW services</li> </ul>                                                                                                                                                            |
| <b>8. Chemotherapy</b><br><i>(7-9 days / Inpatient)</i>                                                                                               | <b>Patient returns to transplant center for conditioning (chemotherapy).</b> Before infusion of the gene therapy, the patient receives intense chemotherapy (4-6 days of receiving infusions, followed by three days of rest) on an inpatient basis. The conditioning chemotherapy typically renders an individual infertile and results in significant mucositis, low blood counts, and fever.                                                                   | <ul style="list-style-type: none"> <li>• Access to out-of-state providers, if there is no qualified SCD gene therapy provider (or no capacity) in the state</li> <li>• Timely access to NEMT</li> <li>• Access barriers, including childcare</li> <li>• Access to mental health providers and health care providers specializing in pain management and addiction</li> <li>• Access to care coordination/patient navigation/CHW services</li> </ul> |
| <b>9. Gene Therapy Infusion and Recovery</b><br><i>(35-45 days / Inpatient)</i>                                                                       | <b>Modified stem cell product infusion</b> occurs in hospital, followed by an inpatient stay, all of which lasts 35-45 days, during which time the patient receives frequent blood tests and assessments of lung and heart function, echocardiogram, CT scans, red blood cell and platelet infusions, bone marrow assessments, and pain management services.                                                                                                      | <ul style="list-style-type: none"> <li>• Access to out-of-state providers, if there is no qualified SCD gene therapy provider (or no capacity) in the state</li> <li>• Timely access to NEMT</li> <li>• Access barriers, including childcare</li> <li>• Access to mental health providers and health care providers specializing in pain management and addiction</li> </ul>                                                                        |

|                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
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|                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <ul style="list-style-type: none"> <li>• Access to care coordination/patient navigation/CHW services</li> </ul>                                                                                                                                                                                                                                                                                                                                                                        |
| <b>10. Follow-up Care</b><br><i>(15 years / Outpatient)</i> | <p><b>Follow-up care.</b> For the first 60 days after discharge, patient follow-up may consist of twice-weekly blood work, as determined by a hematologist. Some patients may require more intense follow-up that requires them to stay near the transplant center during this time.</p> <p>100 days after the infusion, the frequency of follow-up visits may be reduced to monthly for the next year and at least annually for 15 years after infusion.</p> <p>If the transplant team is not the hematologist/SCD specialist, patients require ongoing close follow-up by their SCD specialist. Follow-up care includes weaning opioid medications in the first-year post-treatment, monitoring for SCD complications that might not be eradicated long-term (e.g., stability or progression of existing organ damage), and mental health support (including peer counseling).</p> | <ul style="list-style-type: none"> <li>• Access to hematologists specializing in SCD</li> <li>• Timely access to NEMT</li> <li>• Access barriers, including childcare</li> <li>• Access to peer counseling and support</li> <li>• Access to mental health providers and health care providers specializing in pain management and addiction</li> <li>• Access to care coordination/patient navigation/CHW services</li> <li>• Help navigating changes in insurance coverage</li> </ul> |

## A6. Program Requirements

CMS will award Cooperative Agreements to successful Applicants to implement the Model as well as to support states that achieve performance milestones.

- While the Model performance period begins on January 1, 2025, Cooperative Agreement funding will not begin until July 1, 2025.
- Recipients may not use Cooperative Agreement funding for expenses incurred *prior* to July 1, 2025.

Cooperative Agreements are anticipated to conclude on December 31, 2035 (at the conclusion of the Model performance period) or earlier if a State's participation in the Model is terminated earlier. See Section A4, Table 2 *Relationship between Calendar Years, Model Performance Years (PYs) and Cooperative Agreement Budget Periods (BPs)*.

### A6.1 Model Participation

The following sections describe how States and Manufacturers of Model Drugs will participate in the Model.

#### A6.1.1 State Participation

To be eligible to receive Cooperative Agreement funding for this Model, the following must occur:

- 1) applicant receives a Cooperative Agreement award for which this NOFO is soliciting applications, and
- 2) applicant signs a State Agreement.

### Cooperative Agreement

States that apply for and are awarded funding under the NOFO will receive a Cooperative Agreement award from CMS. Cooperative Agreement funding will support implementation of both required and optional state activities and will be awarded to Recipients that achieve performance milestones (see Section A6.8 *Cooperative Agreement Funding Structure*).

To be considered for funding under this NOFO, the State must:

- Apply to the State Request for Applications (RFA) by no later than March 14, 2025
- Apply to this NOFO by no later than March 14, 2025
- Sign a State Agreement with CMS (See Section A6.3 *Legal Agreements/Cooperative Agreement Award*, Table 4, 2. *CMS and State: State Participation in Model (State Agreement)*) by no later than June 1, 2025

CMS encourages States to read the State RFA in full before submitting a NOFO application.

### State Agreement

The State Agreement will govern each State's participation in the Model, including the requirements of the Model (See Section A6.3 *Legal Agreements/Cooperative Agreement Award*). States that choose to participate in the Model **without** funding from CMS must respond to the State RFA **and** sign a State Agreement, but **do not** need to respond to this NOFO. The Cooperative Agreement and the State Agreement are both expected to conclude on December 31, 2035, at the conclusion of the Model performance period (see Section A6.3 *Legal Agreements/Cooperative Agreement Award*).

#### **A6.1.2 Manufacturer Participation**

In the 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.

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 Participation Agreement (PA) with CMS before the conclusion of the pre-implementation period.

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:

- 3) Participated in negotiations with CMS during the Model pre-implementation period;
- 4) Entered into a PA with CMS before conclusion of the pre-implementation period; and
- 5) Maintains compliance with the PA.

#### **A6.2 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.

In response to the State RFA, States will specify a start date with respect to each type of beneficiary in the Model population: Medicaid beneficiaries enrolled in fee-for-service (Model Performance Period Start Date); Medicaid beneficiaries enrolled in managed care plans (Managed Care Start Date); and separate CHIP beneficiaries (separate CHIP Start Date, if applicable). See the State RFA, released on June 28, 2024, for more information.

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 was 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.

#### **A6.2.1 Children’s Health Insurance Program (CHIP)**

Participation with respect to beneficiaries in Title XXI-funded Medicaid expansion CHIPs (i.e., 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 NOFO apply to both Title XIX-funded Medicaid and Title XXI-funded Medicaid expansion CHIPs.

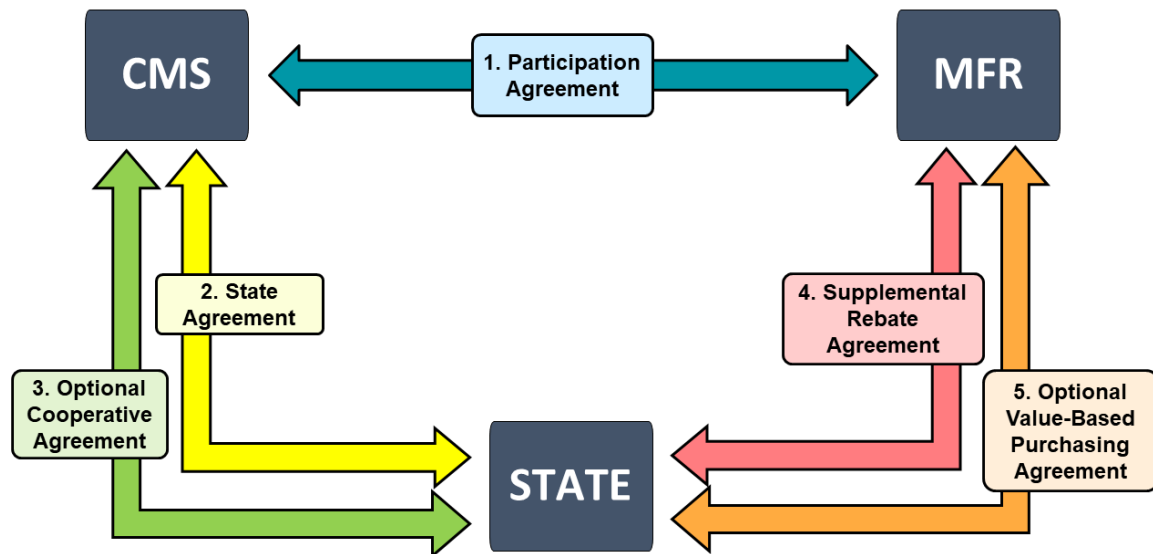
Participation with respect to beneficiaries in separate CHIPs is optional for Manufacturers and States. CMS and Manufacturers may, during Key Term negotiation, structure supplemental Key Terms that constitute a VBP arrangement that meets the definition of such an arrangement at 42 CFR § 447.502 (hereinafter, “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 the State RFA must apply to any agreement reached for the separate CHIP population.

#### **A6.3 Legal Agreements/Cooperative Agreement Award**

The 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 4.

**Figure 2: Legal Agreements/(optional) Cooperative Agreement Award**



Key: CMS = Centers for Medicare & Medicaid Services, MFR = Manufacturer

**Table 4: Legal Agreements/Cooperative Agreement Award**

**1. CMS and Manufacturer: Manufacturer Participation in Model (Participation Agreement)**

**Anticipated Effective Dates:** No later than January 1, 2025 – December 31, 2035

**Description:**

- 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:
  - 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 Model 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 March 2025).

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

**Anticipated Effective Dates:** July 1, 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 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: Participation with respect to 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.

## A6.4 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 A6.2.1). After the Key Terms have been disclosed, States may submit an application to participate in the Model in response to the State RFA and may submit an application for funding in response to this NOFO.

The Key Terms may include the following (Table 5), 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 5: 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. <sup>29</sup> States may create their own criteria and policies so long as they are no more restrictive than the standardized access policy.                                                                                                                                                                                                                                                                        |
| <b><i>CMS Responsibilities</i></b>            | <p>CMS' 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.</p> <p>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.</p> |
| <b><i>Coverage Shifts</i></b>                 | 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.                                                                                                                                                                                                                                                                       |
| <b><i>Fertility Preservation Services</i></b> | CMS will require participating Manufacturers to provide payment for certain fertility preservation services for individuals who receive a Model Drug.                                                                                                                                                                                                                                                                                      |
| <b><i>Guaranteed Rebates</i></b>              | 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.                                                                                                                                                                                                     |
| <b><i>Measurement Period</i></b>              | The time period following administration of the Model Drug during which Outcome Measures for an individual or cohort will be monitored.                                                                                                                                                                                                                                                                                                    |
| <b><i>OBA Term</i></b>                        | <p>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.</p> <p>The OBA Term is expected to be no more than 6 years, and no related obligations are expected to extend beyond 2035.</p>                                                       |
| <b><i>Outcome Measure Benchmarks</i></b>      | 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.                                                                                                                                   |

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<sup>29</sup> Manufacturers and States will have the option of including their separate CHIP beneficiaries in a separate VBP arrangement, discussed further in Section A6.2.1.

|                                                                   |                                                                                                                                                                                                                                 |
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| <b><i>Outcome Measures</i></b>                                    | 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.                                                 |
| <b><i>Outcome-Based Rebates</i></b>                               | The rebate amount paid by the Manufacturer due to failure to reach an Outcome Measure Benchmark. Can be a calculation based on pricing.                                                                                         |
| <b><i>Rebate Documentation</i></b>                                | The materials and data required to confirm that an outcome-based or volume-based rebate is owed to the State.                                                                                                                   |
| <b><i>Reconciliation Period</i></b>                               | The time period following the conclusion of the Measurement Period in which financial settlement and payment of rebates will occur. The Reconciliation Period may include interim and final calculation and payment of rebates. |
| <b><i>Termination, Renewals, Renegotiation or Alterations</i></b> | 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.     |
| <b><i>Volume Accrual Period</i></b>                               | The time period in which additional units of the Model Drug count towards the volume-based rebate before resetting to baseline.                                                                                                 |
| <b><i>Volume-Based Rebates</i></b>                                | The amount paid by Manufacturer based on the number of eligible units of the Model Drug counted during the Volume Accrual Period.                                                                                               |

### **A6.5 State Requirements**

See Section A6.3 *Legal Agreements/Cooperative Agreement Award*, Table 4, 2. *CMS and State: State Participation in Model (State Agreement)* for State requirements under the Model. More details on State Requirements are provided in the State RFA.

### **A6.6 Optional State Activities**

States are encouraged to engage in optional activities that would increase access to SCD gene therapy and promote multi-disciplinary, comprehensive care for beneficiaries with SCD who are potential candidates for or recipients of SCD gene therapy (see Section A5.2 *Recommended Care Journey for SCD Gene Therapy and Potential Access Barriers*).

These optional activities fall into five domains and are summarized below. See Section A6.8 *Cooperative Agreement Funding Structure* for information about how CMS would measure and fund these activities.

*Awareness, Education, and Access to Specialty Care:*

- Implementing policy changes that improve/expand access to hematologists (and other physicians) that specialize in SCD for Medicaid beneficiaries with SCD.

- Raising awareness and improving education among hematologists and beneficiaries with SCD about gene therapy and the care journey.
- Raising awareness among beneficiaries about how to access necessary NEMT and related travel expenses, per the assurance of transportation in section 1902(a)(4)(a) of the SSA.<sup>30</sup> Related travel expenses include the cost of transportation, meals, and lodging for the beneficiary and transportation attendant, when necessary for accessing covered services. If the attendant is not a family member, related travel expenses may also include a salary for the attendant.
- Providing access to dental care.

#### *Behavioral Health Services:*

- Providing access to mental health care (including by non-physicians, such as psychologists or clinical social workers) as well as to addiction treatment and pain management services as necessary. Such services may be provided in-person or via telehealth, where appropriate.
- Providing peer support.

#### *Access Barriers:*

- Conducting screening and referral services related to access barriers patients may experience.
- Providing direct services to address access barriers, such as housing, nutrition, and childcare necessary to ensure beneficiaries can receive the medical services subject to the Model. CMS encourages States to review the November 2023 [CMCS Informational Bulletin](#) for a framework of services and supports to address access barriers that CMS considers allowable under specific Medicaid and CHIP authorities.<sup>31</sup> Cooperative Agreement funding may also be used to fund services not allowable by Medicaid, such as childcare.<sup>32</sup>

#### *Care Coordination:*

- Providing case management/care coordination/patient navigation/community health worker support.

#### *Family Planning:*

- Providing access to fertility preservation services not covered by participating Manufacturers, including creation, cryopreservation, and storage of embryos, as well as in-vitro fertilization.<sup>33</sup>

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<sup>30</sup> See also 42 CFR 440.170(a) and SMD #23-006, “Assurance of Transportation: A Medicaid Transportation Coverage Guide.” Center for Medicaid & CHIP Services (Sept. 2023), available [here](#).

<sup>31</sup> For a list of allowable housing and nutrition services, see also “Coverage of Health-Related Social Needs (HRSN) Services in Medicaid and the Children’s Health Insurance Program (CHIP).” Center for Medicaid & CHIP Services (Nov. 2023), available [here](#).

<sup>32</sup> Childcare cannot be covered as a Medicaid benefit, but States may partner with CBOs or non-profits to assist beneficiaries with these services.

<sup>33</sup> Under the CGT Access Model, manufacturers are required to pay for a defined scope of fertility preservation services that includes collection, cryopreservation, and storage of reproductive material (i.e., eggs, sperm, ovarian tissue, testicular tissue) for at least five years and up to fifteen years. Manufacturers may not pay for the creation, cryopreservation, and storage of embryos, but Medicaid may cover such services under the family planning provision.

States may go about these activities by:

- Expanding or increasing services and reimbursement rates for Medicaid benefits and services, including under the Optional Benefit for Sickle Cell Disease (see Section A6.7 *Optional Benefit for Sickle Cell Disease*).
- Conducting direct information and outreach campaigns to beneficiaries and SCD providers.

**Note:** Cooperative Agreement funding **cannot** be used to pay for state share of any expanded Medicaid benefits or increased reimbursement rates. Funding may be used to pay for staff/contractor time and infrastructure costs related to *implementing* these benefits and services.

- Partnering with Community-Based Organizations (CBOs) and non-profit organizations as subrecipients or contractors to:
  - Educate providers and patients about gene therapy for SCD and NEMT services
  - Conduct screening and referral services for access barriers patients may experience
  - Assign care coordination/patient navigation/community health worker services to patients to help them navigate the SCD gene therapy care journey and to help them resolve access barriers related to preparation for, receipt of, or follow-up care for SCD gene therapy
  - Resolve beneficiaries' documented access barriers related to the preparation for, receipt of, or follow-up care for gene therapy medical appointments (i.e., childcare, transportation, nutritional supports, and lodging)
  - Provide peer supports
  - Help patients navigate changes in insurance coverage

### **A6.7 Optional Benefit for Sickle Cell Disease**

Under Section 712 of the American Jobs Creation Act of 2004 (AJCA), Title XIX of the SSA was amended to provide an optional benefit in the Medicaid program and to make Federal matching funds available for a variety of benefits and activities targeted at Medicaid beneficiaries with SCD. Such benefits and services include:

- Education and outreach
- Genetic counseling and testing
- Additional services not otherwise covered in the state plan (e.g., optional fertility preservation services, optional adult dental benefits)
- Reimbursement for SCD services at a different rate than the State pays for similar services provided to individuals with other diseases (e.g., increase reimbursement rates for SCD-related substance use treatment for individuals with SCD)

For more information about the Optional Benefit for Sickle Cell Disease, CMS encourages States to review the relevant letter to State Medicaid Directors ([SMDL #05-003](#)) regarding the optional Medicaid benefit for SCD.

### **A6.8 Cooperative Agreement Funding Structure**

Cooperative Agreement funding will be available to Recipients throughout the entire Cooperative Agreement Period of Performance from Budget Period 1-Budget Period 10, conditional upon continued compliance with the terms and conditions of the award.

- Maximum dollar amounts available per Budget Period are stated in Section B4 *Cooperative Agreement Funding Schedule*.

- Implementation Funding may be available in Budget Periods 1-10 (see Section A6.8.1 *Implementation Funding*).
- Milestone Funding may be available in Budget Periods 1-6 (see Section A6.8.2 *Milestone Funding*).
- The availability and maximum amount of each type of funding depends on the length of the OBA Term and the overall duration of the Model.<sup>34</sup>
- During Budget Periods 1-6, Recipients may allocate funding to Implementation Funding, Milestone Funding (if available), or both.<sup>35</sup>
- Milestone Funding will not be available during Budget Periods 7-10 and therefore, Recipients may only use Implementation Funding during those Budget Periods.

### **A6.8.1 Implementation Funding**

Recipients may use Implementation Funding to support required and optional Model activities that involve staff/contractor time and infrastructure costs (see Section A6.5 *State Requirements* and Section A6.6 *Optional State Activities*).

- Data collection is an example of a *required* Model activity for which Applicants may request Implementation Funding.
- Costs related to partnering with a CBO is an example of an *optional* activity for which Applicants may request Implementation Funding.
- All activities and costs for which Applicants request Implementation Funding must be detailed in the Budget Narrative section (Section D2 *Content and Form of Application Submission*) of their application.

Note that the Budget Narrative for the initial application to the NOFO must include budget estimates for the entire Cooperative Agreement Period of Performance (i.e., all Budget Periods). Such estimates should be as detailed as possible. Recipients may make changes to their budget requests in their annual non-competing continuation application. The total amount requested for any year may not exceed the original amount proposed and approved by CMS during the initial application review process, without prior approval from CMS. The total budget for all years may not exceed the total maximum amount allowed and approved for all years.

The Budget Narrative section provides a non-exhaustive list of eligible implementation activities. Applicants may propose, and CMS may approve, additional implementation activities. See Section F5.1.1 *Implementation Funding Reporting* for information about reporting requirements associated with Implementation Funding.

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<sup>34</sup> Greater amounts may be allocated to Implementation Funding to support activities during the OBA Term of the Model, and Milestone Funding is linked to Recipient performance during the OBA Term of the Model. The duration of the OBA Term will be negotiated by CMS and Manufacturers and is expected to be no more than 6 years. Therefore, availability and amounts of each type of funding for Budget Periods 2-6 will be dependent on the negotiated OBA Term (see Section B4 *Cooperative Agreement Funding Schedule*). The OBA Term will be disclosed to States in December 2024.

<sup>35</sup> See Section B4 *Cooperative Agreement Funding Schedule* for exceptions. For the first 6 months of Budget Period 1, Recipients may only allocate their Cooperative Agreement funding to Implementation Funding. For the Budget Period following the end of the OBA Term, both Milestone Funding and Implementation Funding are available, but only a limited amount of funding may be allocated to Implementation Funding.

Continuation of Implementation Funding each year is subject to the availability of funds. Greater maximum funding amounts are available to be allocated to Implementation Funding during the OBA Term of the Model. The amount of Implementation Funding available for BP2-BP6 depends on the duration of the OBA Term negotiated with Manufacturers. **See Section B4, Table 6 for the maximum amount of funding available to each Recipient per Budget Period and calendar year.**

### Partnerships with CBOs

Implementation Funding may also be used by States to partner with CBOs as subrecipients or contractors.<sup>36</sup> In the Project and Budget Narrative sections, the State may propose providing funding to CBOs with a focus on providing services to individuals with SCD for any of the following purposes: increasing awareness and education of gene therapy among patients and health care providers; increasing awareness and access to supportive ancillary services necessary for beneficiaries to receive gene therapy (e.g., transportation, nutritional, lodging, and childcare supports); providing services related to addressing access barriers (subject to the cost restrictions discussed in Section D6), and providing community health worker/patient navigator and peer supports.

States may request Implementation Funding to pay CBOs to provide housing and nutrition services and supports to applicable beneficiaries, consistent with the following requirements:

- Services and supports may be provided to beneficiaries in the state’s Model population<sup>37</sup> meeting eligibility criteria for SCD gene therapy.
- Services must be necessary for the beneficiary to initiate and complete the SCD gene therapy care process (e.g., attend appointments, remain healthy enough to receive gene therapy).
- Interventions must be evidence-based and medically appropriate for SCD beneficiaries receiving gene therapy based on clinical and social risk factors.
- Services may be provided no earlier than the beneficiary’s evaluation for gene therapy at a transplant center, and no later than the conclusion of the beneficiary’s OBA Measurement Period. (“Measurement Period” means the time period following administration of the gene therapy during which outcome measures for an individual or cohort will be monitored. The Measurement Period will be determined in CMS-Manufacturer negotiations and will be part of the Key Terms disclosed to States in December 2024.)
- Services must be voluntary for beneficiaries, and beneficiaries may refuse or opt out of services at any time. States may not condition coverage of any benefit or service on receipt of services to address access barriers.
- The CBO must ensure that the beneficiary does not otherwise have access to the services through another public program.
- Services cannot already be provided by the State in accordance with the Medicaid assurance of transportation (which includes travel, lodging and meals for the beneficiary and caregiver for long-distance travel to medically necessary care).<sup>38</sup>

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<sup>36</sup> States must determine whether to classify CBOs as subrecipients or contractors, in accordance with 45 CFR 75.351.

<sup>37</sup> 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 the Model gene therapies. Manufacturers and States will have the option to include separate CHIP beneficiaries alongside Medicaid beneficiaries.

<sup>38</sup> Social Security Act § 1902(a)(4)(A); *see also* 42 CFR 440.170(a).

States may request Implementation Funding to pay CBOs to provide childcare, consistent with the following requirements:

- Childcare services must be limited to payment/reimbursement for childcare (for the patient's children or the caregiver's children) while the patient is traveling overnight to/from treatment and during inpatient stays and outpatient visits.
- Childcare must be necessary for the beneficiary to initiate and complete the SCD gene therapy care process (e.g., attend appointments) and receive other medical services subject to the Model.
- Costs for childcare services must be reasonable. States must specify how CBOs will pay for both short-term (e.g., for an outpatient appointment) and long-term (e.g., during an inpatient stay) childcare services, including any caps on payment amounts.
- The CBO must maintain documentation that the childcare provided was consistent with these requirements, including records of payment for the childcare services.

#### **A6.8.2 Milestone Funding**

In addition to Implementation Funding, States may seek Milestone Funding linked to achievement of performance milestones during the OBA Term. Performance milestones will be linked to successful completion of research projects related to increasing access to SCD gene therapy and promoting multi-disciplinary, comprehensive care for beneficiaries with SCD who are considering or receiving SCD gene therapy.

Research projects eligible for Milestone Funding must be related to the patient care journey for SCD gene therapy (see Section A5.2 *Recommended Care Journey for SCD Gene Therapy and Potential Access Barriers*). States may propose projects in one or more of the following categories:

- Awareness, Education, and Access to Specialty Care
- Behavioral Health
- Access Barriers
- Care Coordination
- Family Planning

A project must answer a research question about how and whether the State's Medicaid (and CHIP, if applicable) beneficiaries with SCD were able to access SCD gene therapy and/or receive multi-disciplinary, comprehensive care related to SCD gene therapy. Projects may be designed to study the current state of patient care within the State's Medicaid (and CHIP) program and/or to identify barriers and potential opportunities for improvement. For example, a State could propose a project designed to study challenges Model beneficiaries experienced in accessing mental health services before and after gene therapy. Projects may also be designed to study the effect of a policy change or intervention. For example, a State could propose a project designed to examine the effect of a State policy change on Model beneficiaries' access to family planning services.

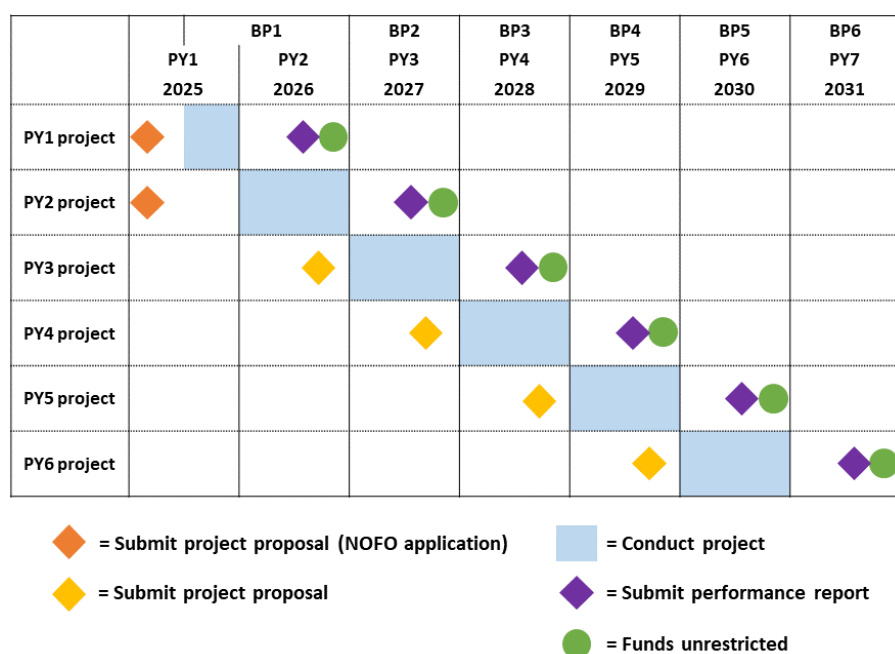
Projects must include primary data collection from Model beneficiaries, caregivers, providers, and/or CBOs providing services to Model beneficiaries. States may supplement their analysis with secondary data from other sources, such as claims data and electronic health records. Recipients must comply with regulations for the protection of human subjects in 45 CFR Part 46 and obtain institutional review board (IRB) approval as applicable.

Recipients may partner with other organizations as contractors or subrecipients to conduct research projects. Partner organizations may include CBOs, treatment centers qualified to administer gene therapy, or academic institutions.

To earn Milestone Funding for a project, the State must submit a report describing their study, research findings, and lessons learned. Lessons learned from Milestone Funding projects can help States improve care for Model beneficiaries. Non-proprietary and non-sensitive information from projects may be shared among the State learning system to support the identification and spread of new knowledge obtained from project activities. Recipients are encouraged to share their research findings publicly.

An example that illustrates the timing of Milestone Funding projects and receipt of funding is shown in Figure 3.

**Figure 3: Milestone Project Timing**



### Receipt of Milestone Funding

Recipients may receive Milestone Funding for performance on a project conducted in the previous PY. In Budget Period 1, beginning in CY 2026, Recipients may receive Milestone Funding for projects conducted in PY1 (CY 2025). Milestone Funding will be available following completion of a project. Milestone Funding is not guaranteed and will be restricted (unavailable for Recipient use) unless the Recipient demonstrates satisfactory completion of the project in its submitted report (see Section F5.1.2 *Milestone Funding Reporting*). Recipients may use unrestricted Milestone Funding only for cost-based reimbursement of their completed Milestone Funding projects.

Continuation of Milestone Funding each year is subject to the availability of funds. The availability of Milestone Funding for BP2-BP6 depends on the duration of the OBA Term negotiated with Manufacturers. **See Section B4, Table 6 for the maximum amount of funding available to each Recipient per Budget Period and calendar year.**

### Project Proposals

States may propose Milestone Funding projects to be conducted in any or all Budget Periods during the OBA Term (potentially BP1-BP5). Projects must be designed to be completed within a single PY (with the exception of projects conducted in BP1). However, if a State provides sufficient justification as to why a larger multi-year project would produce insights that could not be gained from a single-year project, CMS may approve a multi-year project with distinct phases corresponding to separate PYs.

In the Project Narrative, Applicants must propose any Milestone Funding projects they plan to conduct during BP1. Milestone Funding associated with these projects may be awarded in BP1 and BP2. Applicants may propose either:

- a) Separate projects to be conducted in PY1 and/or PY2
  - For a PY1 project, Milestone Funding for BP1 would be based on a full performance report due in CY 2026.
  - For a PY2 project, Milestone Funding for BP2 would be based on a full performance report due in CY 2027.
- b) A single 18-month project to be conducted over PY1 and PY2
  - For a joint PY1-PY2 project, Milestone Funding for BP1 would be based on an interim report due in CY 2026, describing progress on the project during PY1. Milestone Funding for BP2 would be based on the full performance report due in CY 2027.

Along with each non-competing continuation (NCC) application, Recipients must propose any Milestone Funding project that they plan to conduct in the upcoming Budget Period. If CMS approves the project, the Recipient's Terms and Conditions will stipulate that Milestone Funding associated with the project is to be awarded in the following Budget Period.

A project may be a continuation of a project from a previous Budget Period; however, in order to earn additional Milestone Funding the project must build upon the previous project and require additional effort.

In the Budget Narrative, Applicants must include budget estimates for all Milestone Funding projects they plan to conduct during the entire Cooperative Agreement Period of Performance (i.e., all Budget Periods). However, since projects in later Budget Periods may build on lessons learned in previous research projects, Applicants are not expected to submit a detailed research proposal for projects planned beyond BP1 in their initial application to the NOFO.

### **A7. Technical Assistance and Information for Prospective Applicants**

Prior to the application deadline, CMS will host one or more webinars to provide details about the Model and answer questions from potential applicants regarding this funding opportunity. Information about the webinars will be posted on the Innovation Center CGT Access Model website at <https://www.cms.gov/priorities/innovation/innovation-models/cgt>.

## **B. Federal Award Information**

There are two periods of performance to be aware of in this Model:

- **Model Performance Period (anticipated):** *January 1, 2025 - December 31, 2035*
  - The first Model Performance Year (PY1) is January 1, 2025-December 31, 2025.
  - Each participating State has the flexibility of joining the Model anytime from January 1, 2025 to January 1, 2026. In other words, States may choose whether or not to begin performance in the Model during Performance Year 1 but must begin performance by the start of Performance Year 2 (January 1, 2026).
- **Cooperative Agreement Period of Performance (anticipated):** *July 1, 2025 - December 31, 2035*

For all participating States, the Model Performance Period and the Cooperative Agreement Period of Performance are anticipated to conclude on December 31, 2035 (see Section A4. *Model Performance Period and Cooperative Agreement Period of Performance*).

## **B1. Total Funding**

The total amount of funding available is \$95.5 million, subject to availability of funds.

## **B2. Award Amount**

Individual awards will not exceed \$9.55 million, subject to availability of funds.

The initial amount of Implementation Funding for each Cooperative Agreement Award will depend upon the applicant's:

- total proposed budget,
- the allowability and reasonableness of the costs proposed, and
- need, as demonstrated in the application submitted in response to this NOFO.

If awarded, a Recipient is required to comply with all requirements in the Terms & Conditions and submit non-competing continuation applications to continue receiving Implementation Funding during subsequent budget periods. Milestone Funding begins in CY 2026 of Budget Period 1 (see Section A6.8.2 *Milestone Funding* and Section B4 *Cooperative Agreement Funding Schedule*) and will depend on achievement of reporting and performance milestones and the availability of funds.

An Applicant must provide estimated budgets for all budget periods as instructed in Appendix I *Guidance for Preparing a Budget Request and Narrative*. CMS will distribute the initial award funds through the initial Notice of Award (see Section B3); subsequent non-competing continuation awards will be issued throughout the Cooperative Agreement Period of Performance and Recipients may adjust their estimated budgets in subsequent non-competing continuation applications. The total amount requested for any year may not exceed the original amount proposed and approved by CMS during the initial application review process, without prior approval from CMS. The total budget for all years may not exceed the total maximum amount allowed and approved for all years.

## **B3. Anticipated Award Dates**

The anticipated initial award date is July 1, 2025.

## **B4. Cooperative Agreement Funding Schedule**

The availability of Cooperative Agreement funding in each Budget Period will depend on the duration of the OBA Term and duration of the Model, as negotiated between CMS and Manufacturers. The OBA Term will be part of the Key Terms disclosed to States in December 2024. Recipients may allocate

funding to Implementation Funding, Milestone Funding, or both. Maximum funding amounts per Recipient in each Budget Period are as follows:

- For Budget Period 1, a maximum of \$2,118,000 is available.
  - In CY 2025 (July – Dec 2025), a maximum of \$794,800 is available, which may only be allocated to Implementation Funding.
  - The remaining \$1,323,200 is restricted until the start of CY 2026. In CY 2026, a maximum of \$125,000 may be allocated to Milestone Funding.<sup>39</sup>
- For subsequent Budget Periods during the OBA Term (BP2-BP5 in the example below), a maximum of \$1,323,200 will be available, of which a maximum of \$250,000 may be allocated to Milestone Funding.
- For the Budget Period following the end of the OBA Term (BP6 in the example below), a maximum of \$1,323,200 will be available, of which a maximum of \$1,073,200 may be allocated to Implementation Funding and a maximum of \$250,000 may be allocated to Milestone Funding.
- For all subsequent Budget Periods through the end of the Model (BP7-BP10 in the example below), a maximum of \$204,000 will be available, which may only be allocated to Implementation Funding.

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<sup>39</sup> If a Recipient begins Model performance after the beginning of Budget Period 1 (BP1) (July 1, 2025), its maximum Milestone Funding allocation for BP1 will be pro-rated based on the Recipient's Model Performance Period Start Date. For example, if a State begins Model performance on December 1, 2025, it will be eligible to receive a pro-rated maximum of \$20,833.33 (1/6th of \$125,000). If a Recipient begins Model performance on January 1, 2026, it will not be eligible to receive Milestone Funding in BP1.

Table 6 illustrates an example of maximum funding amounts, based on an OBA Term of 6 years (CY 2025 - CY 2030):

| <b>Table 6: Maximum Cooperative Agreement Funding Available Per Recipient, By Budget Period (BP) and Calendar Year (CY)</b> |                                                                                                                                         |                                                            |                                                                                                                     |
|-----------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| <b>Budget Period (Calendar Years)</b>                                                                                       | <b>Maximum Total Funding Amount</b>                                                                                                     | <b>Maximum Allocation to Implementation Funding</b>        | <b>Maximum Allocation to Milestone Funding</b>                                                                      |
| BP1<br>(CY2025<br>Jul - Dec 2025<br>CY 2026<br>Jan – Dec 2026)                                                              | <b>\$2,118,000</b><br><br>• <b>\$794,800 is available in CY 2025.</b><br>• <b>\$1,323,200 is restricted until the start of CY 2026.</b> | <br><br>• \$794,800 in CY 2025<br>• \$1,323,200 in CY 2026 | <br><br>• N/A in CY 2025<br>• \$125,000 in CY 2026, available to States that begin Model performance during CY 2025 |
| BP2 (CY 2027)*                                                                                                              | <b>\$1,323,200</b>                                                                                                                      | \$1,323,200                                                | \$250,000                                                                                                           |
| BP3 (CY 2028)*                                                                                                              | <b>\$1,323,200</b>                                                                                                                      | \$1,323,200                                                | \$250,000                                                                                                           |
| BP4 (CY 2029)*                                                                                                              | <b>\$1,323,200</b>                                                                                                                      | \$1,323,200                                                | \$250,000                                                                                                           |
| BP5 (CY 2030)*                                                                                                              | <b>\$1,323,200</b>                                                                                                                      | \$1,323,200                                                | \$250,000                                                                                                           |
| BP6 (CY 2031)*                                                                                                              | <b>\$1,323,200</b>                                                                                                                      | \$1,073,200                                                | \$250,000                                                                                                           |
| BP7 (CY 2032)                                                                                                               | <b>\$204,000</b>                                                                                                                        | \$204,000                                                  | N/A                                                                                                                 |
| BP8 (CY 2033)                                                                                                               | <b>\$204,000</b>                                                                                                                        | \$204,000                                                  | N/A                                                                                                                 |
| BP9 (CY 2034)                                                                                                               | <b>\$204,000</b>                                                                                                                        | \$204,000                                                  | N/A                                                                                                                 |
| BP10 (CY 2035)                                                                                                              | <b>\$204,000</b>                                                                                                                        | \$204,000                                                  | N/A                                                                                                                 |
| <b>Total</b>                                                                                                                | <b>\$9,550,000</b>                                                                                                                      |                                                            |                                                                                                                     |

\*Maximum funding amounts available in these Budget Periods is subject to the duration of the OBA Term.

## B5. Number of Awards

Up to 52, including the 50 states, the District of Columbia, and all U.S. territories that participate in the Medicaid Drug Rebate Program (MDRP).<sup>40</sup>

## B6. Type of Award

The type of award issued under this NOFO is a Cooperative Agreement. The difference between grants and Cooperative Agreements is the degree of federal programmatic involvement rather than the type of administrative requirements imposed. A Cooperative Agreement differs from a grant in that it provides for substantial involvement between the federal awarding agency and the non-federal entity in carrying out the activity contemplated by the federal award. Therefore, statutes, regulations, and policies, that are applicable to grants also apply to Cooperative Agreements, unless the award itself provides otherwise.

<sup>40</sup> As of the date of publication of this NOFO, Puerto Rico is the only U.S. territory that participates in the MDRP.

References throughout this NOFO to grants also apply to Cooperative Agreements unless this NOFO states otherwise. Please refer to section F4. *Cooperative Agreement Terms and Conditions of Award* for more information about Cooperative Agreements.

## **B7. Type of Competition**

This NOFO is open to all eligible applicants.

## **C. Eligibility Information**

### **C1. Eligible Applicants**

Eligible applicants are States, the District of Columbia, and any U.S. Territory participating in the Medicaid Drug Rebate Program (MDRP). Eligible applicants must:

- Apply to the State RFA by no later than March 14, 2025
- Apply to this NOFO by no later than March 14, 2025
- Sign a State Agreement with CMS (See Section A6.3 *Legal Agreements/Cooperative Agreement Award*, Table 4, 2. *CMS and State: State Participation in Model (State Agreement)*) by no later than June 1, 2025

### **C2. Cost Sharing or Matching**

Cost Sharing or Matching is not required for this program.

### **C3. Letter of Intent**

N/A.

### **C4. Ineligibility Criteria**

CMS reserves the right to disqualify an applicant based on the following criteria:

- The applicant is not a State, the District of Columbia, or U.S. territory that participates in the Medicaid Drug Rebate Program
- The State has not submitted an application to the State RFA
- The State's RFA application was not approved by CMS
- The State did not sign a State Agreement with CMS to participate in the Model

### **C5. Single Application Requirement**

Each State may submit only one application.

### **C6. Continued Eligibility**

Continued funding is contingent on satisfactory progress, compliance with the terms and conditions, and the availability of funds.

Recipients must meet reporting and certification deadlines (as outlined in section F) to be eligible throughout the initial budget period and to remain eligible for a non-competing continuation award for subsequent budget periods in multi-year projects. In addition, recipients must demonstrate satisfactory performance during the previous funding cycle(s) to be issued additional year funding. At any time in the

award cycle, recipients could receive decreased funding, or their award could be terminated in accordance with 45 CFR Part 75.372 “Termination” if they fail to perform the requirements of the award.

Expectations for satisfactory progress will be included in the Cooperative Agreement terms and conditions. Satisfactory performance for selected award recipients includes but is not limited to meeting reporting milestones listed in Section F5 *Reporting*.

## **C7. EIN, UEI, Login.gov and SAM Regulations**

All applicants must have the following to apply to submit an application to Grants.gov:

- a valid Employer Identification Number (EIN), otherwise known as a Taxpayer Identification Number (TIN)
- a Unique Entity Identifier (UEI)
- a Login.gov account, and
- active registration in the System for Award Management (SAM) database (<https://www.sam.gov/>).

(See Appendix II. *Application and Submission Information* for descriptions of EIN, UEI, and SAM)

## **C8. Faith-Based Organization**

This grant opportunity is available for State participants of the CGT Access Model only.

## **C9. Other Eligibility Requirements**

Non-Applicable.

# **D. Application and Submission Information**

## **D1. Address to Request Application Package**

You must submit your application through Grants.gov. Grants.gov has information about the online application process. See “How to Apply for Grants” at Grants.gov for electronic submission instructions. Refer to Appendix II. *Application and Submission Information* for additional requirements and instructions.

## **D2. Content and Form of Application Submission**

### **D2.1 Application Format**

Applications determined to be ineligible, incomplete, and/or nonresponsive based on the initial screening may be eliminated from further review.

*Disqualifying Factors.* CMS will not consider an application that:

- Is from an organization that does not meet eligibility conditions.
- Requests funding above the award ceiling shown in the funding range.
- Is not submitted through Grants.gov.
- Is incomplete based on the initial screening.

However, the CMS, Division of Grants Management Director/Deputy Director may continue the review process for an ineligible application if it is in the best interests of the government to meet the objectives of the program.

Each application must include all contents of the application package, in the order indicated, and conform to the following formatting specifications:

- The required page size is 8.5” x 11” letter-size pages (one side only) with 1” margins (top, bottom, and sides).
- All pages of the project and budget narratives as well as other required narrative documents must be paginated in a single sequence.
- Font size must be at least 12-point with an average of 14 characters per inch (CPI).
- The Project Narrative must be double-spaced. The page limit for this document is 80 pages.
- The Budget Narrative may be single-spaced. The page limit for this document is 10 pages.
- The Business Assessment of Applicant Organization may be single spaced. The page limit for this document is 12 pages.
- Tables included within any portion of the application must have a font size of at least 12- point with a 14 CPI and may be single spaced. Tables are counted towards the applicable page limits.
- The project abstract is restricted to a one-page summary that may be single-spaced.
- The following required application documents are **excluded** from the page limitations described previously:
  - Standard Forms, (SF-424, SF-424A, SF-LLL)
  - Application Cover Letter/Cover Page (if applicable),
  - Project/Performance Site Location(s) Form
  - Cost Allocation Plan
- The Program Duplication Assessment may be single-spaced. The page limit is 5 pages.

## D2.2 Standard Forms

You must complete the five standard forms identified below. You can also view them and see their instructions at [Grants.gov Forms](https://www.grants.gov/forms).

### 1. Project Abstract Summary (required)

Write a one-page summary of the proposed project including the purpose and outcomes. Do not include any proprietary or confidential information. We will use this document for information sharing and public information requests if you get an award. Be succinct and use plain language.

Include:

- Goals of the project
- Total budget
- Description of how funds will be used.

### 2. SF-424: Official Application for Federal Assistance (required)

You must complete all sections of the SF-424. Special instructions include:

☐ In Item 15 “Descriptive Title of Applicant’s Project,”:

HHS awarding agencies must establish detailed and accurate award descriptions at the time they make a federal financial assistance award. Award descriptions are:

- critical to ensuring accountability and transparency and
- a primary means to inform the public of the purpose of the federal funding that is distinct from the programmatic level information in the Assistance Listings.

#### Elements of a Strong Award Description

Robust award descriptions provide an understanding of the award's purpose and include a description of award-specific activities and purpose. A strong award description will have all the following elements:

- Specifics about the award purpose
- Activities to be performed
- Expected deliverables and outcomes
- Intended beneficiary(ies) or recipients
- Subrecipient activities (if known)

#### Characteristics of a Strong Award Descriptions

A strong award description will have the following characteristics:

- Uses plain language an average reader can fully understand
- Is brief and succinct
- Is unique on USA Spending
- Does not use or limits abbreviations or acronyms

#### Examples of Strong Award Descriptions:

The Council of Inspectors General on Integrity and Efficiency's Pandemic Response Accountability Committee (PRAC) shared the following examples of effective award descriptions. These, or other agency-specific examples, can be shared with applicants to assist them in developing their award descriptions.

- **Example One:** Construction of pedestrian & bicycle facilities on the Broadway corridor. Broadway @ St. James St- Foxhall Ave. Streetscape improvements & enhancements include sidewalks, curbing, bike lanes, ped bump-outs, and lighting.
- **Example Two:** Levittown Beauty Academy, LLC is creating distance education for students affected by Covid-19. Schools cannot use physical location and students are now doing their schoolwork online.

☐ Check "No" to item 19c. as Review by State Executive Order 12372 does not apply.

☐ The Authorized Organizational Representative (AOR) completes and electronically signs this form.

Note: The signature of the individual that submits the application to Grants.gov populates throughout the application. The signature must match the name of the AOR. Other signatures will not be accepted.

**Authorized Organizational Representative (AOR)**, the AOR is the applicant’s designated representative, who can make legally binding commitments for your organization. When the AOR authorizes an application, they agree that the organization will assume all award obligations.

3. SF-424A: Budget Information Non-Construction (required)
4. SF-LLL: Disclosure of Lobbying Activities (required)

You must submit the SF-LLL form. If you do not engage in lobbying, please insert “Non-Applicable” on the form and include the required AOR name, contact information, and signature.

Please note that the application kit available online on the Grants.gov website is used for many programs and therefore Grants.gov may designate this form as optional to allow for flexibility amongst programs. **However, this form is required as part of the application package and must be submitted for the application to be considered eligible for review.**

5. Project Site Location Form(s) (required)

All applicants must submit the Project Site Location form. Please note that the application kit available online in Grants.gov is utilized for many programs and therefore Grants.gov may designate this form as optional to allow for flexibility amongst programs. However, this form is **required** as part of the application package and must be submitted for the application to be considered eligible for review.

### **D2.3 Application cover letter or cover page (optional)**

The applicant may choose to include a cover letter or cover page to detail its interest in participation in the CGT Access Model; however, a cover letter is not required.

### **D2.4 Project Narrative (required)**

The applicant must provide a project narrative that articulates in detail the proposed goals, measurable objectives, and milestones in accordance with the instructions and content requirements provided below, consistent with the criteria described in Sections A6.8 *Cooperative Agreement Funding Structure*.

Below are the elements (sections) of the project narrative including a brief description of the type of information required within each specific section. The project narrative must be double-spaced and cannot exceed 80 pages in length. The elements of the project narrative include:

- I. Model Implementation Plan (required):** Applicants must submit information about their plans to implement the Model, including:
  1. Which required Model activities the State plans to carry out in-house vs. outsourcing to an external subrecipient or contractor.
  2. Which, if any, of the optional Model activities the State plans to carry out.
    - a. For each optional Model activity, the State must describe their plan for implementing each activity (e.g., provider education implementation plan, implementation plan for raising awareness about NEMT services and related travel expenses; implementation plan for increasing numbers of beneficiaries

seen by a hematologist, etc.) and propose quarterly reporting milestones for each activity.

- b. If the State plans to outsource any optional Model activity to a CBO, the State must submit a CBO Funding Proposal, which will:
  - i. Provide a detailed plan for the identification and recruitment of CBOs providing care and support to individuals with SCD in the applicant State, including CBO program integrity and compliance requirements.
  - ii. Include minimum CBO requirements, and a description of the types of CBO activities for which the State will seek support (e.g., educating providers and patients about gene therapy, screening and referral services for access barriers patients may experience, nutritional supports, housing/lodging supports, transportation, childcare, peer support). For each activity for which the State is seeking support from CBOs, the State must specify the scope of each service being contemplated and what would be out of scope with respect to each service. If the State is seeking support from CBOs to provide housing, nutrition, or childcare services, the State must describe how it will meet the requirements enumerated in Section A6.8.1 *Implementation Funding*.
  - iii. Specify whether the CBO is a subrecipient or contractor, in accordance with 45 CFR 75.351.
  - iv. Specify maximum dollar amounts that will be provided to CBOs per year and frequency with which the State would receive CBO invoices.
  - v. Specify anticipated CBO agreement start and end dates.
  - vi. Identify the number of CBOs/non-profit entities the State plans to partner with, and their names, if available.
  - vii. Provide CBO monitoring and reporting plans.
3. Whether the State plans to expand or increase services and/or reimbursement rates for any Medicaid benefits or services, and if so, which ones. Responses must also describe whether the State plans to do so for the entire eligible Medicaid population or just for beneficiaries with SCD (using the SCD optional benefit). The Applicant must describe in detail any policy changes the State intends to undertake and specifically what the expansion or enhancement will be relative to what is currently offered under the state plan.
4. How the State will customize its implementation plan for populations that may live far from hematologists, gene therapy providers, and other providers that are considered critical to successful completion of the gene therapy journey for individuals with SCD. Responses must include plans for populations that live in areas without reliable access to internet.

**II. Organizational capacity of applicant organization (required):** Applicants must demonstrate their capacity to organize and manage the Model, and to work collaboratively across key State agencies, payers, providers, and (if applicable) subrecipients or contractors. Applicants must provide a description of their organization, including:

1. Staff capacity (e.g., providing job descriptions including positions that may be currently vacant for all key staff that will be involved in the Model),

2. The individual(s) who will have management authority over the Model and provide a resume or CV for each identified manager,
  3. The individual who will be the Project Director (primary liaison to CMS for the Model) and provide a resume or CV for that person,
  4. An organizational chart that identifies lines of authority and name the Authorized Organizational Representative (AOR),
  5. The anticipated role of any subrecipients or contractors that may be engaged to help implement the Model (including CBOs, non-profit entities, treatment centers, or academic institutions)
  6. Any relevant experience designing and implementing programs to support coordinated, patient-centered care for complex medical conditions, including provision of multi-disciplinary medical care and services to address access barriers.
- III. Existing collaborations with community-based organizations (CBOs) (required only if the State plans to request implementation funding to partner with a CBO):** Describe existing State collaborations with CBOs aimed at identifying and addressing access barriers, including those specifically focused on beneficiaries with SCD.
- IV. Participation of CHIP enrollees and applicable activities (required):** Under the Model, States have the option to include separate CHIP beneficiaries (see Section A6.2.1 *Children's Health Insurance Program*). In the response to this NOFO, the Applicant must identify if it will include separate CHIP beneficiaries as participants in the Model (provided that CMS-Manufacturer negotiated separate CHIP Key Terms are available) and which optional activities will apply to separate CHIP beneficiaries.
- V. Optional Medicaid Benefits (required):** Provide a summary of optional Medicaid benefits currently provided by the State that are relevant to the recommended gene therapy care journey described in Section A5.2 *Recommended Care Journey for SCD Gene Therapy and Potential Access Barriers*. This includes, but is not limited to, optional benefits related to screening and referral for access barriers patients may experience; care management, case management, patient navigation, and/or care coordination; provision of direct services to address access barriers; behavioral health services (including mental health, pain management, addiction treatment), or services provided under the optional benefit for SCD as included in the American Jobs Creation Act of 2004 (AJCA) (Pub. L. No. 108-357).
- VI. Milestone Funding Project Proposal(s) (required only if State plans to seek Milestone Funding for BP1 or BP2):** Milestone Funding is available to States that successfully complete projects related to increasing access to SCD gene therapy and promoting multi-disciplinary, comprehensive care for beneficiaries with SCD who are considering or receiving SCD gene therapy. Applicants must submit a proposal for each project they plan to conduct during BP1 (if the State proposes to conduct two separate projects in PY1 and PY2, the State must duplicate this section and complete it for each), including:
1. Timeframe of project (i.e., PY1 only, PY2 only, or joint PY1-PY2).
  2. Category of project (i.e., Awareness, Education, and Access to Specialty Care; Behavioral Health; Access Barriers; Care Coordination; Family Planning). A project may be related to more than one category.
  3. Description of the research question(s) the project is designed to answer.

4. Justification for how the research question(s) is related to increasing access to SCD gene therapy or promoting receipt of multi-disciplinary, comprehensive care for beneficiaries with SCD who are considering or receiving SCD gene therapy, per the patient care journey for SCD gene therapy (see Section A5.2 *Recommended Care Journey for SCD Gene Therapy and Potential Access Barriers*).
5. Research methodology to be used (e.g., patient surveys, focus groups, interviews).
6. Target population and estimated number of participants.
7. Whether the State will seek IRB approval, and whether patients will be asked for consent to data collection activities.
8. Explanation for how the research findings are expected to be used to help the State improve care for Model beneficiaries.
9. Whether the State plans to partner with another organization to conduct the project, and if so:
  - a. The type of organization (CBO, treatment center qualified to administer gene therapy, academic institution)
  - b. Anticipated agreement start and end dates
  - c. The number of organizations the State plans to fund, and their names, if available
  - d. The frequency and type of organization reporting requirements
  - e. Whether the organization is a subrecipient or contractor, in accordance with 45 CFR 75.351.

**VII. Medicaid (and CHIP) Authorities (required):** CMS does **not** anticipate that awardees will *require* new federal statutory authority or a new SPA or Section 1115 waiver to participate in this Model. However, some States may need a new or revised SPA or program waiver to comply with Model requirements (see the State RFA) or to carry out optional Model activities described in this NOFO (for example, if the State intends to expand or increase reimbursement rates for Medicaid benefits, including through the optional benefit for SCD) and adjacent services related to the gene therapy patient journey for SCD (as outlined in Section A5.2 *Recommended Care Journey for SCD Gene Therapy and Potential Access Barriers*).

- The applicant should incorporate a description of the Medicaid and CHIP authorities that it proposes to use to implement the Model, including authorities currently in place as well as authorities the applicant has requested or would request if its NOFO application were successful.
- Information included in the 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, for successful applications, the identification of current and planned Medicaid and CHIP authorities will help support state and federal planning efforts related to new statutory authorities or SPAs/Section 1115 Medicaid waivers.

#### **D2.5 Budget Narrative (required if seeking Implementation Funding)**

Applicants must supplement Form SF-424A with a Budget Narrative. The Budget Narrative includes a yearly breakdown of costs for each line item outlined in the SF-424A, according to a 12-month period (with the exception of Budget Period 1, which will cover 18 months).

- Applicants must include a clear description of the proposed set of services covered with award funds for each activity/cost within the line item.
- The application must clearly define the proportion of the requested funding designated for each activity and justify the applicant's readiness to receive funding.
- The budget separates out funding administered directly by the Recipient from funding allocated to subrecipients or contractors.

Voluntary committed cost sharing or matching is not expected unless specifically stated otherwise in section C2.

Detailed budget justifications must be provided for each activity/cost proposed to be funded under this award along with full computations for budget estimates. Also clearly link each activity to the goals/milestones of this NOFO and be consistent with program requirements. Indirect costs must be reasonable and are only reimbursable in accordance with HHS grants policy.

For additional information and instructions for completing the SF-424A and Budget Narrative, please refer to Appendix I. Guidance for Preparing a Budget Request and Narrative.

Applicants must distinguish between Implementation Funding and Milestone Funding.

Applicants may request Implementation Funding for activities that are necessary to implement requirements of the Model, as outlined in Section A6.5 *State Requirements*. Such activities may include, but are not limited to:

- Developing new State statutory authorities or State Plan Amendments (SPAs).
- Expanding Medicaid staff capacity/personnel, or hiring subrecipients or contractors to improve the quality, completeness, and timeliness of T-MSIS claims data submissions, or implement other aspects of the Model.
- Conducting outreach to and engaging with interested parties, who may be impacted by the Model.
- Establishing and maintaining agreements with managed care plans and in-state/out-of-state gene therapy providers.

Applicants may also request Implementation Funding for optional activities that would increase access to SCD gene therapy and promote multi-disciplinary, comprehensive care for beneficiaries with SCD who are considering, or undergoing, gene therapy. Such optional activities may include (see Section A6.6 *Optional State Activities*):

- Staff time and infrastructure costs related to expanding or increasing Medicaid benefits or reimbursement rates (including through the Optional Benefit for Sickle Cell Disease).
- Staff time and infrastructure costs related to gene therapy for sickle cell disease outreach and education campaigns.
- Partnering with CBOs that are designated to carry out optional Model activities (e.g., conducting screening to address access barriers patients may experience; providing peer support; raising awareness and improving education among hematologists and beneficiaries with SCD about gene therapy)

Applicants may request Milestone Funding for research projects related to increasing access to SCD gene therapy and promoting multi-disciplinary, comprehensive care for beneficiaries with SCD who are considering or receiving SCD gene therapy (see Section A6.8.2 *Milestone Funding*). Milestone Funding will be restricted and is not guaranteed. If a Recipient meets the requirements to warrant release of

Milestone Funding, the funding may be used to reimburse the costs incurred to conduct the research project.

#### **D2.6 Program Duplication Assessment (required, maximum 5 pages)**

Recipients must not use funding to supplant or duplicate current funding activities. This means that funding must not be used to reimburse providers for the provision of services already funded by Medicaid or CHIP. The following information on program duplication provides more direction on how an applicant should incorporate information in their application about their understanding of program duplication risk and their plan for avoiding program duplication.

Applicants should conduct a budget analysis to identify current funding streams they propose to apply to required and optional State activities (if any). As part of this analysis, applicants should also identify new and distinct activities toward which they could apply Cooperative Agreement funding.

CMS will consider an applicant's understanding of program duplication risks as well as the thoroughness of their plan to avoid program duplication during application review. The U.S. Government Accountability Office (GAO) defines program duplication as two or more agencies or programs engaged in the same activities or providing the same services to the same beneficiaries (2017 Annual Report: Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits, 2017).

Applicant must submit a document which addresses the following:

1. Confirms its responsibility to avoid program duplication;
2. Confirms that it will ensure award funds are not used to duplicate or supplant current federal, state, or local funding, or be used for the non-federal share of Medicaid payments;
  - (sample question to consider): Is this expense paid for by another federal, state or local program (i.e., Medicaid, Medicare, Title V block grant funds, the local health department, or another innovation model)?
  - (Sample question to consider): Is the activity a service already provided directly to an attributed beneficiary (e.g., under current Medicaid benefits)?
3. Explain how this funding builds upon current programs and initiatives, if applicable, while avoiding duplication; and
4. Summarizes its standard operating procedures and best practices for avoiding program duplication. If available, please attach as an appendix to the application your standard operating procedure for preventing program duplication.

#### **D2.7 Business assessment of applicant organization (required, maximum 12 pages)**

CMS evaluates the risk posed by an applicant before they receive an award. This analysis of risk includes items such as financial stability, quality of management systems, internal controls and the ability to meet the management standards prescribed in 45 CFR Part 75.

An applicant must review, answer, and submit the business assessment questions outlined in Appendix III. Business Assessment of Applicant Organization.

### **D3. Unique Entity Identifier and System for Award Management (SAM)**

Unless the applicant is an individual or Federal awarding agency that is excepted from those requirements under 2 CFR 25.110(b) or (c), or has an exception approved by the Federal awarding agency under 2 CFR 25.110(d), each applicant is required to:

1. Register in SAM.gov before submitting its application;
2. Provide a valid unique entity identifier in its application; and
3. Continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency.

The Federal awarding agency may not make a Federal award to an applicant until the applicant has complied with all applicable unique entity identifier and SAM requirements. If an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant.

#### **D4. Submission Dates and Times**

All applications must be submitted electronically and be received through <https://www.grants.gov> by the date and time set forth below. Applications received after the date and time set forth below will not be reviewed or considered for award.

Due Date for Applications is March 14, 2025, 11:59 PM Eastern U.S. Time (Baltimore, MD)

#### **D5. Intergovernmental Review**

Program is not subject to Executive Order 12372, “Intergovernmental Review of Federal Programs” (45 CFR 100). Please check box “C” on item 19 of the SF-424 (Application for Federal Assistance) as Executive Order 12372 does not apply to these Cooperative Agreements.

#### **D6. Cost Restrictions**

##### **Direct Costs**

Funding cannot be used:

- For any direct service provision that is already paid for by another federal, state or local program
- To reimburse providers for the provision of Medicaid-funded services.
- To duplicate or supplant other funding sources. For example, Cooperative Agreement funding cannot be used in the following ways:
  - Paying for partnerships with CBOs that already existed prior to participation in the Model (unless, and only to the extent that, the partnerships will be more extensive/costly under the Model).
  - Paying for CBO activities that the State already carries out (e.g., screening and referral related to access barriers a patient may experience).
  - Paying for data collection activities and T-MSIS improvements that were planned using alternate funding sources prior to participation in the Model.

##### **Indirect Costs**

See section F2. Administrative and National Policy Requirements of this NOFO for more information on indirect costs.

### Prohibited Uses of Award Funds

CMS prohibits funds under this award for any of the activities/costs outlined below unless an exception is specifically authorized by statute.

- To reimburse for pre-award costs.
- To match any other Federal funds.
- To provide services, equipment, or supports that are the legal responsibility of another party under Federal, State, or Tribal law (e.g., vocational rehabilitation or education services) or under any civil rights laws. Such legal responsibilities include, but are not limited to, modifications of a workplace or other reasonable accommodations that are a specific obligation of the employer or other party.
- To provide goods or services not allocable to the approved project.
- To supplant existing State, local, Tribal or private funding of infrastructure or services, such as staff salaries, etc.
- To be used by local entities to satisfy state matching requirements.
- To pay for construction.
- To pay for capital expenditures for improvements to land, buildings, or equipment which materially increase their value or useful life as a direct cost, except with the prior written approval of the Federal awarding agency.
- To pay for the cost of independent research and development, including their proportionate share of indirect costs (unallowable in accordance with 45 CFR 75.476).
- To expend funds related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive Order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body in accordance with 45 CFR 75.450 and 45 CFR Part 93.
- To pay for certain telecommunications and video surveillance equipment. See 2 CFR 200.216 to make sure this does not apply to any proposed equipment in your application.
- To pay for meals unless in limited circumstances such as:
  - Subjects and patients under study;
  - Where specifically approved as part of the project or program activity (not grantee specific); and
  - As part of a per diem or subsistence allowance provided in conjunction with allowable travel.
  - Under the assurance of transportation, per the assurance of transportation in section 1902(a)(4)(a) of the SSA.<sup>41</sup>
- To pay for any direct service provision that is already paid for by another federal, state or local program.
- To reimburse providers for the provision of Medicaid-funded services already covered by Medicaid.
- To duplicate or supplant other funding sources.

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<sup>41</sup> See also 42 CFR 44.170(a) and SMD letter on [Assurance of Transportation: A Medicaid Transportation Coverage Guide](#)

## **D7. Mandatory Disclosure**

Submission is required for all applicants, in writing, to the awarding agency and to the HHS Office of Inspector General (OIG), all information related to violations of federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the federal award.

Disclosures must be sent in writing to:

U.S. Department of Health and Human Services  
Centers for Medicare and Medicaid Services  
Office of Acquisition and Grants Management  
Attn: Director, Division of Grants Management  
7500 Security Blvd, Mail Stop B3-30-03 Baltimore, MD 21244-1850

AND

U.S. Department of Health and Human Services  
Office of Inspector General  
ATTN: Mandatory Grant Disclosures, Intake Coordinator  
330 Independence Avenue, SW, Cohen Building  
Room 5527  
Washington, DC 20201

URL: <https://oig.hhs.gov/fraud/report-fraud/index.asp> (Include “Mandatory Grant Disclosures” in subject line)

Fax: (202) 205-0604 (Include “Mandatory Grant Disclosures” in subject line) or Email:  
[MandatoryGranteeDisclosures@oig.hhs.gov](mailto:MandatoryGranteeDisclosures@oig.hhs.gov)

Materials should be scanned and emailed to the Grants Management Specialist assigned to this NOFO.

## **D8. HHS Form 690**

If you receive an award, you must follow all applicable nondiscrimination laws. You agree to this when you register in SAM.gov. You must also submit an Assurance of Compliance ([HHS-690](#)). To learn more, see the [HHS Office for Civil Rights](#) website.

The HHS 690 form may be filed electronically via the U.S. Department of Health and Human Services’ Assurance of Compliance online portal at: <https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf>.

Subrecipients that receive funding from Recipients (including contractors under grants) rather than directly from CMS, also are required to file an HHS 690. The applicant/recipient is responsible for determining whether those organizations have the required Assurance on file and, if not, ensuring that it is filed with OCR.

## **E. Application Review Information**

### **E1. Criteria**

Applications must be submitted in the required format, no later than the deadline. If an applicant does not submit all the required documents and does not address each of the topics described in D2. *Content and*

*Form of Application Submission* (with cross reference to E1. *Criteria*), the applicant risks not being eligible and/or awarded. Applications are reviewed in accordance with criteria outlined below.

Merit reviewers use the NOFO to evaluate each application. Applicants should pay particular attention to sections A6. *Program Requirements*, D2. *Content and Form of Application Submission*, and E1 *Criteria*. The merit review panelists will assess and score applicants' responses in accordance with the criteria below, using a scale of 130 total base points.

All applicants must submit the following:

- Standard Forms (SF-424, SF-424-A, SF-LLL)
- Project Site Location Form(s)
- Project Abstract
- Project Narrative
- Business Assessment of Applicant Organization; and
- Budget Narrative
- Appendices
  - Resumes or Curriculum Vitae for Key Personnel
  - Job Descriptions
  - An Organization Chart
- Federally Negotiated Indirect Cost Rate Agreement (if applicable)
- Program Duplication Assessment

The following documents are optional:

- Application Cover Letter

Below are the review criteria for the Project Narrative, Budget Narrative, and Program Duplication Assessment (Table 7). All elements of the Project Narrative and Budget Narrative are used to assess an Applicant's ability to implement required and optional Model activities.

Incomplete, unclear, and confusing proposals will receive point deductions. Project Narratives with significant content deficiencies may receive a score of zero. Proposals that merely restate the content of the NOFO, without responding to the Program Requirements and Application Review Criteria, will receive a score of zero. Each component of the Project Narrative is weighted as indicated below. The scoring criteria breakdown is reflective of the total possible number of points available, but each item is scored on a range starting from zero. Points are awarded based on the quality of the applicant's response.

You must document all source material. If any text, language, or materials are from another source, you must be clear if it is a quote and cite it. Also cite any sources if you use numbers, ideas, or other material that are not your own. If you do not follow this requirement, the reviewers will reduce their scores accordingly. They may choose to award no points at all.

**Table 7: Project Narrative, Budget Narrative, and Program Duplication Assessment Review Criteria**

| Section                            | Topics                    | Total Available Points | Scoring Criteria Breakdown                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|------------------------------------|---------------------------|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>(100 Pts) Project Narrative</b> |                           |                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| D2.4.I                             | Model Implementation Plan | 53 Pts                 | <p><b>(1 Pt)</b> Description of which required Model activities the State plans to carry out in-house vs. outsourcing to an external contractor or subrecipient. <i>(There is no preference given to in-house vs. outsourcing, or to contractors vs. subrecipients.)</i></p> <p><b>(15 Pts)</b> Description of which, if any, of the optional Model activities the State plans to carry out, the State's plan for implementing each, and the state's proposed reporting milestone(s) for each activity.</p> <p><b>(15 Pts)</b> If the State plans to partner with a CBO, a CBO Funding Proposal including:</p> <ul style="list-style-type: none"> <li>• <b>(1 Pt)</b> A detailed plan for the identification and recruitment of CBOs providing services and support to individuals with SCD in the applicant State.</li> <li>• <b>(9 Pts)</b> Minimum CBO requirements, and a description of the types of CBO activities for which the State will seek support, including the scope of each service being contemplated and what would be out of scope with respect to each service.</li> <li>• <b>(1 Pt)</b> Dollar amounts that will be provided to CBOs.</li> <li>• <b>(1 Pt)</b> When the agreement with the CBO will begin and the expected duration.</li> <li>• <b>(1 Pt)</b> The number of CBOs/non-profit entities the State plans to partner with, and their names, if available.</li> <li>• <b>(1 Pt)</b> Monitoring and Reporting Plan.</li> <li>• <b>(1 Pt)</b> Whether the CBO will be a subrecipient or contractor, in accordance with 45 CFR 75.351.</li> </ul> <p><i>(If the State does not plan to partner with a CBO, the State will get zero points for this portion of the Model Implementation Plan.)</i></p> <p><b>(20 Pts)</b> Description of whether the State plans to expand or increase services and/or reimbursement rates for any Medicaid benefits or services, and if so, which ones. Also, description of whether the State plans to do so for the entire Medicaid population or just for beneficiaries with SCD (using the optional SCD benefit), and description of any policy changes</p> |

|          |                                                   |        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|----------|---------------------------------------------------|--------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|          |                                                   |        | <p>the State intends to undertake and specifically what the expansion or enhancement will be relative to what is currently offered under the state plan.</p> <p><i>(States will receive up to 2 points for each benefit/service that is either expanded or receives increased reimbursement for a maximum of 20 points. If the State does not plan to expand or increase reimbursement to more benefits/services, the State will get zero points for this portion of the Model Implementation Plan.)</i></p> <p><b>(2 Pts)</b> Description of how the State will customize its implementation plan for populations that may live far from hematologists, gene therapy providers, and other providers that are considered critical to successful completion of the gene therapy journey for individuals with SCD, and for those that may lack reliable access to internet.</p>                                                                                                                                                                                                                                                                                                                                                                            |
| D2.4.II  | Organizational Capacity of Applicant Organization | 12 Pts | <p>A description of the State's organization, including:</p> <ul style="list-style-type: none"> <li>• <b>(2 Pts)</b> Staff capacity (e.g., providing job descriptions including positions that may be currently vacant for all key staff that will be involved in the Model).</li> <li>• <b>(2 Pts)</b> The individual(s) who will have management authority over the Model and provide a resume or CV for each identified manager.</li> <li>• <b>(2 Pts)</b> The individual who will be the Project Director (primary liaison to CMS for the Model) and provide a resume or CV for that person.</li> <li>• <b>(2 Pts)</b> An organizational chart that identifies lines of authority and name the Authorized Organizational Representative (AOR).</li> <li>• <b>(2 Pts)</b> The anticipated role of any subrecipients or contractors that may be engaged to help implement the Model (including CBOs, non-profit entities, treatment centers, or academic institutions).</li> <li>• <b>(2 Pts)</b> Any relevant experience designing and implementing programs to support coordinated, patient-centered care for complex medical conditions, including provision of multi-disciplinary medical care and services to address access barriers.</li> </ul> |
| D2.4.III | Existing Collaborations with CBOs                 | 4 Pts  | <p>If the State plans to partner with a CBO, description of existing State collaborations with CBOs aimed at identifying and addressing access barriers, including those specifically focused on beneficiaries with SCD. <i>(There is no preference given for those with existing relationships.)</i></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

|         |                                       |        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|---------|---------------------------------------|--------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| D2.4.IV | Participation of CHIP enrollees       | 2 Pts  | Description of whether the State will include CHIP enrollees as participants in the Model and which optional activities will apply to CHIP enrollees. <i>(There is no preference given to any complete answer provided, i.e., any applicant that fully and clearly provides a response to this question receives 2 pts.)</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| D2.4.V  | Optional Medicaid Benefits            | 4 Pts  | Description of optional Medicaid benefits currently provided by the State that are relevant to the recommended gene therapy care journey described in Section A5.2 <i>Recommended Care Journey for SCD Gene Therapy and Potential Access Barriers</i> .                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| D2.4.VI | Milestone Funding Project Proposal(s) | 20 Pts | <p>If the State plans to conduct a Milestone Funding project during BP1, a Milestone Funding Project Proposal including:</p> <ul style="list-style-type: none"> <li>• <b>(1 Pt)</b> Timeframe of project.</li> <li>• <b>(1 Pt)</b> Category of project.</li> <li>• <b>(2 Pts)</b> Description of the research question(s) the project is designed to answer.</li> <li>• <b>(5 Pts)</b> Justification for how the research question(s) is related to access to gene therapy or receipt of multi-disciplinary, comprehensive care for beneficiaries with SCD who are considering or receiving gene therapy, per the patient care journey for SCD gene therapy (see Section A5.2 <i>Recommended Care Journey for SCD Gene Therapy and Potential Access Barriers</i>).</li> <li>• <b>(2 Pts)</b> Research methodology to be used (e.g., patient surveys, focus groups, interviews).</li> <li>• <b>(2 Pts)</b> Target population and estimated number of participants.</li> <li>• <b>(1 Pt)</b> Whether the State will seek IRB approval, and whether patients will be asked for consent to data collection activities.</li> <li>• <b>(1 Pt)</b> Explanation for how the research findings are expected to be used to help the State improve care for Model beneficiaries.</li> </ul> <p><i>(If a State submits multiple project proposals, each will be scored separately and the average score will be assigned for this section.)</i></p> <p><b>(5 Pts)</b> If the State plans to fund one or more organizations to conduct a project:</p> <ul style="list-style-type: none"> <li>• <b>(1 Pt)</b> The type of organization (CBO, treatment center qualified to administer gene therapy, academic institution).</li> </ul> |

|                                               |                                 |        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------------------------------|---------------------------------|--------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                               |                                 |        | <ul style="list-style-type: none"> <li>• <b>(1 Pt)</b> When the agreement(s) will begin and the expected duration.</li> <li>• <b>(1 Pt)</b> The number of organizations the State plans to fund, and their names, if available.</li> <li>• <b>(1 Pt)</b> The frequency and type of reporting requirements.</li> <li>• <b>(1 Pt)</b> Whether the organization is a subrecipient or contractor, in accordance with 45 CFR 75.351.</li> </ul> <p><i>(If the State does not plan to fund an organization to conduct a Milestone Funding project, the State will get zero points for this portion of the Milestone Funding Project Proposal.)</i></p>                                                                                             |
| D2.4.VII                                      | Medicaid (and CHIP) authorities | 5 Pts  | Description of the Medicaid and CHIP authorities the State proposes to use to implement the Model, including authorities currently in place as well as authorities the State has requested or would request if their application were successful. <i>(States that require additional authorities will not receive higher points than States that do not.)</i>                                                                                                                                                                                                                                                                                                                                                                                |
| <b>(25 Pts) Budget Narrative</b>              |                                 |        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| D2.5                                          |                                 | 25 Pts | <p><b>(15 Pts)</b> Detailed budget, adhering to the format outline in Appendix I, <i>Guidance for Preparing a Budget Request and Narrative</i>, for the period of performance.</p> <p><b>(5 Pts)</b> Funds requested are reasonable based on the total available Cooperative Agreement funding and each activity is linked to the goals of this NOFO and consistent with the Model requirements and optional State activities (see Section A6.6 <i>Optional State Activities</i>).</p> <p><b>(5 Pts)</b> The budget separates out funding administered directly by the Medicaid agency and State from funding distributed to other partners (e.g., CBOs) and has described the specific tasks for which this entity will be responsible.</p> |
| <b>(5 Pts) Program Duplication Assessment</b> |                                 |        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| D2.6                                          |                                 | 5 Pts  | <p><b>(2 Pts)</b> Explanation of how this funding builds upon current programs and initiatives, if applicable, while avoiding duplication.</p> <p><b>(3 Pts)</b> Summary of the State's standard operating procedures and best practices for avoiding program duplication.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Total Available Points</b>                 |                                 |        | <b>130 Pts</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

## E2. Merit Review and Selection Process

CMS will consider the quality of applications in making final award determinations.

Awards may be adjusted to a lower amount if the applicant fails to meet reporting milestones (refer to section F5. Reporting).

The application itself is not a legally binding contract and does not require any applicant or CMS to enter into a Cooperative Agreement. CMS will select Recipients at CMS's sole discretion unless statutorily prohibited. Such selection will not be subject to administrative or judicial review, per Section 1115A(d)(2)(B) of the Act.

Please refer to Appendix V. Merit Review and Selection Process for more information on the review and selection process.

### **E3. Federal Awardee Performance Integrity Information System (FAPIIS)**

In accordance with 45 CFR Part 75:

- a. CMS, prior to making a Federal award with a total amount of Federal share greater than the simplified acquisition threshold<sup>42</sup>, is required to review and consider any information about the applicant that is in the designated integrity and performance system accessible through SAM (see 41 U.S.C. 2313);
- b. An applicant, at its option, may review information in the designated integrity and performance systems accessible through SAM and comment on any information about itself that the HHS awarding agency previously entered and is currently in the designated integrity and performance system accessible through SAM.
- c. CMS will consider any comments by the applicant, in addition to the other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicant as described in 45 CFR §75.205.

## **F. Federal Award Administration Information**

### **F1. Federal Award Notices**

If successful, applicants will receive a Notice of Award (NoA) signed and dated by the CMS Grants Management Officer. The NoA is the legal document authorizing the Cooperative Agreement award and issued to the applicant as listed on the SF-424. The NoA is available to the applicant organization through the online grants management system used by CMS and recipient organizations, GrantSolutions. Any communication between CMS and applicant prior to issuance of the NoA is not an authorization to begin performance of a project.

If unsuccessful, CMS notifies the applicant electronically to the email address as listed on its SF- 424, within 30 days of the award date of the program.

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<sup>42</sup> *Simplified acquisition threshold* means the dollar amount below which a non-Federal entity may purchase property or services using small purchase methods. Non-Federal entities adopt small purchase procedures to expedite the purchase of items costing less than the simplified acquisition threshold. The simplified acquisition threshold is set by the Federal Acquisition Regulation at 48 CFR Subpart 2.1 (Definitions) and in accordance with 41 U.S.C. 1908.

## **F2. Administrative and National Policy Requirements**

### **A. National/Public Policy Requirements**

By signing the application, the authorized organizational official certifies that the organization will comply with applicable public policies. Each recipient is responsible for establishing and maintaining the necessary processes to monitor its compliance and that of its employees and, as appropriate, subrecipients and contractors under the award with these requirements. Recipients should consult the applicable Appropriations Law, Exhibit 3 of the HHS Grants Policy Statement, titled Public Policy Requirements, located in Section II, pages 3-6, as well as the terms and conditions of award for information on potentially applicable public policy requirements.

Recipients should review and comply with the reporting and review activities regarding accessibility requests outlined in Appendix IV, Accessibility Requirements.

### **B. Administrative Requirements**

- All equipment, staff, and other budgeted resources and expenses must be used exclusively for the projects identified in the applicant's original application or agreed upon subsequently with CMS, and may not be used for any prohibited uses.
- Consumers and other stakeholders must have meaningful input into the planning, implementation, and evaluation of the project.
- This award is subject to 45 CFR Part 75, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS awards [available at <http://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75>], which implements 2 CFR Part 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards ("Uniform Guidance") effective December 26, 2014. See below for more information.

### **Uniform Administrative Requirements, Cost Principles, and Audit Requirements**

Applicant and recipients should take note of the following information found in 45 CFR Part 75:

#### **Uniform Administrative Requirement**

In accordance with 45 CFR §75.112, all award recipients receiving federal funding from CMS must establish and comply with the conflict of interest policy requirements outlined by CMS (available for applicant upon request).

In accordance with 45 CFR §75.113, **Mandatory Disclosures**, the non-Federal entity or applicant for a Federal award must disclose, in a timely manner, in writing to the HHS awarding agency or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. Non-Federal entities that have received a Federal award including the term and condition outlined in Appendix XII to 45 CFR Part 75 are required to report certain civil, criminal, or administrative proceedings to SAM. Failure to make the required disclosures can result in the imposition of any of the remedies described in §75.371, including suspension or debarment. (See also 2 CFR Parts 180 and 376, and 31 U.S.C. 3321). For specific information on reporting such disclosures to CMS and HHS please see Section F3. *Terms and Conditions* of this NOFO.

#### **Cost Principles**

CMS grant and Cooperative Agreement awards provide for reimbursement of actual, allowable costs incurred and are subject to the Federal cost principles. The cost principles establish standards for the

allowability of costs, provide detailed guidance on the cost accounting treatment of costs as direct or indirect, and set forth allowability and allocability principles for selected items of cost. Applicability of a set of cost principles depends on the type of organization.

Recipients must comply with the cost principles set forth in HHS regulations at 45 CFR Part 75, Subpart E with the following exceptions:

- 1) hospitals must follow Appendix IX to part 75; and
- 2) commercial (for-profit) organizations are subject to the cost principles located at 48 CFR subpart 31.2. As provided in the cost principles in 48 CFR subpart 31.2, allowable travel costs may not exceed those established by the Federal Travel Regulation (FTR). There is no universal rule for classifying certain costs as either direct or indirect (also known as Facilities & Administration (F&A) costs) under every accounting system. A cost may be direct with respect to some specific service or function, but indirect with respect to the Federal award or other final cost objective. Therefore, it is essential that each item of cost incurred for the same purpose is treated consistently in like circumstances either as a direct or F&A cost to avoid double-charging of Federal awards. Guidelines for determining direct and F&A costs charged to Federal awards are provided in 45 CFR §§75.412 to 75.419. Requirements for development and submission of indirect (F&A) cost rate proposals and cost allocation plans are contained in Appendices III-VII, and Appendix IX to Part 75.

### **Indirect Costs**

CMS will reimburse indirect costs to recipients under an award if

- 1) allowable under the governing statute, regulations, or HHS grants policy;
- 2) the recipient requests indirect costs; and
- 3) the recipient has a federally approved indirect cost rate agreement covering the grant supported activities and period of performance, or the non-federal entity has never received an indirect cost rate, except for those non-Federal entities described in Appendix VII(D)(1)(b) to 45 CFR part 75, and elects to charge a de minimis rate of 10% of Modified Total Direct Costs (MTDC).

If the applicant entity has a current negotiated indirect cost rate agreement (NICRA) and is requesting indirect costs, a copy of the current NICRA must be submitted with the application.

Commercial (For-Profit) Organizations: Indirect Costs are allowable under awards to for-profit organizations. The for-profit recipient must have a federally-approved indirect cost rate agreement covering the grant supported activities and period of performance. Indirect cost rates for for-profit entities are negotiated by DFAS in the Office of Acquisition Management and Policy, National Institutes of Health (if the preponderance of their federal awards are from HHS), available at <http://oamp.od.nih.gov/dfas/indirect-cost-branch>, or other Federal agency with cognizance for indirect cost rate negotiation. If there is no federally-approved indirect cost rate for the specific period of performance and the for-profit recipient has never received an indirect cost rate, then the non-federal entity may elect to charge a de minimis rate of 10% of MTDC.

### ***Cost Allocation***

In accordance with 45 CFR §75.416 and Appendix V to Part 75 – State/Local Government-wide Central Service Cost Allocation Plans, each state/local government will submit a plan to the HHS Cost Allocation Services for each year in which it claims central service costs under Federal awards. Guidelines and illustrations of central service cost allocation plans are provided in a brochure published by the HHS

entitled “A Guide for State, Local and Indian Tribal Governments: Cost Principles and Procedures for Developing Cost Allocation Plans and Indirect Cost Rates for Agreements with the Federal Government.”

A copy of this brochure may be obtained from the HHS Cost Allocation Services at <https://www.hhs.gov/about/agencies/asa/psc/indirect-cost-negotiations/index.html>. A current, approved cost allocation plan must be provided to CMS if central service costs are claimed.

### ***Public Assistance Cost Allocation Plans***

Appendix VI to Part 75 – Public Assistance Cost Allocation Plans, provides that state public assistance agencies will develop, document and implement, and the Federal Government will review, negotiate, and approve, public assistance cost allocation plans in accordance with Subpart E of 45 CFR part 95. The plan will include all programs administered by the state public assistance agency. Where a letter of approval or disapproval is transmitted to a state public assistance agency in accordance with Subpart E, the letter will apply to all Federal agencies and programs. This Appendix (except for the requirement for certification) summarizes the provisions of Subpart E of 45 CFR part 95.

### **Audit Requirements**

The audit requirements in 45 CFR Part 75, Subpart F, apply to each award recipient fiscal year that begins on or after December 26, 2014. A non-Federal entity that expends \$750,000 or more during the non-Federal entity's fiscal year in Federal awards must have a single or program-specific audit conducted for that year in accordance with the provisions of Subpart F, Audit Requirements.

Commercial Organizations (including for-profit hospitals) have two options regarding audits, as outlined in 45 CFR §75.501 (see also 45 CFR §75.216).

## **F3. Terms and Conditions**

This Notice of Funding Opportunity is subject to the Department of Health and Human Services [Grants Policy Statement \(HHS GPS\)](http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf) at <http://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>.

The general terms and conditions in the HHS GPS will apply as indicated unless there are statutory, regulatory, or award-specific requirements to the contrary. Standard and program specific terms of award will accompany the NoA. Potential applicants should be aware that special requirements could apply to Cooperative Agreement awards based on the circumstances of the effort to be supported and/or deficiencies identified in the application by the HHS review panel.

**HHS regulation (45 CFR Part 75)** supersedes information on administrative requirements, cost principles, and audit requirements for grants and Cooperative Agreements included in the current HHS Grants Policy Statement where differences are identified. Recipients must also agree to respond to requests that are necessary for the evaluation of national efforts and provide data on key elements of their own grant or Cooperative Agreement activities.

### **Non-Discrimination Legal Requirements for Recipients of Federal Financial Assistance**

A recipient must follow all applicable nondiscrimination laws. Applicants agree to this when they register in SAM.gov. Applicants must also submit an Assurance of Compliance (HHS-690). To learn more, see the HHS Office for Civil Rights website.

### **Material Noncompliance**

CMS may terminate any award for material noncompliance. Material noncompliance includes, but is not limited to, violation of the terms and conditions of the award; failure to perform award activities in a satisfactory manner; improper management or use of award funds; or fraud, waste, abuse, mismanagement, or criminal activity.

**Bankruptcy.** In the event a recipient or one of its subrecipients enters proceedings relating to bankruptcy, whether voluntary or involuntary, the Recipient agrees to provide written notice of the bankruptcy to CMS. The recipient must furnish the written notice within five (5) days of the initiation of the proceedings relating to bankruptcy filing and sent to the CMS Grants Management Specialist and Project Officer. This notice includes:

- the date on which the bankruptcy petition was filed,
- the identity of the court in which the bankruptcy petition was filed,
- a copy of all the legal pleadings, and
- a listing of Government grant and Cooperative Agreement numbers and grant offices for all, and
- Government grants and Cooperative Agreements against which final payment has not been made.

### **Intellectual Property**

Recipients under this funding opportunity must comply with the provisions of 45 CFR § 75.322, Intangible property and copyrights. The non-Federal entity may copyright any work that is subject to copyright and was developed, or for which ownership was acquired, under a Federal award. The Federal awarding agency reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use the work for Federal purposes, and to authorize others to do so. The non-Federal entity is subject to applicable regulations governing patents and inventions, including government-wide regulations issued by the Department of Commerce at 37 CFR part 401.

The Federal Government has the right to:

- 1) Obtain, reproduce, publish, or otherwise use the data produced under a Federal award; and
- 2) Authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes.

### **Prohibition on certain telecommunications and video surveillance services or equipment:**

As described in 2 CFR 200.216, recipients and subrecipients are prohibited to obligate or spend grant funds (to include direct and indirect expenditures as well as cost share and program) to:

- 1) Procure or obtain;
- 2) Extend or renew a contract to procure or obtain; or
- 3) Enter into contract (or extend or renew contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. As described in Pub. L. 115-232, section 889, covered telecommunications equipment is telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities).
  - a. For public safety, security of government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation,

Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities).

- b. Telecommunications or video surveillance services provided by such entities or using such equipment.
- c. Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of the National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise, connected to the government of a covered foreign country.

#### **F4. Cooperative Agreement Terms and Conditions of Award**

The administrative and funding instrument used for this program is a Cooperative Agreement, an assistance mechanism used when CMS anticipates substantial CMS programmatic involvement with each recipient during the performance of the activities. Under each Cooperative Agreement, CMS' purpose is to support and stimulate the recipient's activities by involvement in, and otherwise working jointly with, the award recipient in a partnership role. To facilitate appropriate involvement during the period of this Cooperative Agreement, CMS and the recipient will be in contact at least once a month, and more frequently when appropriate.

There are specific roles for both the recipient and CMS.

*CMS will:*

- Have overall programmatic responsibility for monitoring the project's conduct and progress, including possible site visits.
- Collaborate with the Recipient and provide substantial project planning and implementation input.
- Provide substantial input in evaluation activities.
- Make recommendations on continuing the project.
- Review and approve website content before launch and updates.
- Review and approve all key personnel.
- Maintain regular communication with the Recipient through at least monthly conference calls and providing technical assistance (TA) and consultation.
- Review and provide feedback on all required performance assessment reports.
- Review and approve all required submitted data.
- Provide a structured approach to sharing, integrating, and actively applying improvement concepts, tactics, and lessons learned. Refer to the State RFA for information on learning system supports.

*Recipients will:*

- Comply with the terms and conditions of the award.
- Collaborate with CMS staff to implement and monitor the project.
- Submit performance measures as requested by CMS.
- Submit all required performance assessments, evaluations, and financial reports as stated in the Terms and Conditions.
- Attend and take part in monthly calls with the CMS Project Officer (PO) on progress and challenges. The meetings will include key personnel and the PO.

- Attend and take part in any virtual meetings.

## **F5. Reporting**

Federal reporting requirements include:

- Progress Reports
- Federal Financial Report (FFR)
- Federal Funding Accountability and Transparency Act (FFATA)
- Responsibility and Qualification Reports
- Payment Management System (PMS)
- Audit Reporting (Federal Audit Clearing House)
- Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

CMS will monitor the performance of each Recipient pursuant to the Terms and Conditions of the Notice of Award.

### **a. Progress Reports**

Recipients will be required to submit quarterly progress reports (QPR) and a final progress report (FPR). CMS will provide Recipients with guidance and templates ahead of the due date for QPR and FPR submissions. These reports will include narrative updates on model activities as well as information on progress the Recipient is making on Model operational requirements and performance milestones in accordance with the Model's Cooperative Agreement (See Section F5.1. *Reporting Requirements and Milestones Linked to NOFO Funding*). CMS will use the quarterly reports to track progress on model goals, identify technical assistance needs, and inform learning activities for all Recipients. The reporting requirements will support CMS' efforts to confirm that Recipients are using implementation funding to successfully implement the Model and, if applicable, making progress to improve access and promote multi-disciplinary, comprehensive care for individuals with SCD receiving gene therapy under the Model.

CMS will also share feedback with Recipients individually and on an ongoing basis for quality improvement purposes. Recipients must maintain records of all source data used to calculate program milestone measures and make such data available to CMS for periodic audits. CMS may consider for corrective action, funding restrictions, or termination of any Recipient that does not meet the model requirements outlined in the Cooperative Agreement Notice of Award, Terms and Conditions, or other federal award documentation.

### **b. Financial Reports**

CMS recipients are required to record recipient expenses in real-time as well as submit semi-annual or annual expenditure FFRs.

You must submit a Federal Financial Report (FFR) SF-425 at least annually via the Payment Management System. Frequency of required expenditure reporting, whether semi-annually or annually, is stipulated in the Program Terms and Conditions of the Notice of Award. Instructions on how to complete the FFR can be found (after logging on) at: <https://pms.psc.gov/grant-recipients/ffr-updates.html>.

### **c. Federal Funding Accountability and Transparency Act Reporting Requirements**

Recipients are required to report certain information about themselves and their first-tier sub-recipients for awards. A specific term is included on your NoA. If your organization is a recipient of grants or cooperative agreements, you must report on subawards of \$30,000 or greater. There are additional reporting requirements if:

- 80% or more of your prior year annual gross revenues are from federal awards
- \$25 million or more in annual gross revenues are from federal awards
- The public does not have access to compensation information filed under Securities and Exchange Commission (SEC) and IRS requirements

#### Additional Guidance on FFATA

- Prime recipients report their own executive compensation if they meet all the criteria, as part of their profile at System for Award Management (SAM)
- Prime recipients report subaward information at the [FFATA Subaward Reporting System \(FSRS\)](#)
- [2 Code of Federal Regulations \(CFR\) 25](#)

#### d. **Responsibility and Qualification Reporting**

Recipients that have active federal contract, grant, or cooperative agreement awards with a cumulative value greater than \$10,000,000 are **required** to disclose semi-annual information about criminal, civil, and administrative proceedings that reached final disposition within the most recent five-year period and that were connected with the award or performance of an award. Recipients must also make semi-annual disclosures regarding such proceedings and/or affirm that there is no new information to provide. This information will be made publicly available in **Responsibility and Qualification** records (formerly Federal Awardee Performance and Integrity Information System) on SAM.gov.

#### Additional Guidance

- [Responsibility/Qualification Information](#)  
Federal Awarding Agency Review of Risk Posed by Applicants, 45 CFR 75.205

#### e. **Audit Requirements**

Recipients must comply with audit requirements outlined in HHS regulation 45 CFR Part 75 (implementing 2 CFR Part 200). Reports on these audits must be submitted to the Federal Audit Clearinghouse (FAC) either within 30 days after receipt or nine months after the end of the fiscal year, whichever is earlier. The audit reports and a completed data collection form (SF-SAC) must be submitted electronically to clearinghouse. FAC operates on behalf of the Office of Management and Budget (OMB).

For specific questions and information about the submission process, call the FAC toll-free number at 800-253-0696.

#### f. **Payment Management System Reporting Requirements**

Once CMS issues an award, the funds are posted in recipient accounts established in the Payment Management System (PMS). Recipients may then access their funds by using the PMS funds request process.

The PMS funds request process enables recipients to request funds using a Personal Computer with an Internet connection. The funds are delivered to the recipient via Electronic Funds Transfer (EFT). If you are a new recipient, please go to PMS Access Procedures to find information to register in PMS. If you need further help with that process, please contact the One-DHHS Help Desk via email at [pmssupport@psc.gov](mailto:pmssupport@psc.gov) or call (877) 614-5533 for assistance.

g. **Government-wide Suspension and Debarment Reporting Requirements**

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification;

1. You certify on behalf of the applicant organization, by submission of your proposal, that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
2. Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. § 3354).
3. If you are unable to attest to the statements in this certification, you must include an explanation and insert in “Other Relevant Documents”.

**F5.1 Reporting Requirements and Milestones Linked to NOFO Funding**

**F5.1.1 Implementation Funding Reporting**

CMS will monitor each State’s progress on implementation of required Model elements through required, periodic, reporting submissions. If a State seeks Implementation Funding for required Model activities, it must comply with reporting requirements that are detailed in the State RFA and will be included in Recipient’s Terms and Conditions.

If a State seeks Implementation Funding for *optional* Model activities, in the Project Narrative Section of this NOFO, it must propose and CMS must approve, reporting milestones and an implementation plan for each of these activities. The state must then submit QPRs that are consistent with those reporting requirements, and that describe the Recipient’s progress with the implementation plan. If funding is sought for partnerships with CBOs, then the Recipient will be required to include the following items in its reporting submissions:

- I. **Community Based Organization Performance Report:** The Recipient must submit a full performance report of all funded CBOs on an annual basis. The performance report will adhere to the monitoring and reporting plan finalized in the Cooperative Agreement Terms and Conditions. In addition, the performance report must include the following information:
  1. The number of beneficiaries with SCD in the State who received an identified service due to the funding provided through this award.
  2. The number of beneficiaries with SCD in the State who received gene therapy who received an identified service due to the funding provided through this award.
- II. **Updated Partnership List:** In each QPR, the Recipient must submit an updated Partnership List that includes the following details of all funded CBOs:
  1. Name
  2. Mailing Address
  3. Primary Contact

4. Primary Contact Email and Telephone
5. Amount of Award

If a CBO is no longer a recipient of implementation funds (due to unsatisfactory performance, the conclusion of planned activities, or other issues), the Recipient must note and provide the reason for the conclusion of that relationship in the next QPR.

For a State to receive continued funding for an implementation activity, it must comply with the reporting requirements outlined in the Recipient's Terms and Conditions. On an annual basis, the State must attest to the continued need for cooperative agreement funding to support these activities during the non-competing application process.

### **F5.1.2 Milestone Funding Reporting**

If a State seeks Milestone Funding for performance on a research project, it must verify its progress through quarterly and annual reporting. In each QPR, the Recipient must describe the status of all Milestone Funding projects approved by CMS.

Milestone Funding is not guaranteed and will be restricted (unavailable for Recipient use) unless the Recipient demonstrates satisfactory completion of a project. The Recipient must submit a full performance report to CMS no later than the third QPR to verify satisfactory completion of the project from the prior PY. Performance reports must include the following information:

1. Description of the research question(s) the project was designed to answer.
2. Background on how the project is related to increasing access to SCD gene therapy or promoting receipt of multi-disciplinary, comprehensive care for beneficiaries with SCD who are considering or receiving SCD gene therapy, per the patient care journey for SCD gene therapy (see Section A5.2 *Recommended Care Journey for SCD Gene Therapy and Potential Access Barriers*).
3. Description of the research methodology used in the project (including but not limited to: the study population, participant recruitment, any interventions implemented or studied, data collection, and data analysis).
4. The number of participants included in the study
5. Description and analysis of results
6. Limitations of the study
7. Identification and analysis of policy options for improvement
8. Explanation for how the State intends to use the research findings to improve care for Model beneficiaries
9. List of costs incurred to conduct the research project
10. The roles of any partner organizations in conducting the project

Additional report components and requirements may be detailed in Recipient's Terms and Conditions for the award. CMS reserves the right to change report components based on individual Recipients' project proposals and unforeseen circumstances that arise during Model pre-implementation and implementation periods. CMS also reserves the right to revise the method of data submission to CMS based on new information or unforeseen circumstances that arise during Model implementation.

If CMS approves the Recipient's performance report and verifies that the Recipient has successfully completed the project, Milestone Funding associated with the project will be unrestricted and available for Recipient use. CMS may award partial funding for partial completion of a project.

## **G. CMS Contacts**

Applicants should refer to the sources listed below for application questions including administrative, budgetary, or program requirements. Please reference "NOFO Inquiry" in the email subject line.

### **G1. Programmatic Questions**

For programmatic questions about this funding opportunity, please contact: [CGTModel@cms.hhs.gov](mailto:CGTModel@cms.hhs.gov)

### **G2. Administrative/Budget Questions**

For administrative or budget questions about this funding opportunity, please contact:  
[CGTModel@cms.hhs.gov](mailto:CGTModel@cms.hhs.gov)

### **G3. Other Information**

CMS is not obligated to make any Federal award because of the publication of this NOFO. Publication of this NOFO does not oblige CMS to award any specific project or to obligate any available funds.

CMS may cancel or withdraw this NOFO at any time.

Award decisions are discretionary and are not subject to appeal to any CMS or HHS official or board.

Applicants must identify proprietary information.

Please visit [the CGT Access Model website](#) for additional details regarding this program.

## Appendix I. Guidance for Preparing a Budget Request and Narrative

All applications must include a detailed budget and narrative that explains the federal and the non-federal expenditures broken out by the object class cost categories listed on SF-424A – Section B (Budget Category) for non-construction awards.

- You must request funding only for activities that will support this specific Notice of Funding Opportunity.
- The budget and narrative must be consistent with and support the Project Narrative. The proposed costs must be reasonable, allowable, allocable, and necessary for the supported activity.
- Both the Standard Form SF-424A and the Budget Narrative must include a yearly breakdown of costs for the entire period of performance.
- Refer to the program specific Funding Restrictions and Limitations and Standard Funding Restrictions, as well as to 45 CFR Part 75 (for applicable administrative requirements and cost principles).

### Cost Sharing

Voluntary committed cost sharing or matching is not expected unless specifically stated otherwise in section C2 of the NOFO. Including voluntary committed cost sharing will require CMS to monitor the recipient's compliance with non-federal cost sharing. Monitoring includes CMS reviewing the non-federal expenditures on the FFR, SF-425.

### Standard Form SF-424A

All applicants must submit an SF-424A. **Since the total Period of Performance is 10.5 calendar years (10 budget periods), then the Applicant must submit two, additional SF-424A Forms (for an overall total of three (3) SF-424A Forms).**

- **(Form 1) SF-424A Form – Costs for Years 1-4**
- **(Form 2) SF-424A Form – Costs for Years 5-8**
- **(Form 3) SF-424A Form – Costs for Years 9-11**

Blank SF-424A forms (Budget Information for Non-Construction Programs) can be found at Grants.gov: <https://www.grants.gov/forms/forms-repository/sf-424-family>

**The total aggregate federal costs for all three SF-424A forms reflecting calendar years 1-11 (i.e., combining the total costs from column 5 of each SF-424A form) should be consistent with the total Federal costs requested on the SF-424, Application for Federal Assistance (field 18a of SF-424).**

Review the general instructions provided for form SF-424A and comply with the instructions outlined below.

- Note: The directions in the Notice of Funding Opportunity (NOFO) may differ from those provided by Grants.gov. Please follow the instructions included in this NOFO as outlined below when completing the SF-424A.

- Note: The total requested on the SF-424 (Application for Federal Assistance) reflects the overall total requested on the SF-424A (Budget Information – Non-Construction) for the entire period of performance.

#### Section A – Budget Summary

- Grant Program Function or Activity (column a) = Enter “Name of Notice of Funding Opportunity” in row 1.
- New or Revised Budget, Federal (column e) = Enter the Total Federal Budget Requested for the project period in rows 1 and 5.
- New or Revised Budget, Non-Federal (column f) = Enter Total Amount of any Non-Federal Funds Contributed (if applicable) in rows 1 and 5. Voluntary committed cost sharing or matching is not expected unless specifically stated otherwise in section C2.
- New or Revised Budget, Total (column g) = Enter Total Budget Proposed in rows 1 and 5, reflecting the sum of the amount for the Federal and Non-Federal Totals.

#### Section B – Budget Categories

- Enter the total costs requested for each Object Class Category (Section B, number 6) for each year of the period of performance.
- **First SF-424A Form**
  - Column (1) = Enter Year 1 costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges are reflected in row j. The total for direct and indirect charges for all year 1 line items is entered in column 1, row k (sum of row i and j).
  - Column (2) = Enter Year 2 estimated costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges are reflected in row j. The total for direct and indirect charges for all year 2 line items is entered in column 2, row k (sum of row i and j).
  - Column (3) = Enter Year 3 estimated costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges are reflected in row j. The total for direct and indirect charges for all year 3 line items are entered in column 3, row k (sum of row i and j).
  - Column (4) = Enter Year 4 estimated costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges are reflected in row j. The total for direct and indirect charges for all year 4 line items are entered in column 4, row k (sum of row i and j).
  - Column (5) = Enter total costs for years 1-4 for each line item (rows a-h), direct total costs (row i), and indirect costs (row j). The total costs for all line items are entered in row k (sum of row i and j). The total in column 5, row k should match the total provided in Section A – Budget Summary, New or Revised Budget, column g, row 5.
- **Second SF-424A Form**
  - Column (1) = Enter Year 5 costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges are reflected in row j. The total for direct and indirect charges for all year 5 line items is entered in column 1, row k (sum of row i and j).

- Column (2) = Enter Year 6 estimated costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges are reflected in row j. The total for direct and indirect charges for all year 6 line items is entered in column 2, row k (sum of row i and j).
  - Column (3) = Enter Year 7 estimated costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges are reflected in row j. The total for direct and indirect charges for all year 7 line items are entered in column 3, row k (sum of row i and j).
  - Column (4) = Enter Year 8 estimated costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges are reflected in row j. The total for direct and indirect charges for all year 8 items are entered in column 4, row k (sum of row i and j).
  - Column (5) = Enter total costs for years 5-8 for each line item (rows a-h), direct total costs (row i), and indirect costs (row j). The total costs for all line items are entered in row k (sum of row i and j). The total in column 5, row k should match the total provided in Section A – Budget Summary, New or Revised Budget, column g, row 5.
- **Third SF-424A Form**
    - Column (1) = Enter Year 9 costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges are reflected in row j. The total for direct and indirect charges for all year 9 line items is entered in column 1, row k (sum of row i and j).
    - Column (2) = Enter Year 10 estimated costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges are reflected in row j. The total for direct and indirect charges for all year 10 line items is entered in column 2, row k (sum of row i and j).
    - Column (3) = Enter Year 11 estimated costs for each line item (rows a-h), including the sum of the total direct charges (a-h) in row i. Indirect charges are reflected in row j. The total for direct and indirect charges for all year 11 line items are entered in column 3, row k (sum of row i and j).
    - Column (4) = N/A (\$0)
    - Column (5) = Enter total costs for years 9-11 for each line item (rows a-h), direct total costs (row i), and indirect costs (row j). The total costs for all line items are entered in row k (sum of row i and j). The total in column 5, row k should match the total provided in Section A – Budget Summary, New or Revised Budget, column g, row 5.

## **Budget Narrative – Sample Narrative and Instructions**

Applicants must complete a Budget Narrative and upload it to the Budget Narrative Attachment Form in the application kit. Applicants must request funding only for activities not already funded/supported by other funding sources. Awards support separate activities and new federal funding cannot be supplanted by other federal funding. In the budget request, applicant distinguishes between activities funded under this application and activities funded with other sources. Other funding sources include other HHS grant programs, and other federal funding sources as applicable. Insufficient budget detail and justification may negatively impact the review of the application.

A sample Budget Narrative is included below.

## A. (Personnel) Salaries and Wages

For each requested position, provide the following information:

- title of position
- name of staff member occupying the position, if available
- annual salary
- percentage of time budgeted for this program (FTE or level of effort)
- total months of salary budgeted, and
- total salary requested

Also, provide a justification and describe the scope of responsibility for each position, relating it to the accomplishment of program objectives. These individuals must be employees of the applicant organization.

**Note:** The Consolidated Appropriations Act restricts the amount of direct salary to Executive Level II of the Federal Executive Pay Scale. This salary cap applies to direct salaries and to those salaries covered under indirect costs, also known as facilities and administrative (F & A). See the following link for the applicable current salary cap: <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/>

### Sample Budget

|                   |          |
|-------------------|----------|
| Personnel Total   | \$ _____ |
| Grant             | \$ _____ |
| Recipient Share * | \$ _____ |

| Position Title        | Name (if known) | Annual   | Time | Months    | Amount Requested |
|-----------------------|-----------------|----------|------|-----------|------------------|
| Project Director      | Susan Taylor    | \$45,000 | 100% | 12 months | \$45,000         |
| Finance Administrator | John Johnson    | \$28,500 | 50%  | 12 months | \$14,250         |
| Outreach Supervisor   | Vacant          | \$27,000 | 100% | 12 months | \$27,000         |
| Total:                |                 |          |      |           | \$86,250         |

\*Cost sharing only.

### Sample Justification

The format may vary, but the description of responsibilities should be directly related to specific program objectives.

#### *Job Description: Project Director - (Name)*

*This position directs the overall operation of the project; responsible for overseeing the implementation of project activities, coordination with other agencies, development of materials, provisions of in-service and training, conducting meetings; designs and directs the gathering, tabulating and interpreting of required data; responsible for overall program evaluation and for staff performance evaluation; and is*

*the responsible authority for ensuring necessary reports/documentation are submitted to CMS. This position relates to all program objectives.*

## **B. Fringe Benefits**

Fringe benefits are usually applicable to direct salaries and wages. Provide information on the rate of fringe benefits used and the basis for their calculation (reference NICRA if applicable). If a fringe benefit rate is not used, itemize how the fringe benefit amount is computed. This information must be provided for each position (unless the rates for all positions are identical).

### Sample Budget

|                   |         |
|-------------------|---------|
| Personnel Total   | \$_____ |
| Grant             | \$_____ |
| Recipient Share * | \$_____ |

| <b>Fringe Benefit</b> | <b>Rate</b>                                  | <b>Salary Requested</b> | <b>Amount Requested</b> |
|-----------------------|----------------------------------------------|-------------------------|-------------------------|
| FICA                  | 7.65%                                        | \$45,000                | \$3443                  |
| Worker's Compensation | 2.5%                                         | \$14,250                | \$356                   |
| Insurance             | Flat rate - \$2,000 (100% FTE for 12 months) | \$2,000                 | \$2,000                 |
| Retirement            | 5%                                           | \$27,000                | \$1,350                 |
| Total                 |                                              |                         | \$7,149                 |

\*Cost sharing only.

## **C. Travel**

Dollars requested in the travel category are for applicant staff travel only. Travel for consultants is in the consultant category. Allowable travel for other participants, advisory committees, review panel, etc. is itemized in the same way specified below and placed in the "Other" category. Travel incurred through a contract is in the contractual category.

Provide a narrative describing the travel staff members will perform. This narrative includes a justification of why this travel is necessary and how it will enable the applicant to complete program requirements included in the Notice of Funding Opportunity. List where travel will be undertaken, number of trips planned, who will be making the trip, and approximate dates. If mileage is to be paid, provide the number of miles and the cost per mile. The mileage rate cannot exceed the rate set by the General Services Administration (GSA). If travel is by air, provide the estimated cost of airfare. The lowest available commercial airfares for coach or equivalent accommodations is used. If per diem/lodging is to be paid, indicate the number of days and amount of daily per diem as well as the number of nights and estimated cost of lodging. Costs for per diem/lodging cannot exceed the rates set by GSA. Include the cost of ground transportation when applicable. Please refer to the GSA website by using the following link <http://www.gsa.gov/portal/content/104877>.

### Sample Budget

|                   |          |
|-------------------|----------|
| Travel Total      | \$ _____ |
| Grant             | \$ _____ |
| Recipient Share * | \$ _____ |

| Purpose of Travel | Location                 | Item                                 | Rate                                                                                     | Cost    |
|-------------------|--------------------------|--------------------------------------|------------------------------------------------------------------------------------------|---------|
| Site Visits       | Neighboring areas of XXX | Mileage                              | \$0.655 x 49 miles (use mileage rate in effect at time of mileage incurrence) x 25 trips | \$802   |
| Training (ABC)    | Chicago, IL              | Airfare                              | \$200/flight x 2 persons                                                                 | \$400   |
|                   |                          | Luggage Fees                         | \$50/flight x 2 persons                                                                  | \$100   |
|                   |                          | Hotel                                | \$140/night x 2 persons x 3 nights                                                       | \$840   |
|                   |                          | Per Diem (meals)                     | \$49/day x 2 persons x 4 days                                                            | \$392   |
|                   |                          | Transportation (to and from airport) | \$50/shuttle x 2 persons x 2 shuttles                                                    | \$200   |
|                   |                          | Transportation (to and from hotel)   | \$25/shuttle x 2 persons x 2 shuttles                                                    | \$100   |
|                   |                          |                                      |                                                                                          | \$2,834 |

\*Cost sharing only.

### Sample Justification

*The Project Coordinator and the Outreach Supervisor will travel to (location) to attend a conference on the following topic XXXX held once a year in Chicago, IL. Attending this conference is directly linked to project goals/objectives and is a necessity because XXXX. The information and tools we will gather from attending this conference will help us carry out project objectives by XXXX. A sample itinerary is provided upon request. The Project Coordinator will also make an estimated 25 trips to birth center sites to monitor program implementation (# of birth centers, # of trips per site). We are still in the process of identifying all birth center sites, and identified an average mileage total for each site. This travel is necessary to ensure birth center sites are consistently and systematically collecting birth center data and submitting by deadlines provided. On-site monitoring will enable us to address concerns. This travel also furthers our efforts to carry out specific project goals for the following reasons\_\_\_\_\_.*

### **D. Equipment**

Equipment is tangible nonexpendable personal property, including exempt property, charged directly to the award having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit. However, consistent with recipient policy, lower limits may be established.

Note: Technology items such as computers that do not meet the \$5,000 per unit threshold or an alternative lower limit set by recipient policy that may therefore be classified as supplies, must still be individually tagged and recorded in an equipment/technology database. Provide justification for the use of each equipment item and relate it to specific program objectives. List maintenance or rental fees for equipment in the “Other” category. Ensure that all IT equipment is uniquely identified. Show the unit cost of each item, number needed, and total amount.

Sample Budget

|                          |          |
|--------------------------|----------|
| <i>Equipment Total</i>   | \$ _____ |
| <i>Grant</i>             | \$ _____ |
| <i>Recipient Share *</i> | \$ _____ |

| <b>Item(s)</b>                                        | <b>Rate</b> | <b>Cost</b> |
|-------------------------------------------------------|-------------|-------------|
| All-in-one Printer, Copier, and Scanner (large scale) | 1 @ \$5,800 | \$5,800     |
| X-Ray Machine                                         | 1 @ \$8,000 | \$8,000     |
| Total:                                                |             | \$13,800    |

\*Cost sharing only.

Sample Justification

*Provide complete justification for all requested equipment, including a description of how the program uses the equipment. For equipment and tools shared amongst programs, please cost allocate as appropriate. Applicant should provide a list of hardware, software and IT equipment that will be needed to complete this effort. Additionally, they should provide a list of non-IT equipment that will be needed to complete this effort.*

**E. Supplies**

Supplies include all tangible personal property with an acquisition cost of less than \$5,000 per unit or an alternative lower limit set by recipient policy. Individually list each item requested. Show the unit cost of each item, number needed, and total amount. Provide justification for each item and relate it to specific program objectives. Classify technology items such as computers that do not meet the \$5,000 per unit threshold or an alternative lower limit set by recipient policy as supplies and individually tag and record in an equipment/technology database. If appropriate, General Office Supplies may be shown by an estimated amount per month times the number of months in the budget category.

Sample Budget

|                          |          |
|--------------------------|----------|
| <i>Supplies Total</i>    | \$ _____ |
| <i>Grant</i>             | \$ _____ |
| <i>Recipient Share *</i> | \$ _____ |

| Item(s)                 | Rate                           | Cost    |
|-------------------------|--------------------------------|---------|
| Laptop Computer         | 2 @ \$1,000                    | \$2,000 |
| Printer                 | 1 @ \$200                      | \$200   |
| General office supplies | 12 months x \$24/mo x 10 staff | \$2,880 |
| Educational pamphlets   | 3,000 copies @ \$1 each        | \$3,000 |
| Educational videos      | 10 copies @ \$150 each         | \$1,500 |
| Total:                  |                                | \$9,580 |

\*Cost sharing only.

### Sample Justification

*General office supplies will be used by staff members to carry out daily activities of the program. The project coordinator will be a new position and will require a laptop computer and printer to complete required activities under this Notice of Funding Opportunity. The price of the laptop computer and printer is consistent with those purchased for other employees of the organization and is based upon a recently acquired invoice (which can be provided upon request). The pricing of the selected computer is necessary because it includes the following tools XXXX (e.g. firewall, etc.). The education pamphlets and videos will be purchased from XXX and used to illustrate and promote safe and healthy activities. Usage of these pamphlets and videos will enable us to address components one and two of our draft proposal. Word Processing Software will be used to document program activities, process progress reports, etc.*

## **F. Consultant/Subrecipient/Contractual Costs**

A complete description and cost breakdown, as outlined below, is provided for each consultant, subrecipient or contract.

### Required Reporting Information for Consultant Hiring

This category is appropriate when hiring an individual who gives professional advice or provides services (e.g. training, expert consultant, etc.) for a fee and who is not an employee of the Recipient organization. Submit the following required information for consultants:

1. Name of Consultant: Identify the name of the consultant and describe the person's qualifications.
2. Organizational Affiliation: Identify the organizational affiliation of the consultant, if applicable.
3. Nature of Services to be Rendered: Describe in outcome terms the consultation to be provided including the specific tasks to be completed and specific deliverables.
4. Relevance of Service to the Project: Describe how the consultant services relate to the accomplishment of specific program objectives.
5. Number of Days of Consultation: Specify the total number of days of consultation.
6. Expected Rate of Compensation: Specify the rate of compensation for the consultant (e.g., rate per hour, rate per day). Include a budget showing other costs such as travel, per diem, and supplies.
7. Justification of expected compensation rates: Provide a justification for the rate, including examples of typical market rates for this service in your area.

8. Method of Accountability: Describe how the applicant monitors progress and performance of the consultant. Identify who is responsible for supervising the consultant agreement.

Required Reporting Information for Subrecipient Approval

The costs of project activities to be undertaken by a subrecipient is included in this category. Please use formats from “Sample Budget” and “Sample Justification” above. For more information on subrecipient and contractual relationships, please refer to HHS regulation 45 CFR 75.351 Subrecipient and Contractor Determinations and 75.352 Requirements for pass-through entities.

Required Reporting Information for Contract Approval

All recipients must submit to CMS the following required information for establishing a contract to perform project activities.

1. Name of Contractor: Who is the contractor? Identify the name of the proposed contractor and indicate whether the contract is with an institution or organization.
2. Method of Selection: How was the contractor selected? State whether the contract is sole source or competitive bid. If an organization is the sole source for the contract, include an explanation as to why this institution is the only one able to perform contract services.
3. Period of Performance: How long is the contract period? Specify the beginning and ending dates of the contract.
4. Scope of Work: What will the contractor do? Describe in outcome terms, the specific services/tasks performed by the contractor as related to the accomplishment of program objectives. Clearly define the deliverables.
5. Method of Accountability: Describe the monitoring plan of the progress and performance of the contractor during and on close of the contract period. Name who will be responsible for supervising the contract.
6. Itemized Budget and Justification: Provide an itemized budget with appropriate justification. If applicable, include any indirect cost paid under the contract and the indirect cost rate used.

**G. Construction (not applicable)**

**H. Other**

This category contains items not included in the previous budget categories. Individually list each item requested and provide appropriate justification related to the program objectives.

Sample Budget

|                          |         |
|--------------------------|---------|
| <i>Other Total</i>       | \$_____ |
| <i>Grant</i>             | \$_____ |
| <i>Recipient Share *</i> | \$_____ |

| Item(s)                                 | Rate                                     | Cost    |
|-----------------------------------------|------------------------------------------|---------|
| Telephone                               | \$45 per month x 3 employees x 12 months | \$1,620 |
| Postage                                 | \$250 per quarter x 4 quarters           | \$1,000 |
| Printing                                | \$0.50 x 3,000 copies                    | \$1,500 |
| Equipment Rental<br>*specify item       | \$1,000 per day for 3 days               | \$3,000 |
| Internet Provider Service               | \$20 per month x 3 employees x 12 months | \$720   |
| Word Processing Software (specify type) | 1 @ \$400                                | \$400   |
| Total:                                  |                                          | \$8,240 |

\*Cost sharing only.

[Some items are self-explanatory (telephone, postage, rent) unless the unit rate or total amount requested is excessive. If the item is not self-explanatory and/or the rate is excessive, include additional justification. For printing costs, identify the types and number of copies of documents to be printed (e.g., procedure manuals, annual reports, materials for media campaign).]

#### Sample Justification

*We are requesting costs to accommodate telephone and internet costs for the 3 new hires that will be working on this project in the new space designated. We are also requesting printing and postage costs to support producing fliers to disseminate in the community and brochures to educate participants enrolled in the program. The word processing software will be used to help us track data and compile reports. To track and compile the data, we will need to rent \_\_\_\_\_. Without this equipment, we will not be able to produce this information in an accurate and timely manner.*

#### **I. Total Direct Costs**

\$ \_\_\_\_\_

Show total direct costs by listing totals of each category.

#### **J. Indirect Costs**

\$ \_\_\_\_\_

To claim indirect costs, the applicant organization must have a current approved negotiated indirect cost rate agreement (NICRA) set up with the Cognizant Federal agency unless the organization has never established one (see 45 CFR §75.414 for more information). If a rate has been issued, a copy of the most recent indirect cost rate agreement must be provided with the application.

Sample Budget

The rate is \_\_\_\_\_% and is computed on the following direct cost base of \$\_\_\_\_\_.

|              |                                       |
|--------------|---------------------------------------|
| Personnel \$ | _____                                 |
| Fringe \$    | _____                                 |
| Travel \$    | _____                                 |
| Supplies \$  | _____                                 |
| Other \$     | _____                                 |
| Total \$     | _____ x _____% = Total Indirect Costs |

If the applicant organization has never received an indirect cost rate, except for those non- Federal entities described in Appendix VII(D)(1)(b) to 45 CFR part 75, the applicant may choose to charge a de minimis rate of 10% of modified total direct costs (MTDC). If the applicant has never received an indirect cost rate and wants to exceed the de minimis rate, then costs normally identified as indirect costs (overhead costs) can be budgeted and identified as direct costs. These costs should be outlined in the “other” costs category and fully described and itemized as other direct costs.

## Appendix II. Application and Submission Information

Please CTRL/Click to access the links provided in this Appendix or paste to your browser. Please note these are the most up-to-date directions and links at the time of NOFO publication. CMS recommends Applicants check the websites for any changes. Also, phone numbers are provided if additional assistance is needed as several websites have made recent changes to links and directions.

This NOFO contains all the instructions you need to apply. The application is written primarily as a narrative with the addition of standard forms required by the Federal government for all grants and Cooperative Agreements.

With respect to electronic methods for providing information about funding opportunities or accepting applicants' submissions of information, CMS complies with Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d).

### EIN, UEI, LOGIN.GOV AND SAM REQUIREMENTS (ALL APPLICANTS)

#### Employer Identification Number

All applicants under this Notice of Funding Opportunity must have an Employer Identification Number (EIN), otherwise known as a Taxpayer Identification Number (TIN), to apply. You should begin the process of obtaining an EIN/TIN as soon as possible to ensure this information is received in advance of application deadlines. The process to obtain an EIN typically takes up to 5 weeks.

#### Unique Entity Identifier (UEI)

Applicants must have a UEI number to apply.

You must obtain a Unique Entity Identifier (UEI) number as soon as possible to ensure all registration steps are completed in time.

See the following links for additional information on obtaining a UEI:

GAO: <https://www.gsa.gov/about-us/organization/federal-acquisition-service/technology-transformation-services/integrated-award-environment-iae/iae-systems-information-kit/unique-entity-identifier-update>

Grants.gov: <https://www.grants.gov/forms/forms-development/planned-uei-updates>

#### Login.gov

You must sign in to Grants.gov with Login.gov credentials.

<https://grantsgovprod.wordpress.com/2022/05/04/how-to-create-a-grants-gov-account-and-link-to-a-login-gov-account/>

#### System for Award Management (SAM)

The applicant must register in the System for Award Management (SAM) database to be able to submit the application. Applicants can access <https://www.sam.gov/> and complete the online registration. UEI and EIN/TIN numbers are required to complete the registration process. To register one or more domestic entities and appoint an entity administrator, you must send a notarized letter to SAM.

Applicants should begin the SAM registration process as soon as possible after the Notice of Funding Opportunity is posted to ensure that it does not impair your ability to meet required submission deadlines.

The process to register in SAM typically takes up to 2 weeks following receipt of the notarized letter (additional 5 weeks if an EIN must be established first).

After you [register with SAM](#), you must update the information there every 12 months for your account to remain active. Grants.gov rejects electronic submissions from applicants with expired registrations. If your SAM account expires, the renewal process requires the same validation as required for a new account.

You must also successfully register with SAM prior to registering in the Federal Funding Accountability and Transparency Act Subaward Reporting System (FSRS) as a prime recipient user. Please also refer to F5.c (Federal Funding Accountability and Transparency Act Reporting Requirements) of this Funding Opportunity for more information.

Primary awardees must maintain a current registration with the SAM database, and **may make subawards only to entities that have UEI numbers.**

Organizations must report executive compensation as part of the registration profile at <https://www.sam.gov/> by the end of the month following the month in which this award is made, and annually thereafter (based on the reporting requirements of the Federal Funding Accountability and Transparency Act (FFATA) of 2006 (Pub. L. 109-282), as amended by Section 6202 of Public Law 110-252 and implemented by 2 CFR Part 170).

## How to Apply for Grants

[Grants.gov](#) is an online portal for submitting federal award applications. It requires a one-time registration to submit applications. All competitive Notice of Funding Opportunities must be submitted electronically through <http://www.grants.gov/>.

For assistance with this process contact <https://www.grants.gov/support> or 1-800-518-4726. Below is an overview of the instructions from the Grants.gov website. Applicants can access the site directly for more detailed information.

### How to Register to Apply through Grants.gov

- Obtain A UEI number.
- Complete SAM registration
- Create a Login.gov Account (Users must sign in to Grants.gov with Login.gov credentials):  
<https://grantsgovprod.wordpress.com/2022/05/04/how-to-create-a-grants-gov-account-and-link-to-a-login-gov-account/#CreateALoginGovAccount>
- Register to obtain a Grants.gov username and password.
  - Click the Register link and complete the on-screen instructions or refer to detailed instructions here: <https://www.grants.gov/applicants/applicant-registration>.
  - The person submitting your application must be registered with Grants.gov as the Authorized Organizational Representative (AOR) for the specific UEI number cited on the SF-424 (first page). See the <https://apply07.grants.gov/help/html/help/index.htm?callingApp=custom#t=GetStarted%2FGetStarted.htm> for details.

- *To link your Grants.gov account to a Login.gov account:* See detailed instructions here: <https://grantsgovprod.wordpress.com/2022/05/04/how-to-create-a-grants-gov-account-and-link-to-a-login-gov-account/>
- *Add a Profile to the Account:* The profile corresponds to a single applicant organization the user represents (i.e., an applicant) or an individual applicant. If you work for or consult with multiple organizations and have a profile for each, you may log in to one Grants.gov account to access all your grant applications. To add an organizational profile, enter the UEI (Unique Entity Identifier) for the organization in the field while adding a profile. For more detailed instructions about creating a profile refer to: <https://www.grants.gov/applicants/applicant-registration>
- *EBiz POC Authorized Profile Roles:*
  - EBiz POCs will no longer use their UEI or DUNS Number during login. EBiz POCs will use an applicant account associated with their email address and UEI (Unique Entity Identifier) by using an existing applicant account or <https://www.grants.gov/applicants/applicant-registration>.
  - EBiz POCs will login using multi-factor authentication through Login.gov. The Expanded AOR (Authorized Organizational Representative) role will be automatically assigned to the EBiz POC. Users with the Expanded AOR can control organization preferences, user access, and apply for grants with the same account. To be recognized as EBiz POC in Grants.gov, users will need to use an applicant account with an email address that matches the SAM.gov account email address for their organization.
- *Track Role Status:* To track your role request, refer to: <https://www.grants.gov/applicants/applicant-registration>
- *Electronic Signature:* The name of the organization applicant with the AOR role that submitted the application is inserted into the signature line of the application, serving as the electronic signature. The EBiz POC **must** authorize people who are able to make legally binding commitments on behalf of the organization as a user with the AOR role; **this step is often missed and it is crucial for valid and timely submissions.**

#### Grants.gov Workspace:

Grants.gov applicants can apply online using Workspace. Workspace is a shared, online environment where members of a grant team may simultaneously access and edit different webforms within an application. For each NOFO you can create individual instances of a workspace.

*Note:* Search for the application package in by entering the Federal Assistance Listings (CFDA) number. This number is shown on the Federal Assistance Listings (or CFDA) website at <https://sam.gov> and cover page of the funding opportunity.

Applications will not be accepted through any email address or be received via paper mail, courier, or delivery service.

Below is an overview of applying. For access to complete instructions on how to apply for opportunities, refer to: <https://www.grants.gov/applicants/workspace-overview>

1. *Create a Workspace:* Creating a workspace allows you to complete it online and route it through your organization for review before submitting.
2. *Complete a Workspace:* Add participants to the workspace to work on the application together, complete all the required forms online or by downloading PDF versions, and check for errors before submission. The Workspace progress bar will display the state of your application process

as you apply. As you apply using Workspace, you may click the blue question mark icon near the upper-right corner of each page to access context- sensitive help.

- a. *Adobe Reader*: If you decide not to apply by filling out webforms you can download individual PDF forms in Workspace. The individual PDF forms can be downloaded and saved to your local device storage, network drive(s), or external drives, then accessed through Adobe Reader.
3. NOTE: Visit the Adobe Software Compatibility page on Grants.gov to download the appropriate version of the software at: <https://www.grants.gov/applicants/adobe-software-compatibility>
  - a. *Mandatory Fields in Forms*: In the forms, you will note fields marked with an asterisk and a different background color. These fields are mandatory fields that must be completed to successfully submit your application.
  - b. *Complete SF-424 Fields First*: The forms are designed to fill in common required fields across other forms, such as the applicant name, address, and UEI Number. Once it is completed, the information will transfer to the other forms.
4. *Submit a Workspace*: An application may be submitted through workspace by clicking the Sign and Submit button on the Manage Workspace page, under the Forms tab. Grants.gov recommends submitting your application package at least 24-48 hours prior to the close date to provide you with time to correct any potential technical issues that may disrupt the application submission.
5. *Track a Workspace Submission*: After successfully submitting a workspace application, a Grants.gov Tracking Number (GRANTXXXXXXXX) is automatically assigned to the application. The number will be listed on the Confirmation page that is generated after submission. Using the tracking number, access the Track My Application page under the Applicants tab or the Details tab in the submitted workspace.

For additional training resources, including video tutorials, refer to:

<https://www.grants.gov/applicants/applicant-training>

*Applicant Support*: 24/7 support is available via the toll-free number 1-800-518-4726 and email at <https://www.grants.gov/support>. For questions related to the specific grant opportunity, contact the number listed in the application package of the grant you are applying for.

If you are experiencing difficulties with your submission, it is best to call the Grants.gov Support Center and get a ticket number. The Support Center ticket number will assist CMS with tracking your issue and understanding background information on the issue.

#### *Timely Receipt Requirements and Proof of Timely Submission*

All grant and Cooperative Agreement applications must be submitted electronically and received through <https://www.grants.gov> by 11:59 p.m. Eastern Standard or Daylight Time (Baltimore, MD) by the applicable deadline date. Please refer to the Executive Summary of this NOFO for submission deadline date.

Proof of timely submission is automatically recorded and an electronic date/time stamp is generated within the system when the application is successfully received by Grants.gov. The AOR who submitted the application will receive an acknowledgement of receipt and a tracking number (GRANTXXXXXXXX) with the successful transmission of their application. The AOR will also receive the official date/time stamp and Grants.gov Tracking number in an email serving as proof of their timely submission.

Please note, you may incur a time delay before you receive acknowledgement that the application has been accepted by the Grants.gov system. Applicants should not wait until the application deadline to apply. Notification by Grants.gov that the application is incomplete may not be received until close to or after the application deadline. Consequently, you may not be able to correct errors and resubmit the application. Applications submitted after the deadline, because of errors on the part of the applicant, will not be reviewed.

Once CMS successfully downloads the application from Grants.gov, the AOR will receive, an electronic acknowledgment of receipt of the application. Proof of timely submission shall be the official date and time that Grants.gov receives your application. Applications received after the established due date for the program will be considered late and will not be considered for funding by CMS.

Applicants using slow internet, such as dial-up connections, should be aware that transmission can take some time before your application is received. The Support Center reports that some applicants end the transmission because they think that nothing is occurring during the transmission process. Please be patient and give the system time to process the application.

Grants.gov complies with Section 508 of the Rehabilitation Act of 1973. If an individual uses assistive technology and is unable to access any material on the site, including forms contained within an application package, the individual can e-mail the contact center at <https://www.grants.gov/support> for help, or call 1-800-518-4726.

## Appendix III. Business Assessment of Applicant Organization

Applicants must complete the business assessment questions outlined below. There are eleven (11) topic areas labeled A-K, with a varying number of questions within each topic area. **Applicants MUST provide a brief substantive answer to each question (and supporting documentation as applicable).** If the answer to any question is non- applicable, please provide an explanation. If CMS cannot complete its review without contacting the applicant for additional clarification, the applicant risks selection for award.

### A. General Information

1. Provide organization:
  - a. Legal name:
  - b. EIN (include PMS prefix and suffix, if applicable-ex. 1-12356789-A1):
  - c. Organizational Type:
2. What percentage of the organization's capital is from Federal funding? (percentage = total Federal funding received in previous fiscal year / organization's total gross revenue in previous fiscal year).
3. Does/did the organization receive additional oversight (ex: Correction Action Plan, Federal Awardee Performance and Integrity Information System (FAPIIS) finding, reimbursement payments for enforcement actions) from a Federal agency within the past 3 years due to past performance or other programmatic or financial concerns with the organization)?
  - a. If yes, please provide the following information: Name of the Federal agency; reason for the additional oversight as explained by the Federal agency
  - b. If resolved, please indicate how the issue was resolved with the agency.
4. Does the organization currently manage grants with other U.S. Department of Health and Human Services components or other Federal agencies?
5. Explain your organization's process to ensure annual renewal in System for Award Management (to include FAPIIS).
6. Explain your organization's process to comply with
  - a. [45 CFR 75.113](#) Mandatory Disclosures and
  - b. your organization's process to comply with FFATA requirements.
7. Do you have conflict of interest policies? Does your organization or any of its employees have any personal or organizational conflicts of interest related to the possible receipt of these CMS award funds? If yes, please explain and provide a mitigation plan.
8. Does your organization currently, or in the past, had delinquent Federal debt in the last 3 years? If yes, please explain.
9. Have you filed bankruptcy or entered into proceedings for bankruptcy, whether voluntarily or involuntarily?

10. Has the organization obtained fidelity bond insurance coverage for responsible officials and employees of the organization in amounts required by statute or organization policy? What is that amount?
11. Do you have (and briefly describe) policies and procedures in place to meet the requirements below? If not, explain your plan and estimated timeline for establishing these policies and procedures if selected for award.
  - a. make determinations between subrecipients versus contracts in accordance with [45 CFR 75.351](#)?
  - b. notify entities at the time of the award/agreement if they are a subrecipient in compliance with [45 CFR 75.352](#)?
  - c. manage, assess risk, review audits, and monitor the subrecipients as necessary to ensure that subawards are used for authorized purposes in compliance with laws, regulations, and terms and conditions of the award and that established subaward performance goals are achieved (45 CFR § [75.351–75.353](#))?

## **B. Accounting System**

1. Does the organization have updated (last two years) written accounting policies and procedures to manage federal awards in accordance with 45 CFR Part 75?
  - a. If no, please provide a brief explanation of why not.
  - b. Describe the management of federal funds and how funds are separated (not co-mingling) from other organizational funds.
2. Briefly describe budgetary controls in effect to preclude incurring obligations more than:
  - a. Total funds available for an award.
  - b. Total funds available for a budget cost category.
3. Has any government agency rendered an official written opinion within the last 3 years concerning the adequacy of the organization's accounting system for the collection, identification, and allocation of costs under Federal awards?
  - a. If yes, please provide the name and address of the Agency that performed the review.
  - b. Provide a summary of the opinion.
  - c. How did your organization resolve any concerns?
4. How does the accounting system provide for recording the non-Federal share and in-kind contributions (if applicable for a grant program)?
5. Does the organization's accounting system provide identification for award funding by federal agency, pass-through entity, Assistance Listing (CFDA), award number and period of funding? If yes, how does your organization identify awards? If not, please explain why not.

## **C. Budgetary Controls**

1. What are the organization's controls utilized to ensure that the Authorized Organizational Representative (AOR), as identified on the SF-424, approves all budget changes for the federal award?

2. Describe the organization's procedures for minimizing the time between transfer of funds from the U.S. Treasury (e.g. Payment Management System) and disbursement for grant activities (See 45 CFR §75.305, "Payment.").

#### **D. Personnel**

1. Does the organization have a current organizational chart or similar document establishing clear lines of responsibility and authority?
  - a. If yes, please provide a copy.
  - b. If no, how are lines of responsibility and authority determined?
2. Does the organization have updated (last two years) written Personnel and/or Human Resource policies and procedures? If no, provide a brief explanation.
3. Does the organization pay compensation to Board Members?
4. Are staff responsible for fiscal and administrative oversight of HHS awards (Grants Manager, CEO, Financial Officer) familiar with federal rules and regulations applicable to grants and Cooperative Agreements (e.g. [45 CFR Part 75](#))?
5. Please describe how the payroll distribution system accounts for, tracks, and verifies the total effort (100%) to determine employee compensation.

#### **E. Payroll**

1. In preparation of payroll is there a segregation of duties for the staff who prepare the payroll and those that sign the checks, have custody of cash funds and maintain accounting records? Please describe.

#### **F. Consultants** (See appendix I in the NOFO for relevant information)

1. Are there written policies or consistently followed procedures regarding the use of consultants which detail the following (include explanation for each question below)?
2. Briefly describe the organization's method or policy for ensuring consultant costs and fees are allowable, allocable, necessary and reasonable.
3. Briefly describe the organization's method or policy to ensure prospective consultants prohibited from receiving Federal funds are not selected.

#### **G. Property Management**

1. Briefly describe the system for property management (tangible or intangible) utilized for maintaining property records consistent with 45 CFR 75.320(d).  
\*\*Refer to ([45 CFR 75.2](#)) for definitions of property to include personal property, equipment, and supplies.
2. Does the organization have adequate insurance to protect the Federal interest in equipment and real property (see [45 CFR §75.317, "Insurance coverage."](#))? How does the organization calculate the amount of insurance?

## **H. Procurement**

1. Describe the organization's procurement procedures (in accordance with [45 CFR §75.326--§75.335](#), "Procurement procedures")? If there are no procurement procedures, briefly describe how your organization handles purchasing activities. A. Include individuals responsible and their roles. B. Describe the competitive bid process for procurement purchases of equipment, rentals, or service agreements that are over certain dollar amounts.

## **I. Travel**

1. Describe the organizations written travel policy. Ensure, at minimum, that:
  - a. Travel charges are reimbursed based on actual costs incurred or by use of per diem and/or mileage rates (see [45 CFR §75.474](#), "Travel costs.").
  - b. Receipts for lodging and meals are required when reimbursement is based on actual cost incurred.
  - c. Subsistence and lodging rates are equal to or less than current Federal per diem and mileage rates.
  - d. Commercial transportation costs incurred at coach fares unless adequately justified. Lodging costs do not exceed GSA rate unless adequately justified (e.g. conference hotel).
  - e. Travel expense reports show purpose and date of trip.
  - f. Travel costs are approved by organizational official(s) and funding agency prior to travel.

## **J. Internal Controls**

1. Provide a brief description of the applicant's internal controls that will provide reasonable assurance that the organization will manage award funds properly. (see [45 CFR §75.303](#), "Internal controls.")
2. What is your organization's policy on separation of duties as well as responsibility for receipt, payment, and recording of cash transactions?
3. Does the organization have internal audit or legal staff? If not, how do you ensure compliance with the award? Please describe.
4. If the organization has a petty cash fund how is it monitored?
5. Who in the organization reconciles bank accounts? Is this person familiar with the organization's financial activities? Does your organization authorize this person to sign checks or handle cash?
6. Are all employees who handle funds required to be bonded against loss by reason of fraud or dishonesty?

## **K. Audit**

1. What is your organization's fiscal year?
2. Did the organization expend \$750,000 or more in Federal awards from all sources during its most recent fiscal year?
3. Has your organization submitted:

- a. an audit report to the *Federal Audit Clearing House (FAC)* in accordance with the Single Audit Act in the last 3 years? (see 45 CFR §75.501, “Audit requirements” and 45 CFR §75.216 “Special Provisions for Awards to Commercial Organization as Recipient.”) or
  - b. an independent, external audit? If no, briefly explain. If yes, address the following:
    - i. The date of the most recently submitted audit report.
    - ii. The auditor's opinion on the financial statement.
    - iii. If applicable, indicate if your organization has findings in the following areas: 1) internal controls, 2) questioned or unallowable costs, 3) procurement/suspension and debarment, 4) cash management of award funds, and 5) subrecipient monitoring.
    - iv. Include (if applicable):
      - 1. A description of each finding classified as Material Weakness.
      - 2. A description of each finding classified as Significant Deficiency.
4. Does the organization have corrective actions in the past 2 years for the findings identified above (3(iii))? If yes, describe the status (closed or open) and progress made on those corrective actions.

## Appendix IV. Accessibility Requirements

CMS and its recipients are responsible for complying with federal laws regarding accessibility as noted in the Award Administration Information/Administration and National Policy Requirements Section.

The Recipient may receive a request from a beneficiary or member of the public for information in accessible formats. All successful applicants under this Notice of Funding Opportunity must comply with the following reporting and review activities regarding accessibility requests:

### Accessibility Requirements:

1. **Public Notification:** If you have a public facing website, you shall post a message no later than 30 business days after award that notifies your customers of their right to receive an accessible format. Sample language may be found at: <https://www.medicare.gov/about-us/accessibility-nondiscrimination-notice>. Your notice shall be crafted applicable to your program.
2. **Processing Requests Made by Individuals with Disabilities:**
  - a. **Documents:**
    - i. When receiving a request for information in an alternate format (e.g., Braille, Large print, etc.) from a beneficiary or member of the public, you must:
      1. Consider/evaluate the request according to civil rights laws.
      2. Acknowledge receipt of the request and explain your process within 2 business days.
      3. Establish a mechanism to provide the request.
    - ii. If you are unable to fulfill an accessible format request, CMS may work with you to provide the accessible format as funding and resources allow. You shall refer the request to CMS within 3 business days if unable to provide the request. You shall submit the request, using encrypted e-mail (to safeguard any personally identifiable information), to the [AltFormatRequest@cms.hhs.gov](mailto:AltFormatRequest@cms.hhs.gov) mailbox with the following information:
      1. The e-mail title shall read “Grantee (Organization) Alternate Format Document Request.”
      2. The body of the e-mail shall include:
        - a. Requester’s name, phone number, e-mail, and mailing address.
        - b. The type of accessible format requested, e.g., audio recording on compact disc (CD), written document in Braille, written document in large print, document in a format that is read by qualified readers, etc.
        - c. Contact information for the person submitting the e-mail – Organization (Grantee), name, phone number and e-mail.
        - d. The document that needs to be put into an accessible format shall be attached to the e-mail.
        - e. CMS may respond to the request and provide the information directly to the requester.
      - iii. The Recipient shall maintain record of all alternate format requests received including the requestor’s name, contact information, date of request, document requested, format requested, date of acknowledgment, date request provided, and

date referred to CMS if applicable. Forward quarterly records to the [AltFormatRequest@cms.hhs.gov](mailto:AltFormatRequest@cms.hhs.gov) mailbox.

b. Services

- i. When receiving request for auxiliary aids and services (e.g., sign language interpreter) from a beneficiary or member of the public, you must:
  1. Consider/evaluate the request according to civil rights laws.
  2. Acknowledge receipt of the request and explain your process within 2 business days.
  3. Establish a mechanism to provide the request.
- ii. If you are unable to fulfill an accessible service request, CMS may work with you to provide the accessible service as funding and resources allow. You shall refer the request to CMS within 3 business days if unable to provide the service. You shall submit the request, using encrypted e-mail (to safeguard any personally identifiable information), to the [AltFormatRequest@cms.hhs.gov](mailto:AltFormatRequest@cms.hhs.gov) mailbox with the following information:
  1. The e-mail title shall read “Grantee (Organization) Accessible Service Request.”
  2. The body of the e-mail shall include:
    - a. Requester’s name, phone number, e-mail, and mailing address.
    - b. The type of service requested (e.g., sign language interpreter and the type of sign language needed).
    - c. The date, time, address and duration of the needed service.
    - d. A description of the venue for which the service is needed (e.g., public education seminar, one-on-one interview, etc.)
    - e. Contact information for the person submitting the e-mail – Organization (Grantee), name, phone number and e-mail.
    - f. Any applicable documents shall be attached to the e-mail. CMS will respond to the request and respond directly to the requester.
- iii. The Recipient shall maintain record of all accessible service requests received including the requestor’s name, contact information, date of request, service requested, date of acknowledgment, date service provided, and date referred to CMS if applicable. Forward quarterly records to the [AltFormatRequest@cms.hhs.gov](mailto:AltFormatRequest@cms.hhs.gov) mailbox.

3. Processing Requests Made by Individuals with Limited English Proficiency (LEP):

a. Documents:

- i. When receiving a request for information in a language other than English from a beneficiary or member of the public, you must:
  1. Consider/evaluate the request according to civil rights laws.
  2. Acknowledge receipt of the request and explain your process within 2 business days.
  3. Establish a mechanism to provide the request as applicable.
- ii. If you are unable to fulfill an alternate language format request, CMS may work with you to provide the alternate language format as funding and resources allow. You shall refer the request to CMS within 3 business days if unable to provide the

request. You shall submit the request, using encrypted e-mail (to safeguard any personally identifiable information), to the [AltFormatRequest@cms.hhs.gov](mailto:AltFormatRequest@cms.hhs.gov) mailbox with the following information:

1. The e-mail title shall read “Grantee (Organization) Alternate Language Document Request.”
2. The body of the e-mail shall include:
  - a. Requester’s name, phone number, e-mail, and mailing address.
  - b. The language requested.
  - c. Contact information for the person submitting the e-mail – Organization (Recipient), name, phone number and e-mail.
  - d. The document that needs to be translated shall be attached to the e-mail.
  - e. CMS may respond to the request and provide the information directly to the requester.
- iii. The Recipient shall maintain record of all alternate language requests received including the requestor’s name, contact information, date of request, document requested, language requested, date of acknowledgment, date request provided, and date referred to CMS if applicable. Forward quarterly records to the [AltFormatRequest@cms.hhs.gov](mailto:AltFormatRequest@cms.hhs.gov) mailbox.

b. Services

- i. When receiving request for an alternate language service (e.g., oral language interpreter) from a beneficiary or member of the public, you must:
  1. Consider/evaluate the request according to civil rights laws.
  2. Acknowledge receipt of the request and explain your process within 2 business days.
  3. Establish a mechanism to provide the request as applicable.
- ii. If you are unable to fulfill an alternate language service request, CMS may work with you to provide the alternate language service as funding and resources allow. You shall refer the request to CMS within 3 business days if unable to provide the service. You shall submit the request, using encrypted e-mail (to safeguard any personally identifiable information), to the [AltFormatRequest@cms.hhs.gov](mailto:AltFormatRequest@cms.hhs.gov) mailbox with the following information:
  1. The e-mail title shall read “Grantee (Organization) Accessible Service Request.”
  2. The body of the e-mail shall include:
    - a. Requester’s name, phone number, e-mail, and mailing address.
    - b. The language requested.
    - c. The date, time, address and duration of the needed service.
    - d. A description of the venue for which the service is needed (e.g., public education seminar, one-on-one interview, etc.)
    - e. Contact information for the person submitting the e-mail – Organization (Recipient), name, phone number and e-mail.
    - f. Any applicable documents shall be attached to the e-mail.
    - g. CMS will respond to the request and respond directly to the requester.

- iii. The Recipient shall maintain record of all alternate language service requests received including the requestor's name, contact information, date of request, language requested, service requested, date of acknowledgment, date service provided, and date referred to CMS if applicable. Forward quarterly records to the [AltFormatRequest@cms.hhs.gov](mailto:AltFormatRequest@cms.hhs.gov) mailbox.

Please contact the CMS Office of Equal Opportunity and Civil Rights for more information about accessibility reporting obligations at [AltFormatRequest@cms.hhs.gov](mailto:AltFormatRequest@cms.hhs.gov).

## Appendix V. Merit Review and Selection Process

The review and selection process will include the following:

1. Applications will be screened to determine eligibility for further review using the criteria detailed in Sections C. Eligibility Information, and D. Application and Submission Information (with cross-reference to Appendix II), of this NOFO. Applications that are received late or fail to meet the eligibility requirements as detailed in this NOFO or do not include the required forms will not be reviewed. However, the CMS/OAGM/GMO, in his or her sole discretion, may continue the review process for an ineligible application if it is in the best interest of the government to meet the objectives of the program.
2. Applications will be evaluated by a merit review committee. The merit review committee may include Federal and/or non-Federal reviewers. Merit Reviewers use the criteria described in **Section E1. Criteria** of the NOFO, to evaluate each application. Applicants should pay strict attention to addressing all these criteria, as they are the basis upon which the reviewers will evaluate their applications.
3. The results of the merit review are key in decision-making but are not the only factors. Final award decisions will be made by a CMS approving official. In making these decisions, the CMS approving official will take into consideration:
  - a. Evaluation of the merit review panel;
  - b. the readiness of the applicant to conduct the work required;
  - c. the scope of overall projected impact on the aims;
  - d. reviews for programmatic and grants management compliance;
  - e. the reasonableness of the estimated cost to the government and anticipated results;
  - f. the geographic range of all applications;
  - g. the range of the project types; and
  - h. the likelihood that the proposed project will result in the benefits expected.
4. As noted in 45 CFR Part 75, CMS will do a review of risks posed by applicants prior to award. In evaluating risks posed by applicants, CMS will consider the below factors as part of the risk assessment (applicant should review the factors in their entirety at §75.205)
  - a. Financial stability;
  - b. Quality of management systems and ability to meet the management standards prescribed;
  - c. History of performance (including, for prior recipients of Federal awards: timeliness of compliance with applicable reporting requirements, conformance to the terms and conditions of previous federal awards, extent to which previously awarded amounts will be expended prior to future awards);
  - d. Reports and findings from audits performed under Subpart F of 45 CFR Part 75 and
  - e. Applicant's ability to effectively implement statutory, regulatory, and other requirements imposed on non-federal entities.
5. CMS reserves the right to conduct pre-award Negotiations with potential recipients.

## Appendix VI. Application Check-off List

Use this checklist to make sure you have everything you need to submit a compliant application.

### Required Contents

A complete application consists of the materials organized in the sequence below. Please ensure that the project and budget narratives are page-numbered and the below forms are completed with an electronic signature and enclosed as part of the application. Everything listed below must be submitted to [Grants.gov](https://www.grants.gov). **Place holders are designated in the application kit available on Grants.gov.** Documents without specific placeholders in the application kit available on Grants.gov should be uploaded under “Other Attachments Form.”

- ☐ SF-424: Application for Federal Assistance
- ☐ SF-424A: Budget Information
- ☐ SF-LLL: Disclosure of Lobbying Activities
- ☐ Project Site Location Form(s)
- ☐ Applicant’s Application Cover Letter (**optional; excluded from page limitations**)
- ☐ Project Abstract
- ☐ Project Narrative
- ☐ Business Assessment of Applicant Organization
- ☐ Budget Narrative
- ☐ Appendices
  - (Resumes and/or curriculum vitae (**required** for identified managers, Project Director, and all other Key Personnel identified at the time of application))
  - Job descriptions (**required**)
  - Organizational Chart (**required**)
- ☐ Negotiated Indirect Cost Rate Agreement (NICRA)/Cost Allocation Plan, if applicable (excluded from page limitations)
- ☐ Program Duplication Assessment