

October 2024

CMS releases Notice of Funding Opportunity for Gene Therapy Access Model

Overview

On August 15, 2024, Centers for Medicare & Medicaid Services (CMS) released a Notice of Funding Opportunity (NOFO) related to the [Cell and Gene Therapy \(CGT\) Access Model](#) (“the Model”) for Sickle Cell Disease (SCD) gene therapies that was previously announced in January. Cooperative Agreement funding is intended to support state model implementation activities as well as to support states that take steps to improve equitable access to gene therapy and promote comprehensive, multi-disciplinary SCD care. A total of \$95.5 million over a 10.5-year period ending December 31, 2035, will be available across all 50 U.S. states, the District of Columbia, and Puerto Rico. States may request up to \$9.55 million total for Implementation Funding and/or Milestone funding. Awarded amounts will vary based on factors such as need, availability of funding, as well as the allowability and reasonableness of the costs proposed. States must complete and submit both the State Request for Applications (RFA) and NOFO by February 28, 2025 to be considered for the Cooperative Agreement funds. The NOFO submission is not required to participate in the Model.

One use of Implementation Funding is to support activities necessary to fulfill the requirements of participating in the Model, including expanding staff/capacity or contractor support to implement new or expanded capabilities. Examples of State participation requirements include data and reporting standards/documentation, having a CMS-approved State Plan Amendment (SPA) permitting the State to enter into a Value-Based Purchasing (VBP) Supplemental Rebate Agreement (SRA), and having standardized access policies for the Model drugs. There are no additional reporting requirements outside of those listed in the State RFA when funds are used in this way.

Implementation Funding can also be used for optional activities to enhance access to gene therapy or promote comprehensive care. These activities may include awareness and education outreach, addressing health-related social needs, and supporting care coordination. Implementation funding can be used for engagement/partnership with gene therapy providers, community-based organizations (CBOs), and other stakeholders. For optional activities, states must propose reporting milestones and implementation plans as well as submit regular progress reports.

States may also request Milestone Funding to support research projects focused on the patient care journey for SCD gene therapy. The research plan must include primary data collection from beneficiaries, caregivers, providers and/or CBOs. Allowable study topics include examining the effect of a policy change or intervention and a review of current patient care practices, barriers, and opportunities for improvement. States can partner with CBOs, SCD gene therapy treatment centers, and/or academic institutions. Milestone funding is not guaranteed and is unavailable until CMS approves the required (quarterly and annual) performance reports and verifies successful project completion.

Next Steps for State Medicaid Programs

State Medicaid programs that are considering participating in the Model and requesting Cooperative Agreement funds should evaluate whether to pursue the additional funding and how to use it as soon as possible. In particular, states should consider:

- Review [Model RFA](#), [fact sheet](#), and [webinar content](#) to understand the Model requirements.
- Evaluate Key Terms of the VBP SRA, which will be released in December, and decide on participation in the Model.
- Assess operational readiness as defined in the RFA and identify and address gaps.
- Determine proposed Model Project Performance Period Start Date(s) (between January 1, 2025, and January 1, 2026) for the FFS, managed care, and CHIP programs.
- Create plans to achieve all operational requirements by the projected start date(s).
- Complete and submit the RFA prior to **February 28, 2025**.
- Review the [NOFO](#), [fact sheet](#), and [webinar content](#) to understand how funding may be used and the associated requirements.
- Identify activities that would benefit from Cooperative Agreement Funding.
- Coordinate State resources and staff to develop project plans, including Cooperative Agreement Project Performance Period(s) and cost estimates.
- Engage with potential partners.
- Complete and submit the NOFO prior to **February 28, 2025**.
- Sign State Agreement by June 1, 2025.

Caveats and limitations

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Questions for your specific state?

Please contact [Noah Greenberg, PharmD, CSP](#), [Zach Larsen](#), [Bethany Holderread, PharmD](#), or your Mercer pharmacy consultant to discuss the impact for your specific state programs.

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