# Cell and Gene Therapy (CGT) Access Model Notice of Funding Opportunity (NOFO)

Center for Medicare and Medicaid Innovation
September 24, 2024



CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICARE AND MEDICAID INNOVATION

# Housekeeping & Logistics

## DIAL IN

This event is being recorded. It is recommended that you listen via your computer speakers.

Additional options for audio listening:
Dial-In: +1 929 436 2866
ID: 980 5597 6939
Passcode: 202209

Closed captioning is available on the bottom of the screen.

## PARTICIPATE

If you have questions for the CGT Team, please use the Q&A box at the bottom of your screen.

## SHARE FEEDBACK

Please complete a short survey that will be available at the end of the event.

# Agenda

1. Welcome and Introductions
2. CGT Access Model Overview
3. Cooperative Agreement Funding
4. Application Submission Information
5. Federal Award Administration
6. Question & Answer Session
7. Closing & Resources

# Welcome and Introductions

# Today's Presenters

**Laurie McWright**
*Deputy Director, Seamless Care Models Group*

**Melissa Majerol**
*CGT Access Model Co-Lead, Division of Drug Innovation, Seamless Care Models Group*

**Caroline Horrow**
*CGT Access Model Team Member, Division of Drug Innovation, Seamless Care Models Group*

**Gabe Nah**
*Grants Management Officer, Office of Acquisition & Grants Management*

**Makaria Martin**
*Grants Management Specialist, Office of Acquisition & Grants Management*

**Jason Petroski**
*Director, Division of Drug Innovation, Seamless Care Models Group*

# CGT Access Model Overview

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICARE & MEDICAID INNOVATION

# Model Structure

The CGT Access Model seeks to test whether a CMS-led approach to negotiating and administering Outcomes-Based Agreements (OBAs) for CGTs will improve access and health outcomes for people with Medicaid coverage and reduce health care costs. This test includes a comprehensive strategy for addressing a range of barriers to equitable access to CGTs.

## Role of CMS

CMMI will negotiate key terms for agreements between states and manufacturers, including CGT market access and rebate payments.

## Participant Eligibility

**All States and Territories** that participate in the Medicaid Drug Rebate Program (MDRP) can participate in the model if they meet requirements.

**Manufacturers** that participate in the MDRP and market FDA-approved or -licensed gene therapies for the treatment of SCD can participate in negotiations with CMS.

**CMS will negotiate discounted pricing**

with manufacturers to relieve the burden on states and increase access for beneficiaries.

**CMS will tie manufacturer payment to specific outcomes,**

such as reduction in pain-crises.

**CMS will offer optional funding**

to states to support implementation and activities that promote equitable access to care.

**CMS will support states to operationalize the model,**

such as providing technical assistance, specifying requirements on data collection, and collecting clinical and claims outcomes.

# Overview of Sickle Cell Disease

CMS is initially focusing the CGT Access Model on gene therapies for sickle cell disease (SCD) to increase access to potentially curative therapies for all individuals with SCD for whom gene therapy may be an appropriate option.

## Fast Stats

**100,000+**

**People affected in the U.S.**

**~60%**

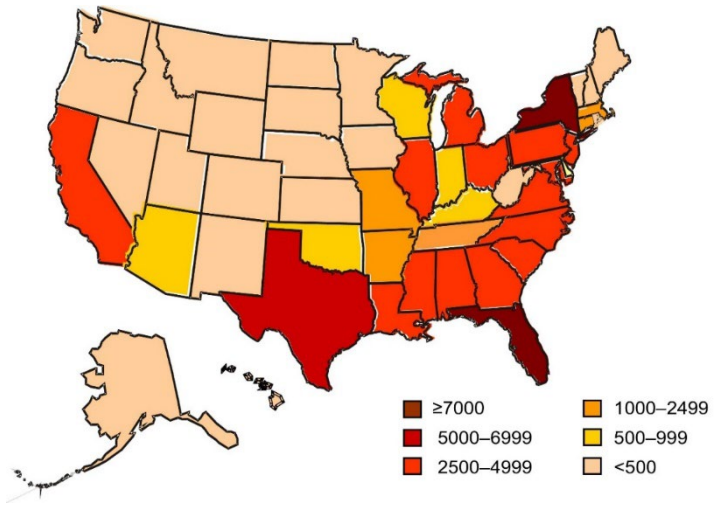
**Of people with SCD are enrolled in Medicaid**

**$2.98B**

**In costs per year to the U.S. health system** *(mostly accrued to Medicaid)*

## Description

SCD is a genetic blood disorder that affects 100,000+ people in the U.S., the majority of whom are Black Americans. This disease is unevenly spread across the U.S., as shown in the state-by-state patient counts to the right.




## Biopsychosocial Challenges of Individuals with Severe SCD

- The lifelong effects of SCD result in individuals' average lifespans being reduced by 20+ years compared to average life expectancy in the U.S.
- Individuals have excruciating pain episodes leading to multiple hospitalizations per year and the need for prescription pain medication.
- Frequent pain has broad effects on a patient's life, impacting educational attainment and employment.
- SCD gives rise to other conditions, such as mental health challenges.

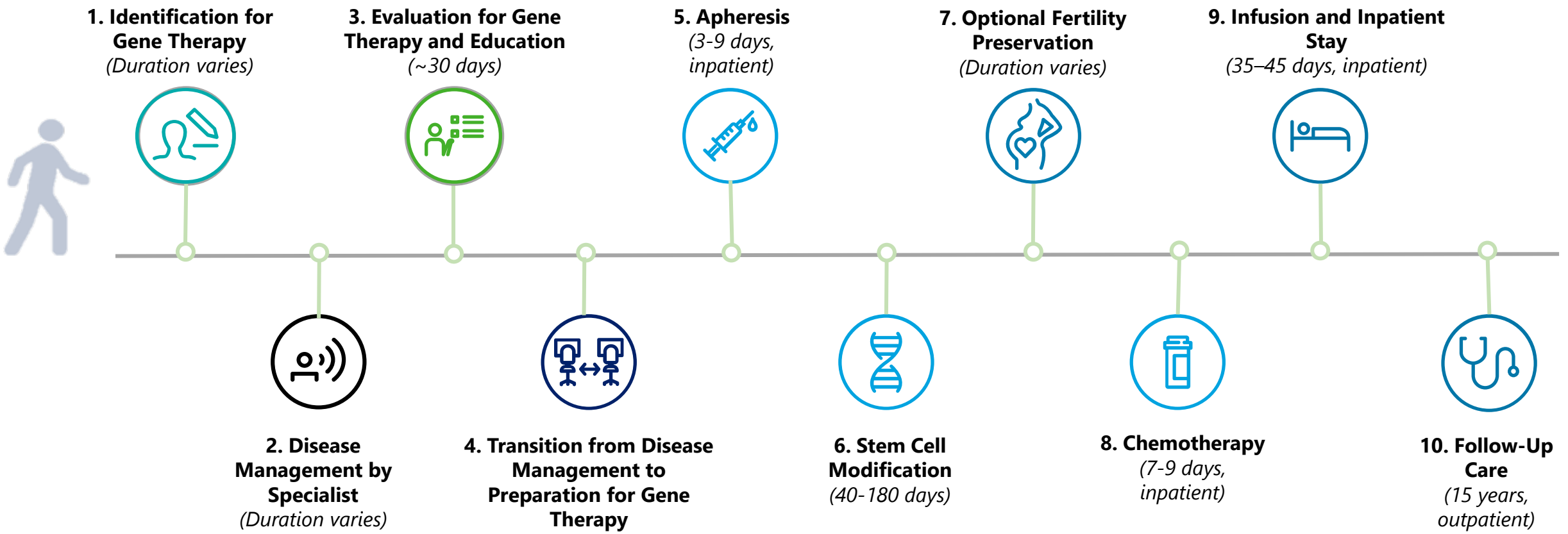
## Potential of CGTs

**On December 8, 2023, the FDA approved two gene therapies for SCD, Casgevy and Lyfgenia.**

Both products hold the promise of dramatically improving the lives of people with SCD by potentially **reducing or fully eliminating the occurrence of severe pain crises.**

# Illustrative Patient Care Journey

The care journey for SCD gene therapy is long, rigorous, and complex.



# Potential Care Delivery Gaps

Cooperative Agreement funding is designed to help states address some of the potential care delivery gaps individuals with Medicaid coverage may experience in the SCD gene therapy care journey.

| Topic | Potential Care Delivery Gaps |
|---|---|
| **Patient Knowledge** | • Patient awareness of gene therapy<br>• Patient knowledge of & access to non-emergency medical transportation (NEMT) |
| **SCD Care** | • Access to SCD specialist<br>• Access to out-of-state providers |
| **Other Specialty Care** | • Access to behavioral health providers<br>• Access to other specialty care services and providers |
| **Social Needs** | • Health-related social needs (HRSNs), including childcare |
| **Care Coordination** | • Care coordination / patient navigation<br>• Navigating changes in insurance coverage |

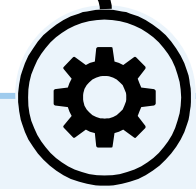
# Purpose of Cooperative Agreement Funding

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

Two types of funding will be available under the Cooperative Agreement:

**Implementation Funding**

for model activities that involve staff/contractor time and infrastructure costs



**Milestone Funding**

for successful completion of research projects

# Role of the State RFA and NOFO

After the negotiated Key Terms have been disclosed to states in December 2024, states can decide whether to apply to the State RFA and the NOFO.

## State Request for Applications (RFA)

*Required for model participation*

- States can apply to participate in the CGT Access Model through the State RFA.
- Participating states will execute a **State Agreement (SA)** with CMS. The SA will govern each state's participation in the model.
- For more information about the CGT Access Model participation requirements, see the State RFA Webinar, which took place on July 29, 2024.

## Notice of Funding Opportunity (NOFO)

*Optional funding for model participants*

- States that respond to the State RFA may also choose to apply for funding via the NOFO to support their participation in the CGT Access Model.
- States that apply for and are awarded funding under the NOFO will receive a **Cooperative Agreement** award from CMS.

To be considered for Cooperative Agreement funding, a state must apply to **both** the State RFA and the NOFO. States seeking to participate in the model **without** funding must **only** apply to the State RFA.

Applications for the State RFA and NOFO are both due on February 28, 2025.

# Cooperative Agreement Funding

# Eligibility for Cooperative Agreement Funding

Eligible applicants can apply to the NOFO to seek Cooperative Agreement funding.

## WHO CAN APPLY?

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 February 28, 2025
- ✓ Apply to the NOFO by no later than February 28, 2025
- ✓ Sign a State Agreement with CMS by no later than June 1, 2025

## PARTNER ORGANIZATIONS

States can use Cooperative Agreement funding to partner with community-based organizations (CBOs), treatment centers qualified to administer gene therapy for SCD, and/or academic institutions. These organizations may be sub-recipients or contractors.

# Federal Award Information

The type of award issued under this Notice of Funding Opportunity is a Cooperative Agreement.

## Funding Details

- More funding will be available in the early years of the model.
- The availability of 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.*
- Recipients may allocate funding to Implementation Funding, Milestone Funding, or both.
- Funding for each year after Budget Period 1 will be issued via non-competing continuation awards, contingent on progress in meeting project goals; timely submission of required data and reports; and compliance with all Terms and Conditions.
- States must request funds for the next budget period via submission of a non-competing continuation application.

**Reminder: the OBA Term will be part of the Key Terms disclosed to States in December 2024.*

The main difference between a Cooperative Agreement and a grant is:

A Cooperative Agreement will generate and require a higher level of collaboration and cooperation between CMS and participating states.

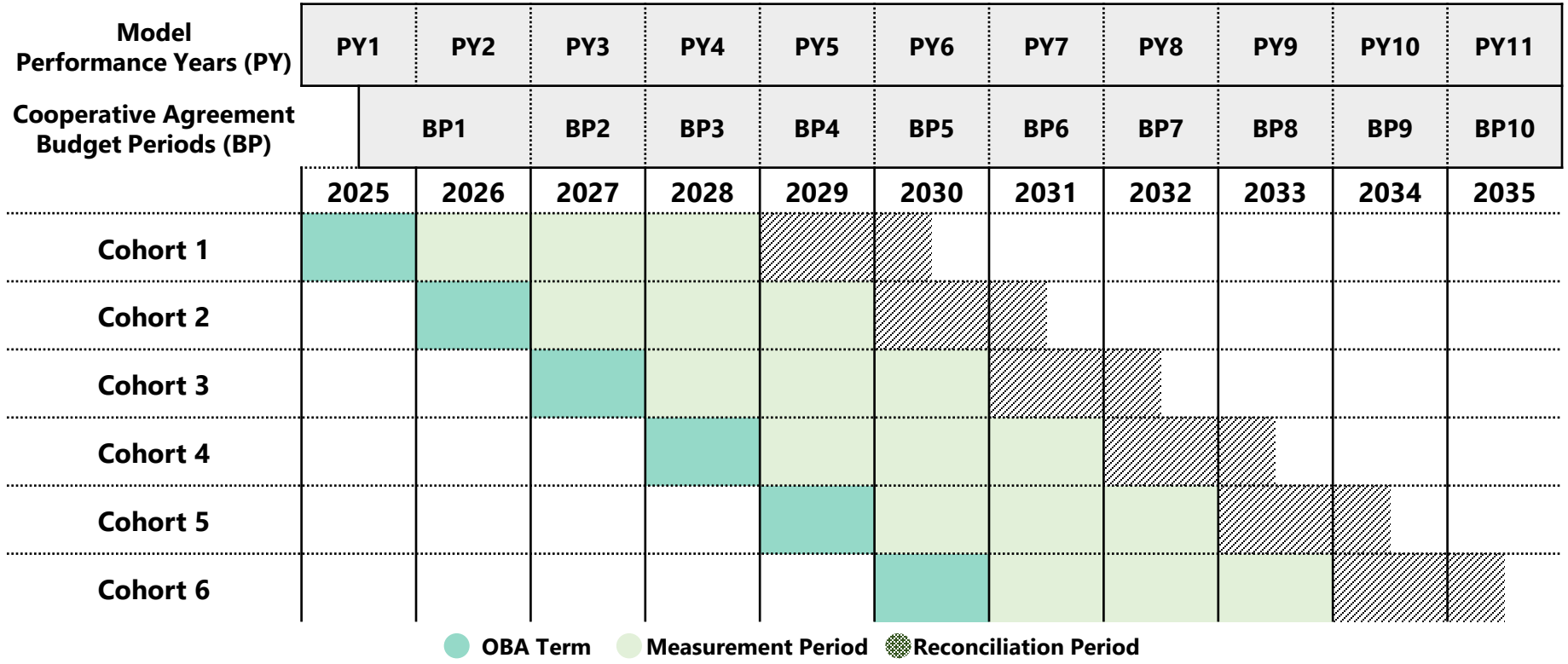
CMS anticipates awards of up to **$9.55 million for each state over the 10.5 years of the award**, pending federal availability of funds.

# Performance Period

There are two periods of performance to be aware of in this model.

| | | | |
|---|---|---|---|
| **Model Performance Period** | Anticipated January 1, 2025 - December 31, 2035 | **Cooperative Agreement Period of Performance** | Anticipated July 1, 2025 - December 31, 2035 |

## EXAMPLE PERFORMANCE PERIOD



# Example Maximum Funding Schedule

CMS may award up to $9.55M to each state. Below is an **example** of maximum funding amounts, based on an OBA Term of 6 years (2025-2030).

Budget Period (BP) 1 is 18 months. In 2025, only Implementation Funding is available. Milestone Funding is available in 2026 to states that begin model performance during 2025.

For the Budget Period following the end of the OBA Term, the allocable Implementation Funding is lower.

| | BP1 Jul 2025 – Dec 2026 | | BP2 2027 | BP3 2028 | BP4 2029 | BP5 2030 | BP6 2031 | BP7 2032 | BP8 2033 | BP9 2034 | BP10 2035 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Maximum Total** | **$2.1M** | | **$1.32M** | **$1.32M** | **$1.32M** | **$1.32M** | **$1.32M** | **$204K** | **$204K** | **$204K** | **$204K** |
| **Implementation Funding** | **$795K** | **$1.32M** | **$1.32M** | **$1.32M** | **$1.32M** | **$1.32M** | **$1.07M** | **$204K** | **$204K** | **$204K** | **$204K** |
| **Milestone Funding** | | **$125K** | **$250K** | **$250K** | **$250K** | **$250K** | **$250K** | | | | |

For subsequent Budget Periods during the OBA Term, both Implementation Funding and Milestone Funding are available.

For all subsequent Budget Periods through the end of the model, only Implementation Funding is available.

Award amounts may vary based on factors such as the applicant's total proposed budget, allowability and reasonableness of the costs proposed, and need as demonstrated in the state's application. All awards are subject to availability of funds. Annual budgets are subject to negotiation, and the maximum funding amounts listed in the graphic above are not guaranteed.

# Implementation Funding

Implementation Funding will support required and optional model activities that involve staff/contractor time and infrastructure costs.

**Applicants may request Implementation Funding for:**

**Required model activities**

Activities that are necessary to implement requirements of the model.

**Optional model activities**

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.

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.

# Implementation Funding for Required Model Activities

Applicants may request Implementation Funding for activities that are necessary to implement requirements of the model.

**Requirements for state participation are described in the State RFA. These include:**

Have or obtain the necessary authority to implement the model, including CMS approval of a SPA to enter into a Value Based Payment (VBP) State Rebate Agreement (SRA). (RFA Section 3.1.1)

Meet minimum data requirements and conduct data quality activities. (RFA Section 3.4.1)

Ensure that applicable Medicaid managed care plan policies align with model requirements. (RFA Section 3.1.6)

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. (RFA Section 3.3.2)

**Activities for which states can request Implementation Funding include:**

Developing new state statutory authorities or State Plan Amendments (SPAs)

Expanding staff capacity/personnel or contractor support to improve the quality, completeness, and timeliness of T-MSIS claims data submissions, or implement other aspects of the model

Establishing and maintaining agreements with managed care organizations and in-state/out-of-state gene therapy providers

# Implementation Funding for Optional Model Activities

Applicants may also request Implementation Funding for optional activities that would increase equitable access to SCD gene therapy and promote multi-disciplinary, comprehensive care for beneficiaries with SCD who are potential candidates for or recipients of gene therapy.

**Optional activities to promote equitable access to gene therapy or promote comprehensive care include:**

### Awareness, Education, and Access to Specialty Care

Improving access to hematologists specializing in SCD; raising awareness about gene therapy and the care journey; raising awareness about how to access non-emergency medical transportation (NEMT); providing access to dental care

### Behavioral Health Services

Providing access to mental health care (including by non-physicians), addiction treatment and pain management services; providing peer support

### Health-Related Social Needs (HRSNs)

Conducting HRSN screening and referral services; providing direct services to address HRSNs, such as housing, nutrition, and childcare necessary to ensure beneficiaries can receive the medical services subject to the model

### 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

**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
- ✓ Conducting direct information and outreach campaigns to beneficiaries and SCD providers
- ✓ Partnering with Community-Based Organizations (CBOs)

# Medicaid Optional Benefit for Sickle Cell Disease

States may choose to address access barriers through the Optional Benefit for Sickle Cell Disease.

Under the Medicaid optional SCD benefit, states may **add new services** (such as behavioral health services provided by psychologists and social workers) for individuals with SCD. Where applicable, services may be provided via telehealth.

States may also use this benefit to **increase the rates at which they pay for mandatory or already covered optional benefits**.

# Partnerships with Community-Based Organizations (CBOs)

States can use Implementation Funding to partner with CBOs with a focus on providing services to individuals with sickle cell disease (SCD).

**Implementation Funding can be used to pay CBOs for 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 to address health-related social needs (HRSNs)*

Providing community health worker/patient navigator and peer supports

*See the NOFO Section A6.8.1 for additional requirements applicable to the use of Implementation Funding to pay CBOs to provide housing and nutrition services and supports or childcare.

# Milestone Funding

Milestone Funding will support successful completion of research projects related to increasing equitable access to SCD gene therapy and promoting multi-disciplinary, comprehensive care for beneficiaries with SCD who are considering or receiving SCD gene therapy.

Projects must answer a research question about how and whether the state's Medicaid (and CHIP, if applicable) beneficiaries with SCD were able to equitably access SCD gene therapy and/or receive multi-disciplinary, comprehensive care related to SCD gene therapy.

Projects must be related to the patient care journey for SCD gene therapy.

***Projects may be designed to study:***

**The current state of patient care, barriers, and potential opportunities for improvement.**

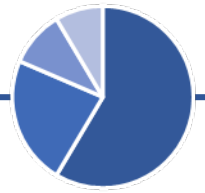
Example: A project designed to study challenges model beneficiaries experienced in accessing mental health services before and after gene therapy.

**The effect of a policy change or intervention.**

Example: a project designed to examine the effect of a state policy change on model beneficiaries' access to family planning services.

# Conducting Milestone Funding Research Projects

States can receive Milestone Funding by conducting research projects and reporting on their findings.



Projects must include primary data collection from model beneficiaries, caregivers, providers, and/or CBOs.

States can partner with organizations to conduct Milestone Funding research projects. Partner organizations may include CBOs, treatment centers qualified to administer gene therapy for SCD, or academic institutions.

To receive Milestone Funding for a project, the state must submit a report describing their study, research findings, and lessons learned. Recipients are encouraged to share their research findings publicly.

# Receipt of Milestone Funding

To receive Milestone Funding for a project, the state must submit a report describing their study, research findings, and lessons learned.

The state must submit a full performance report to CMS demonstrating completion of the project from the prior performance year.

If CMS approves the state's performance report and verifies that the state has successfully completed the project, Milestone Funding associated with the project will be unrestricted.

Recipients may use unrestricted Milestone Funding only for cost-based reimbursement of their completed projects.

**Milestone Funding is not guaranteed and will be restricted (unavailable for recipient use) unless the state demonstrates satisfactory completion of the project.**

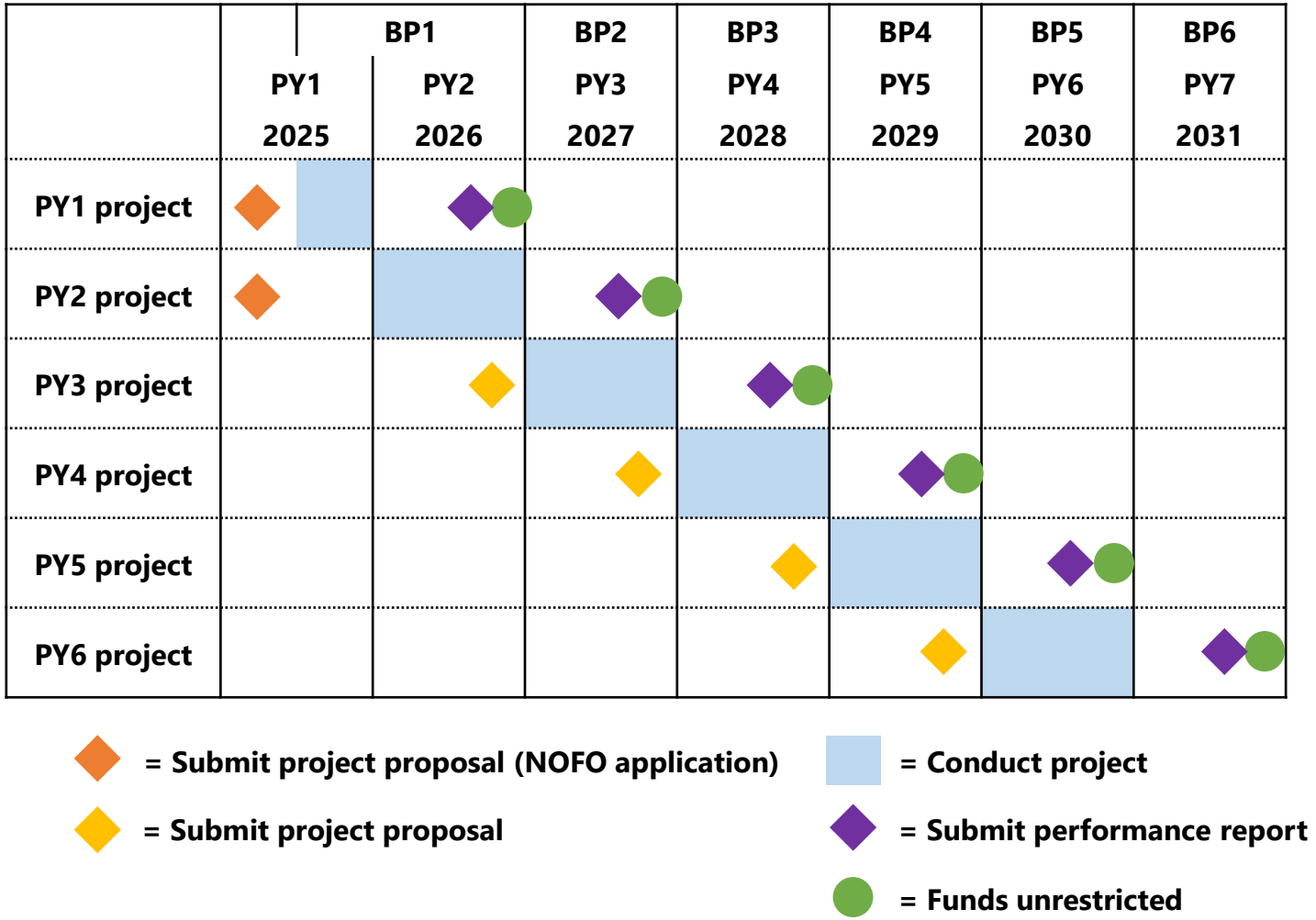
# Timing of Milestone Funding Projects

States may propose Milestone Funding projects to be conducted in any or all Budget Periods during the OBA Term.

Projects must be designed to be completed within a single PY.

Projects can build on a project conducted in a previous Budget Period.

In the Project Narrative, applicants must propose any Milestone Funding projects they plan to conduct during BP1.



# Reporting Requirements

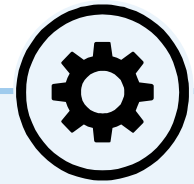
Recipients will be required to comply with federal reporting requirements and submit model-specific progress reports.

## Implementation Funding

For **required model activities,** states must comply with State RFA reporting requirements.

For **optional model activities,** states must propose reporting milestones and an implementation plan for CMS approval and must submit progress reports.

For **partnerships with CBOs,** states must also submit CBO performance reports and partnership lists.



## Milestone Funding

If a state seeks Milestone Funding for **performance on a project**, it must verify its progress through quarterly and annual reporting.

The state must submit a full performance report to CMS demonstrating completion of the project from the prior performance year.

Milestone Funding is not guaranteed and will be restricted (unavailable) unless CMS approves the state's performance report and verifies that the state has successfully completed the project.

# Application Submission Information

# Application Timeline

CMS strongly recommends that states do not wait until the application due date to begin the application submission process.

Applications for both the State RFA and NOFO must be submitted by **February 28, 2025, at 11:59 pm EST**.

- NOFO applications must be submitted to Grants.gov.
- State RFA applications must be submitted through a separate application portal (which will open in December 2024).

**June 2024**
State RFA released

**Aug 2024**
NOFO released

**Dec 2024**
Key Terms disclosed to states; states may begin applying

**Jan 1, 2025**
Model PY1 begins

**Feb 28, 2025**
Applications due for both State RFA and NOFO

**Jun 1, 2025**
State Agreements must be signed

**Jul 1, 2025**
Anticipated issuance of Notice of Award, BP1 begins

**Jan 1, 2026**
Model PY2 begins

Please visit Grants.gov to view the NOFO application materials and begin the registration process.

# Application Submission

CMS strongly recommends that states do not wait until the application due date to begin the application submission process.

## Application Submission Requirements

### Application Requirements

- Have a valid Employer Identification Number (EIN) / Taxpayer Identification Number (TIN)
- Have a Unique Entity Identifier (UEI).
- Register in the System for Award Management (SAM) database to be able to submit an application. This registration must be annually renewed.
- Have a Login.gov account.
- Register in Grants.gov.

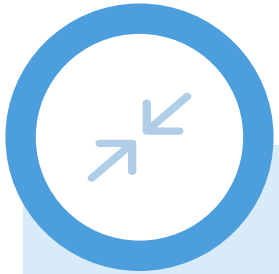
### Electronic Signature

The electronic signature of the individual who is logged in and submits the application to Grants.gov will automatically populate throughout the application. The electronic signature must match the AOR named on the SF-424.

The AOR must submit the application to Grants.gov. The AOR is the individual, named by the applicant/recipient organization, who is authorized to act for the applicant/recipient and to assume the obligations imposed by the federal laws, regulations, requirements, and conditions that apply to grant applications or awards.

# Application Criteria & Formatting

Please reference the NOFO sections highlighted below for application submission criteria and formatting requirements.



## Application Instructions

Applicants should review **Section D AND Appendix II** of the Notice of Funding Opportunity for instructions on how to submit a complete application. Please follow the application instructions.

## Formatting Requirements

Applicants must adhere to the formatting and content requirements included in **Section D2** (e.g., font size, formatting, page limitations, required forms and documents, etc.) to ensure that you have an eligible application.

## Application Criteria Review

Applicants should review **Section E1** for application review criteria. This section explains how applications will be assessed.

# NOFO Application Overview

Applicants should review Section D and Appendix II of the NOFO for instructions on how to submit a complete application. Applications are due no later than February 28, 2025, at 11:59 pm EST.

If an applicant does not submit all the required documents and does not address each of the topics discussed in Section D2 *Content and Form of Application Submission* (with cross reference to Section E1 *Criteria*) including the Project Narrative, the applicant **risks not being eligible for/awarded Cooperative Agreement funding**.

Applications are reviewed in accordance with the information outlined below.

## Application Requirements:

**Standard Forms**

**Cover Letter (optional)**

**Budget Narrative**

**Project Narrative**

*Including:*

- Model Implementation Plan
- Organizational capacity of applicant organization
- Existing collaborations with community-based organizations
- Participation of CHIP enrollees and applicable activities
- Optional Medicaid Benefits
- Milestone Funding Project Proposal(s)
- Medicaid (and CHIP) Authorities

# Application Forms (1/4)

All applications must include the following standard forms[1]:

| | |
|---|---|
| **Project Abstract Summary** | The abstract is used to provide a concise description of the proposed project including the purpose and outcomes, the total budget, and a description of how the funds will be used. |
| **SF-424: Official Application for Federal Assistance** | The SF-424 is used to apply for Federal grants. The Federal awarding agencies and Office of Management and Budget (OMB) use information reported on this form for general management of Federal assistance awards programs. The Authorized Organizational Representative (AOR) completes and electronically signs this form. |
| **SF-424A: Budget Information Non-Construction** | The SF-424A is used to budget and request grant funds for non-construction programs. The Federal awarding agencies and OMB use information reported on this form for general management of Federal assistance awards programs. |

[1]Refer to the CGT Access Model NOFO for the most up-to-date information on eligibility, application submission, and application scoring details.

# Application Forms (2/4)

All applications must include the following standard forms[1]:

| | |
|---|---|
| **SF-LLL: Disclosure of Lobbying Activities** | All applicants must submit this SF-LLL form. If your entity does not engage in lobbying, please insert "Non-Applicable" on the form and include the required AOR name, contact information, and signature. |
| **Project Site Location Form(s)** | All applicants must submit this Project Site Location form. |

[1]Refer to the CGT Access Model NOFO for the most up-to-date information on eligibility, application submission, and application scoring details.

# Application Forms (3/4)

All applications must have the following additional forms[1]:

| | |
|---|---|
| **Project Narrative** | The applicant provides a Project Narrative that articulates in detail the proposed goals, measurable objectives, and milestones in accordance with the instructions and content requirements provided in Section D2.4, consistent with the criteria described in Section A6.8 *Cooperative Agreement Funding Structure*. Maximum 80 pages. |
| **Budget Narrative** | Applicants supplement Form SF-424A with a Budget Narrative that 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 include a clear description of the proposed set of services covered with award funds for each activity/cost. Maximum 10 pages. |

[1]Refer to the CGT Access Model NOFO for the most up-to-date information on eligibility, application submission, and application scoring details.

# Application Forms (4/4)

All applications must have the following additional forms[1]:

| | |
|---|---|
| **Program Duplication Assessment** | The applicant will describe a plan to avoid program duplication[2] by filling out a required questionnaire related to other programs funded by Medicaid, Medicare, Title V block grant funds, the local health department, or another innovation model that will provide a service directly to an attributed beneficiary (e.g., under current Medicaid benefits). Maximum 5 pages. |
| **Business Assessment of Applicant Organization** | As required by 45 CFR §75.205 for Cooperative Agreements, 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. Maximum 12 pages. |

[1]Refer to the CGT Access Model NOFO for the most up-to-date information on eligibility, application submission, and application scoring details.
[2]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).

# Federal Award Administration

# Federal Award Administration Information

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.**

## NoA Administration

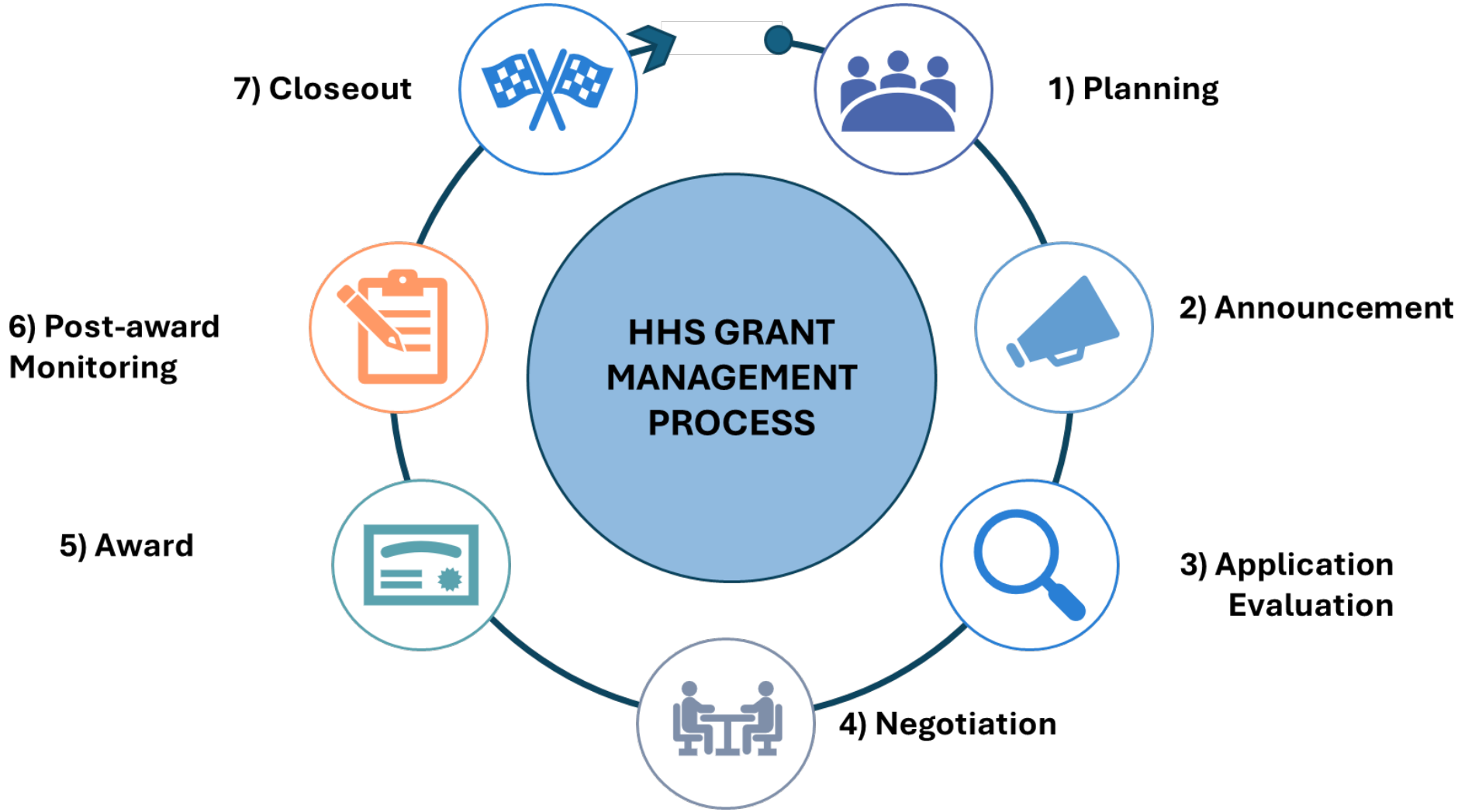
The NoA is available to the applicant organization through the online grants management system used by CMS and Recipient Organizations, GrantSolutions.

Any communication between CMS and the applicant prior to issuance of the NoA is not an authorization to begin performance of a project.

If the application is unsuccessful, CMS will notify the applicant electronically via the email address listed on its SF-424, within 30 days of the award date of the program.

# HHS Grant Management Process

The Grant Management Process describes the steps related to the management of competitive grant awards.



# Grant Regulation and Policy

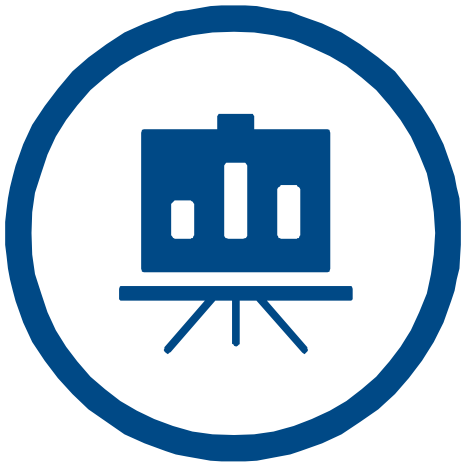
The sources cited below address regulatory and policy requirements which apply to federal grant and cooperative agreement awards.

## Grant Policy

- **Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards**
  - 45 CFR Part 75 which implements 2 CFR Part 200, Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (“Uniform Guidance”) effective December 26, 2014.
- **HHS Grants Policy Statement**
- **SAM.gov**
  - Exclusions
  - Central Contractor Registration (CCR)
  - Responsibility/Qualification (R/Q)

# Question & Answer Session

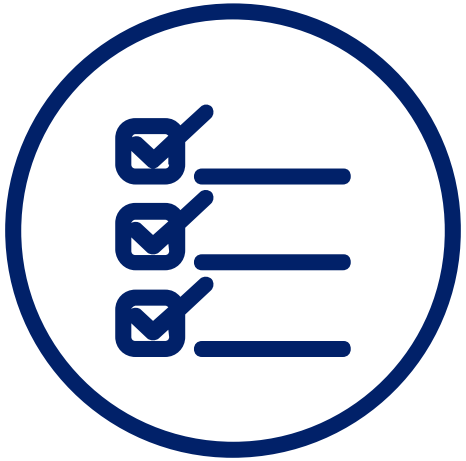
# Audience Poll



For those joining us today who represent a state Medicaid agency, **does your state intend to apply to the CGT Access Model and seek Cooperative Agreement funding?**

a) Intend to apply to the model **without** funding
b) Intend to apply to the model **and** apply for funding
c) Do not intend to apply to the model
d) Unsure - Please share more about your answer in the chat
e) Not applicable – We are not a state Medicaid agency

# Please Complete Our Survey



**We appreciate your input!**

Please click the link posted in the chat to take our survey.

We would love to learn how to make our events better.

# Question & Answer

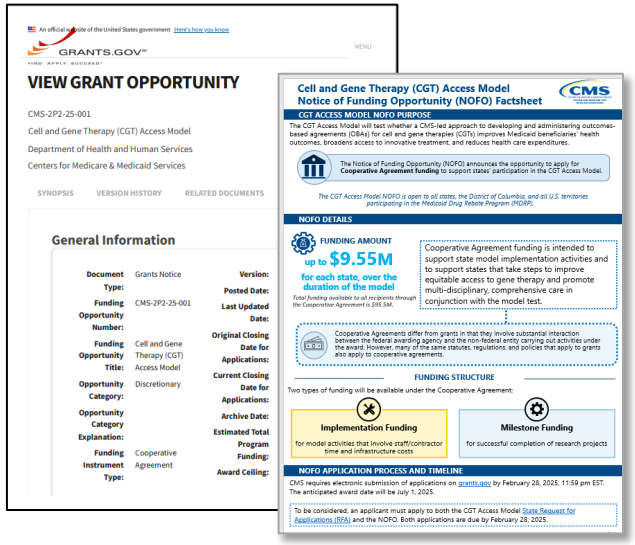
## Open Q&A

Please **submit questions via the Q&A pod** to the right of your screen.
Specific questions about your organization can be submitted to CGTModel@cms.hhs.gov.

# Closing and Resources

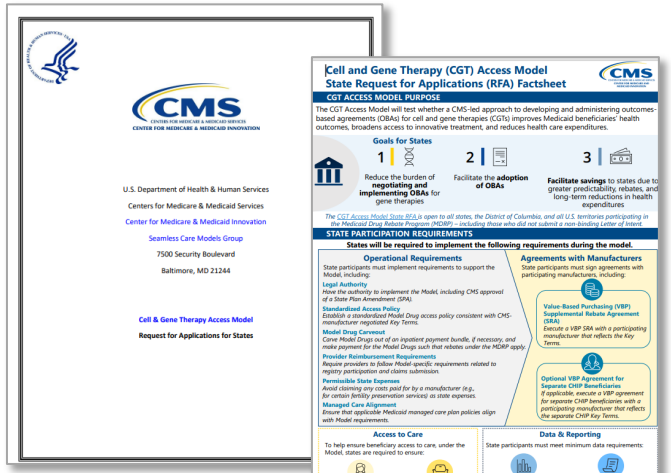
# Model Resources

The CGT Access Model team has a host of resources to support interested states. To see the latest resources, visit the model's website at https://www.cms.gov/priorities/innovation/innovation-models/cgt.



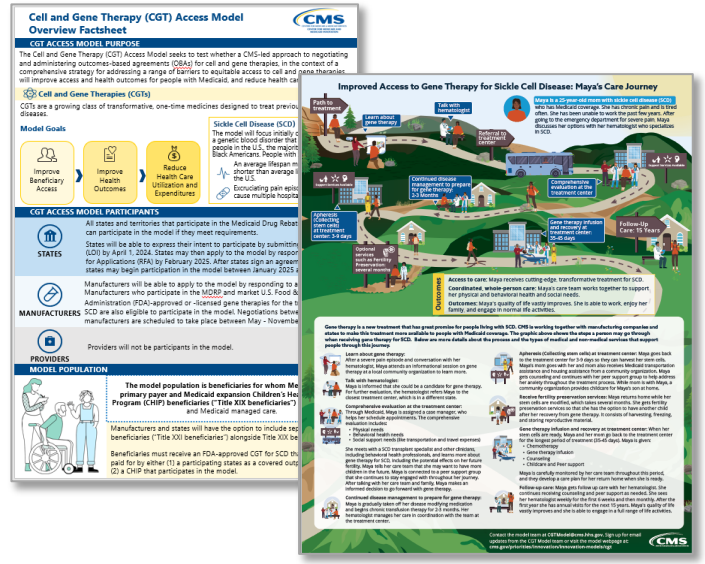

## NOFO Resources

The NOFO is on Grants.gov. Read through the CGT NOFO Factsheet and the CGT NOFO Frequently Asked Questions on the model website to learn more about applying for model funding.




## State RFA Resources

The State RFA is on the model webpage. Read through the CGT State RFA Factsheet and the CGT State RFA Frequently Asked Questions to learn more about applying to participate in the model.




## Other Model Resources

Read through the CGT Model Overview Factsheet, the CGT Model Infographic, and the Patient Care Journey Visual to learn more about the CGT Access Model and the patient care journey for SCD gene therapy.

*If you have questions or would like to meet with the model team, please reach out to us via email at CGTModel@cms.hhs.gov.*

# Thank You for Attending this Webinar

**We appreciate your time and interest!**

Please take the survey following this webinar so we can learn how to make our events better.

Do you have questions? Email your comments and feedback to CGTModel@cms.hhs.gov with subject line ***CGT Access Model NOFO Webinar***

# THANK YOU!