Cell & Gene Therapy (CGT) Access Model
Notice of Funding Opportunity (NOFO)
September 24, 2024

>>Arbre'ya Lewis, SEA: Good afternoon everyone, and thank you for joining today's CGT Access Model Notice of Funding Opportunity Webinar.

There are a few housekeeping items to discuss before we get started. Today's presentation is being recorded and streamed live. If you have any objections, please hang up at this time. All participants will be in listen-only mode. Please feel free to submit any questions you have throughout today's presentation in the Q&A pod displayed on the bottom of the meeting room window. Given time constraints, we may not get to every question, but we will collect questions for future events and FAQs on the CGT Access Model website. You can also reach out to the CGT Access Model team at CGTModel@cms.hhs.gov.

There will also be a short survey available at the end of the event. We'd greatly appreciate if you could spend one or two minutes filling it out so we can improve the quality of future events. This slide deck, and a recording of today's presentation, and transcript, will be made available on the CGT Access Model website in the coming days. If you would like to be added to the model listserv, please visit the model website and follow the link that is being pasted in the chat. Next slide, please.

Before we dive into the content, I will give a brief overview of the agenda for today's event. We will begin with a welcome from Laurie McWright, the Deputy Director of the Seamless Care Models Group, and an introduction of today's speakers. Then, staff from the Office of Acquisition - the model team will provide a brief overview of the CGT Access Model. After that, we will talk more about the Cooperative Agreement funding for the CGT Access Model. Then, staff from the Office of Acquisition and Grants Management will describe the application submission process. Following that, they will talk more about the Federal Award Administration. Finally, we will have about 15 minutes for a Q&A session, where CMS will answer questions submitted by audience members. As a reminder, you can submit questions using the Q&A function at the bottom right-hand corner of your screen.

Again, thank you for joining us today. We've got a great presentation planned for you. Now I'm going to pass the mic to Laurie McWright to formally welcome you to today's event, and to introduce you to today's speakers. Next slide, please.

>>Laurie McWright, CMS: Thank you so much. Good afternoon, everyone. I'm Laurie McWright, and I'm the Deputy Director of the Seamless Care Models Group at the CMS Innovation Center, and I'm so excited to welcome all of you to this webinar.

First, I want to mention, that this Notice of Funding Opportunity is an optional, but very important component of the Cell and Gene Therapy Access Model, because it provides financial support to states not just to implement the required components of the model, but to go beyond that and address gene therapy equity and access issues. Now as many of you know, this model initially focuses on gene therapy for sickle cell disease, or SCD. And I would certainly be remiss today, if I didn't thank all those with whom we've spoken over, I'd say, the last year and a half, close to two years, including the patient advocacy groups, the SCD experts, the providers, states, manufacturers of the cell and gene therapies

for sickle cell disease, to better understand the SCD gene therapy patient care journey, and the potential care delivery gaps patients may face along the way. That has certainly informed, all the information that we've gathered, has informed the content of this NOFO.

And we have learned so much from so many of you. One thing in particular, I want to mention, is that we've learned the importance of multi-disciplinary and comprehensive care for this particular patient population. And it has made us think about how this model could help states address these important issues for their state's Medicaid population.

So, I want to go ahead and introduce our speakers for today. I want to start out with Melissa Majerol, who is one of the Cell and Gene Therapy Access Model Co-Leads. Caroline Horrow, who is one of the model team members. And two of our colleagues from the Office of Acquisition and Grants Management: Gabe Nah, who is a Grants Management Officer, and Makaria Martin, who is a Grants Management Specialist. And finally, Jason Petroski, Director of the Division of Drug Innovation in the Seamless Care Models Group within the Innovation Center, will run the Q&A portion of the webinar. During this Q&A, you may also hear from other members of the model team, as well as colleagues, as well as some of our colleagues from the Center for Medicaid and CHIP Services including Cathy Traugott, Senior Policy Advisor in the Division of Pharmacy, and Kenya Cantwell, who is the Technical Director in the Division of Benefits and Coverage.

Together, we hope to help you understand more about this Notice of Funding Opportunity for the Cell and Gene Therapy Access Model, and whether it's right for your state. The team has worked hard, in partnership with our Office of Acquisition and Grants Management colleagues, to assemble a presentation that enables you to understand a variety of important items, including the goals for this NOFO funding, as well as requirements, in particular, to receive this funding. So, without further ado, I'd like to pass the mic to Melissa Majerol.

>> Melissa Majerol, CMS: Thanks so much Laurie. Hi everyone, I am Melissa Majerol, a CGT Access Model Co-Lead, and I'm really excited that you've decided to join us for today's event. During this section of the webinar, I will walk us through a bit of background information related to the CGT Access Model. Next slide.

So, the aim of this model is to increase access to innovative cell and gene therapies for people with Medicaid by making it easier for states to pay for these therapies. And through that improved access, lower the long-term health care expenditure trajectory of these patients and improve their health outcomes. Under this model, CMS negotiates with manufacturers of cell and gene therapies on behalf of state Medicaid agencies to develop the Key Terms of what we call an outcomes-based agreement, or OBA. These are agreements that, among other things, tie payment to the actual clinical outcomes experienced by Medicaid beneficiaries. These Key Terms would include the pricing structure, reflecting both outcomes-based components and other types of discounts, and coverage criteria for the product. States would then decide whether or not they want to sign-on to a deal with those Key Terms.

This model is voluntary for both manufacturers and states. So, all U.S. states, the District of Columbia, and territories that participate in the Medicaid Drug Rebate Program are eligible to apply. In June, we released a Request for Applications for States, describing the requirements for state participation. Manufacturers could apply if they participate in the MDRP and market FDA-approved or -licensed gene therapies for the treatment of sickle cell disease. In March, we released a Request for Applications for

Manufacturers, through which eligible manufacturers could submit an application and then begin negotiations with CMS. So right now, we are in that negotiation phase of the model.

CMS is going to play a few key roles throughout this process, including on the front-end, by negotiating the overall set of Key Terms that reflect a pricing structure that includes discounted pricing and outcomes-based payments. CMS will also offer states optional funding through the Notice of Funding Opportunity, which of course is the subject of today's webinar, to support activities that promote equitable access to care. And finally, CMS will support states to operationalize the model, both through technical assistance and by collecting, analyzing, and reconciling data required to adjudicate the amounts owed under these outcomes-based agreements. Next slide, please.

So, as Laurie mentioned, the initial focus for the CGT Model is on gene therapies for sickle cell disease, or SCD. SCD is a condition that affects over 100,000 Americans. The majority of people affected by this condition are Black Americans, and they are heavily concentrated in certain states, as you can see from this map, mostly in the southern and eastern regions of the U.S. SCD can be a profoundly challenging condition, associated with acute pain episodes, or what are called vaso-occlusive crises, that may lead to frequent hospitalizations. The disease is also associated with other complications, such as stroke or kidney disease. All of this together costs the U.S. health care system a staggering nearly three billion dollars annually, with roughly 60% of SCD patients enrolled in Medicaid.

Individuals with SCD have a life expectancy, on average, that is 20 years shorter than the general population. And the impacts of the disease can create substantial challenges in the lives of patients, especially those with severe SCD, affecting educational attainment, employment, and the ability to participate in their communities. Patients with SCD may also experience mental health challenges related to their disease.

As many of you are aware, last December, the FDA approved two gene therapies for sickle cell disease, Casgevy, by Vertex and Lyfgenia, by bluebird bio. These therapies hold the promise of substantially reducing or even eliminating a patient's experience of vaso-occlusive crises, and thereby dramatically improving the lives of patients with SCD. Next slide, please.

So, this slide shows the patient care journey for these two gene therapies. And what you can see is that it is a very long and complex process, similar to a bone marrow transplant. And at each step of this care journey, patients may encounter barriers and gaps. This care journey requires months of evaluation and preparation before patients can have their cells collected. Then, patients may have to wait several months while their cells are modified by the manufacturer. And then when they ultimately receive the gene therapy infusion, they have an inpatient stay that lasts upwards of 35 days.

Another important thing to know is that the intense chemotherapy patients must receive in preparation for the gene therapy infusion typically results in infertility. And so, through our model, participating manufacturers will be required to pay for a defined scope of fertility preservation services for all model beneficiaries. As a resource, we have developed an illustrative care journey of a fictional patient, Maya, who receives care as a beneficiary living in a state that is participating in this model. You can find that patient journey visual on our website, and we'll share it in the chat here as well. Next slide, please.

So, with such a long and complex care journey, you can imagine how many patients may experience challenges and access barriers along the way, at each step. For example, certain steps in the care journey are only available at a select number of treatment centers across the country, so patients may

be required to travel far from home, or even out-of-state. This means that patients may need to think about transportation, lodging, meals, and in some cases, even childcare.

Through conversations with stakeholders, we have learned that many individuals with sickle cell disease have behavioral health issues, including depression, complex pain, and opioid dependence due to years of dealing with sickle cell-related pain, and that it is absolutely critical to help patients with these behavioral health issues before, during, and after gene therapy. One of the goals of this model is to improve equitable access to cell and gene therapies for all eligible Medicaid beneficiaries, and that means going beyond the simple provision of medical care to also provide supports and services that are critical to equitable access and successful outcomes. And the Cooperative Agreement funding we're discussing today, is designed to do just that. Next slide, please.

So, two types of funding will be available to model participants, to states applying for funding. First, Implementation Funding will support required and also optional model activities that involve staff or contractor time, as well as infrastructure costs. Milestone Funding, on the other hand, will support the successful completion of research projects related to increasing equitable access to SCD gene therapy and promoting multi-disciplinary, comprehensive care. We will share more details about each of these types of funding a little bit later in this presentation. Next slide, please.

But first, I wanted to clarify how the Notice of Funding Opportunity fits into the model as a whole, and in particular, how it differs from the State Request for Applications. So, the State RFA describes the requirements for state participation in the model, and states are required to respond to the State RFA in order to participate in the model. Participating states will then sign a State Agreement with CMS that will govern each state's participation in the model. And for more information about the model participation requirements, we highly encourage you to read the State RFA and review slides from the State RFA Webinar, which was held just this past July, and both of these items are posted to the model website.

The NOFO, on the other hand, announces optional funding to support states' participation in the CGT Access Model. States that are awarded funding under the NOFO will receive a Cooperative Agreement award from CMS. And, to be considered for Cooperative Agreement funding, a state must apply to both the State RFA and the NOFO. But states that want to participate in the model without funding only need to apply to the State RFA. States will have the opportunity to apply to the State RFA and NOFO from December 2024 to February 2025. Next slide, please.

Okay, so now I will pass it over to Caroline Horrow to walk us through the details of the Cooperative Agreement funding. Next slide please.

>> Caroline Horrow, CMS: Thank you, Melissa. It's really great to see everyone here today. And so, I'll start with one of the big questions that may be on your mind: Who can receive Cooperative Agreement funding?

So eligible applicants are states, the District of Columbia, and any U.S. territory participating in the Medicaid Drug Rebate Program, which at this time, only includes Puerto Rico. As Melissa mentioned, to be considered eligible for Cooperative Agreement funding, the eligible applicants must apply to both the State RFA and the NOFO by no later than February 28th, 2025. They must also sign a State Agreement with CMS, to become a model participant, by no later than June 1st, 2025. Each state may submit only one application.

States can choose to use Cooperative Agreement funding to partner with other organizations, which may be considered sub-recipients or contractors. Those partner organizations could include community-based organizations, treatment centers, and academic institutions. So, I'm really excited to see many of you in the audience today from potential partner organizations. Next slide, please.

So, as we've mentioned, the awards issued under this NOFO will be Cooperative Agreement awards. The main difference between a Cooperative Agreement and a grant is the higher degree of federal programmatic involvement. However, many of the same statutes, regulations, and policies that apply to grants also apply to Cooperative Agreements.

CMS anticipates awarding up to 9.55 million dollars to each state recipient, pending federal availability of funds, and depending on the number of states that apply for funding. The total funding available to all recipients is 95.5 million dollars, and that funding would be spread over ten and a half years. Early years of the model will have more funding. Funding in each Budget Period will depend, in part, on certain Key Terms negotiated between CMS and manufacturers, which I'll explain more on the next couple slides. The Key Terms will be disclosed to states in December 2024, so states will have the opportunity to see them before applying.

Recipients can choose to allocate funding to either of the two types of funding, Implementation, or Milestone Funding, or to both. And for each year after the first Budget Period, funding will be issued through non-competing continuation awards, and will be contingent on the state's progress in meeting project goals, timely submission of required data and reports, and compliance with the Terms and Conditions. States must request funds for the next Budget Period by submitting a non-competing continuation application. Next slide, please.

Now, let's talk more about the Performance Period for this award. There are actually two periods of performance to be aware of: the Model Performance Period and Cooperative Agreement Period of Performance. The Model Performance Period will start as early as January 1st, 2025 and is anticipated to last until the end of 2035. As many of you may be aware, the model's rolling start allows states the option to begin their performance in the model anytime from January 1st, 2025, to January 1st, 2026. States will choose their Model Performance Period Start Date when applying to join the model. This allows for adequate preparation and alignment with state-specific needs and capacities. So, for example, states may decide to choose a start date that aligns with existing rebate cycles or budget calendars. The Model Performance Period will be divided into 11 Performance Years, as shown by the "PYs" on this slide.

The Cooperative Agreement Period of Performance is anticipated to start several months after the Model Performance Period, on July 1st, 2025 and last until the end of 2035. That period of time is divided into 10 Budget Periods, shown here as "BPs." The first Budget Period, as you can see here, is 18 months. It includes July through December of 2025, plus all of 2026. The remaining Budget Periods are each 12 months and align with Model Performance Years. The graphic on this slide illustrates how the entire performance period might work, depending on the Key Terms that CMS negotiates with manufacturers.

The OBA Term is one of those Key Terms. The OBA Term is the period of time during which beneficiaries in model-participating states receive gene therapy for sickle cell disease. And in this example, the OBA Term is six years and is shaded with a turquoise color. So, in other words, the Key Terms that CMS negotiates would apply for beneficiaries who receive the model gene therapy, in this example, from

2025 to 2030. As I will describe on the next slide, more funding is available to states during the OBA Term than in later years of the model.

So, after beneficiaries receive the gene therapy, outcomes would be monitored over the duration of the Measurement Period. In this example, the Measurement Period is three years, which you can see throughout this chart in light green. Following the Measurement Period, financial settlement and payment of rebates will occur during the Reconciliation Period. In this example, the Reconciliation Period is one and a half years and is denoted by the black and white diagonal lines. So, you can see from this chart, how these different periods for gene therapy administration, measurement, and reconciliation may overlap for different annual cohorts throughout the Performance Period. Next slide, please.

Now, based on that example we just went through, let's walk through the approximate maximum amounts of funding that would be available to states in each Budget Period. Like in the previous slide, we're using an example OBA Term of six years. You can think of this in terms of four stages.

The first is Budget Period 1, which as a reminder, is 18 months long. In total, a little over 2.1 million dollars is available in Budget Period 1. For the six months in 2025, approximately 795,000 dollars is available, and it can only be allocated to Implementation Funding. The remaining funding of 1.32 million dollars is restricted until the start of 2026. Up to 125,000 dollars in Milestone Funding is available for states that begin model performance during 2025. And this is because, as I'll explain in more detail later, Milestone Funding is awarded for the completion of research projects in the previous Performance Year. So, the Milestone Funding in 2026 is only available to states that completed projects as part of their model performance in 2025.

The second main stage, is the subsequent Budget Periods during the OBA Term. In this example, that would be Budget Periods 2 through 5, shown in gray. Both Implementation and Milestone Funding are available during each of these Budget Periods, and states can choose to allocate up to 1.32 million dollars to Implementation Funding, or up to 250,000 dollars to Milestone Funding, or a combination of both. The total amount of funding a state can be awarded, no matter how it is split between Implementation Funding and Milestone Funding, is a maximum of approximately 1.32 million dollars.

The third stage, is the Budget Period following the end of the OBA Term. In this example, that is Budget Period 6, in the darker blue. In this Budget Period, the maximum allocation to Implementation Funding is slightly lower than before, at 1.07 million dollars. That's because Implementation Funding is largely used to support equitable access to gene therapy under the model, and all the model beneficiaries would have already received the gene therapy during the OBA Term, that's Budget Periods 1 through 5 in this example. The rest of the model is now about their follow-up care, outcomes measurement, and reconciling rebates. This is also the last Budget Period that Milestone Funding is available, and again it would be available to states that conducted research projects in the previous year when model beneficiaries were receiving the gene therapy.

Finally, in each of the subsequent Budget Periods through the end of the model, shown in the lighter blue here, only a maximum of 204,000 dollars is available, which states can allocate for ongoing model implementation activities. I do want to emphasize that this slide only shows maximum approximate funding amounts, and that the actual award a state receives will depend on its proposed budget, allowability and reasonableness of the costs proposed, and need for the funding. All awards are subject to the availability of funds. For more details, please refer to Section B4 of the NOFO.

So now that we've discussed when and how much Implementation and Milestone Funding is available throughout the model, let's turn to how each of those types of funding can be used. Next slide, please.

First, we'll start with Implementation Funding. States can request Implementation Funding to support required and optional model activities that involve staff or contractor time and infrastructure costs. So, what's the difference between a required and an optional activity? Required activities are things that states will need to do to meet model requirements – specifically, the model requirements that are set out in the State RFA. Optional activities are not required under the model, but they are things states can choose to do to increase access to sickle cell gene therapy and promote multi-disciplinary, comprehensive care. These are steps states can take to address those potential gaps in the patient care journey that Melissa shared earlier.

Before we share some examples of Implementation Funding activities, I do want to note that funding cannot be used to pay for the state share of any benefits or services themselves. But, it can be used for staff and contractor time and infrastructure costs that relate to implementing benefit expansions and services. Next slide, please.

Let's go through some examples of how states could use Implementation Funding for required model activities, activities many states will need to do to meet the requirements for model participation. As we've discussed, the model participation requirements are outlined in the State RFA. That document will be linked in the chat for your reference.

So, for example, one of the participation requirements in the State RFA is having or obtaining the necessary authority to implement the model, including a CMS-approved State Plan Amendment, or SPA, for value-based purchasing arrangements. So, a state could request implementation funding to develop new statutory authorities and SPAs that it needs to fulfill that participation requirement. Another requirement of the model is that participating states must meet minimum data requirements, including standards for the quality of T-MSIS data. So, a state could request implementation funding to expand staff capacity or hire contractors in order to improve the quality of their T-MSIS data to meet the standards required by the model.

Finally, other requirements in the State RFA include ensuring that managed care plan policies are aligned with model requirements and that model beneficiaries will have access to care from in-state or out-of-state gene therapy providers. So, to meet those requirements, states could request Implementation Funding to establish and maintain agreements with managed care entities and gene therapy providers. Next slide, please.

And now, let's talk about how states could use Implementation Funding for optional activities. These are activities that would increase equitable access to sickle cell gene therapy or promote multi-disciplinary, comprehensive care for beneficiaries who are potential candidates for or recipients of sickle cell gene therapy. The optional activities fall into five domains.

The first is Awareness, Education, and Access to Specialty Care. So this would include activities such as implementing policy changes that improve or expand Medicaid beneficiary access to hematologists and other physicians that specialize in sickle cell disease, raising awareness and improving education about gene therapy, raising awareness about how to access non-emergency medical transportation, and providing access to dental care.

The second domain is Behavioral Health Services, and it includes activities such as providing access to mental health care, addiction treatment, pain management services, and peer support. The third domain is Health-Related Social Needs, or HRSNs. Activities in this domain include conducting HRSN screening and referral services, as well as providing direct services to address HRSNs. This includes some direct services that are not allowable as a Medicaid benefit, such as childcare. For those services, states can use Cooperative Agreement funding to partner with community-based organizations to provide the services.

The fourth domain is Care Coordination, which includes providing case management, care coordination, patient navigation, or community health worker support. And the fifth domain is Family Planning, which includes providing access to fertility preservation services that are not covered by participating manufacturers. As a reminder, manufacturers participating in the CGT Access Model are required to pay for a defined scope of fertility preservation services that includes collection, cryopreservation, and storage of reproductive material, that is eggs, sperm, ovarian or testicular tissue, for at least five years and up to fifteen years. States can cover additional services including creation, cryopreservation, and storage of embryos, as well as in-vitro fertilization.

Now states can go about these activities in several ways. They could expand or increase services and reimbursement rates for Medicaid benefits and services, including under the Optional Benefit for Sickle Cell Disease. Keeping in mind that Cooperative Agreement funding cannot be used to pay for the state share of any expanded Medicaid benefits or increased reimbursement rates, but it can be used to pay for staff or contractor time and infrastructure costs related to implementing these benefits and services. States can also conduct direct information and outreach campaigns to beneficiaries and SCD providers, and can partner with community-based organizations to go about these activities. Next slide, please.

So we want to spend a moment on Medicaid's Optional Benefit for Sickle Cell Disease, which states can use for a variety of benefits and activities targeted at Medicaid beneficiaries with sickle cell disease. The optional benefit allows states to add new services specifically for beneficiaries with sickle cell disease that are not otherwise covered in the state plan. So, a state could, for example, cover services like optional adult dental benefits or behavioral health services provided by non-physicians, just for beneficiaries with sickle cell disease.

The optional benefit also allows states to reimburse for sickle cell disease-related services at a different rate than the state pays for similar services provided to Medicaid beneficiaries who do not have sickle cell disease. So, states could use this benefit to increase reimbursement rates for existing benefits for individuals with sickle cell disease. We encourage states to look into this optional Medicaid benefit as a way to accomplish some of the optional activities described in the NOFO. Next slide, please.

So, another strategy states can take is to partner with community-based organizations, or CBOs. CBOs would either be contractors or sub-recipients of the Cooperative Agreement. States can request Implementation Funding to pay CBOs for several purposes, which include gene therapy awareness and education, awareness and access to ancillary services, direct services to address HRSNs, and community health worker and peer supports. States should note that they can pay CBOs to provide housing and nutrition supports and childcare services that are necessary for beneficiaries to initiate and complete the sickle cell gene therapy care process. There are several additional requirements in the NOFO related to the use of funding for housing, nutrition, and childcare, and we recommend that you look into those further, if you are interested. Next slide, please.

Now, let's turn to the other type of funding under the Cooperative Agreement, Milestone Funding. Milestone Funding is linked to states' achievement of performance milestones, and in this case, the milestones are the successful completion of research projects.

These research projects must be designed to study how and whether beneficiaries were able to equitably access sickle cell gene therapy and/or receive multi-disciplinary, comprehensive care related to sickle cell gene therapy. Projects should focus on beneficiaries in the model. As a reminder, the model will include beneficiaries in Medicaid and Medicaid expansion CHIPs, that is Children's Health Insurance Programs, but depending on manufacturer negotiations, states might also have the choice to include separate CHIP beneficiaries in the model. And if so, their research projects could include them as well. The research projects also must be related to the patient care journey for sickle cell gene therapy, which we shared earlier in this presentation, and is detailed in the NOFO.

States will be able to propose research projects of their choice. So some potential projects could study current patient care, barriers, and potential opportunities for improvement. For example, a project could study the challenges model beneficiaries experienced in accessing mental health services before and after gene therapy. States could also propose projects designed to examine the effect of a state policy change, for example on model beneficiaries' access to family planning services. You can see that there is flexibility here for states to propose projects that are relevant to their sickle cell populations. Next slide, please.

Now, there are a couple of things for states to keep in mind when planning to conduct Milestone Funding research projects. First, the projects must include primary data collection from model beneficiaries, caregivers, providers, and/or CBOs providing services to model beneficiaries. States can supplement their analysis with secondary data from other sources, such as claims data and electronic health records, but they do need to include primary data collection. This also means that states must comply with regulations for the protection of human subjects in 45 CFR Part 46 and obtain institutional review board approval as applicable.

Additionally, states can partner with other organizations to conduct research projects, such as CBOs, treatment centers, or academic institutions. For a state to ultimately receive Milestone Funding for a project, the state must submit a report describing their study, the research findings, and their lessons learned, which we'll tell you more about in the next slide. Next slide, please.

States can receive Milestone Funding based on their completion of a project conducted in the previous Model Performance Year. The Milestone Funding is not guaranteed and will be restricted, meaning it has been awarded but is unavailable for the state to use, until the state demonstrates satisfactory completion of the research project. So, to demonstrate that a project has been completed, a state will have to submit a full performance report to CMS, which will include components such as the methodology of the study, analysis of results, policy options for improvement, and the costs incurred.

If CMS approves the state's performance report and verifies that the state has successfully completed the project, it will un-restrict the Milestone Funding associated with the project. States can then use the unrestricted Milestone Funding only to reimburse the costs of their completed project. Next slide, please.

Now let me tell you a little more about the timing of the research projects. If you recall from the funding schedule that I shared earlier, states can receive Milestone Funding for projects they conduct during the OBA Term. Remember, that's the period in which model beneficiaries are receiving gene therapy. So, states can conduct Milestone Funding projects in some or all of the Budget Periods during the OBA Term.

Projects should be designed to be completed within a single Model Performance Year. But, since Budget Period 1 is 18 months, states have the option either to conduct separate projects in 2025 and 2026, or to conduct a single 18-month long research project in Budget Period 1. Also, if a state provides sufficient justification, it could conduct a larger, multi-year project, with distinct phases corresponding to separate Performance Years.

States can propose projects that build on a project they conducted in a previous Budget Period. And since projects in later Budget Periods may build on the lessons from earlier research projects, applicants are not expected to submit detailed proposals for every project in their NOFO application. In the Project Narrative section of the NOFO application, applicants are only expected to propose Milestone Funding projects they plan to conduct during Budget Period 1.

As you can see from the graphic on the right of this slide, prior to each subsequent Budget Period, states will propose a Milestone Funding project that they plan to conduct in that upcoming Budget Period. Also, states will submit their performance report and receive funding the year following each project. Next slide, please.

The final component of the Cooperative Agreement that I'd like to review, is the reporting requirements. In addition to standard federal reporting requirements, states will also have model-specific reports linked to each type of funding.

Now, if a state receives Implementation Funding for any required model activities, it must comply with the model reporting requirements that are detailed in the State RFA. If a state seeks Implementation Funding for optional model activities, it must propose reporting milestones and an implementation plan in the Project Narrative section of the NOFO application for CMS approval, and then submit quarterly progress reports consistent with their approved plan. And, if the state is partnering with any CBOs, it must also submit performance reports and partnership lists of its funded CBOs.

For Milestone Funding, states must submit quarterly and annual reports. As I described earlier, a state must submit a performance report to demonstrate completion of its research project from the prior Performance Year. And Milestone Funding will be restricted until CMS approves that report. Next slide, please.

So that wraps up the details of the Cooperative Agreement funding. Now, I'll pass the mic to Gabe Nah from the Office of Acquisition and Grants Management to talk about the information that you'll need to submit an application. Next slide, please.

>>Gabe Nah, OAGM: Thank you, Caroline.

As the model team mentioned, in order to be eligible for Cooperative Agreement funding, a state must apply to both the State RFA and the NOFO, as well as sign a State Agreement with CMS. CMS anticipates that the negotiated Key Terms will be disclosed to states by December 2024. At that time, states can

begin submitting applications for both the State RFA and the NOFO. Both applications are due on February 28th, 2025, at 11:59 PM Eastern Time.

The model team will review State RFA applications on a rolling basis, so that states can begin performance in the model as early as January 1st, 2025, if they choose to do so. All State Agreements must be signed by June 1st, 2025. The Notice of Award is anticipated to be issued on July 1st, 2025.

All NOFO applications must be submitted through Grants.gov. We, CMS, recommend that you begin the application process well in advance of the application due date to avoid any technical difficulties you may experience during that time period. Please visit Grants.gov to view the NOFO application materials and begin the registration process, and to submit your applications through Grants.gov.

Now I will turn it over to Makaria Martin, who will explain more about the application submission process. Next slide, please.

>>Makaria Martin, OAGM: Thank you, Gabe. Now let's discuss the application submission process.

The Authorized Organizational Representative, or AOR, will officially submit an application on behalf of a state, and must do so on Grants.gov. The AOR is the individual, named by the applicant or recipient, in this case a state, who is authorized to act for the applicant or recipient and to assume the obligations imposed by the federal laws, regulations, requirements, and conditions that apply to grant applications or awards. In order to successfully submit an application, the AOR must: Have a valid Employer Identification Number (EIN), or Tax 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; They must also have a Login.gov account; And finally, register in Grants.gov.

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

We will now discuss the NOFO sections that cover application submission criteria and formatting requirements. For application instructions, applicants should review Section D and Appendix II of the NOFO for instructions on how to submit a complete application. These sections will provide detailed application instructions that must be followed. Formatting requirements will be discussed in Section [D]2. Applicants must adhere to the formatting and content requirements for an eligible application such as font size, formatting, page limitations, required forms and documents, etc.

Application review criteria will be covered in Section E1 of the NOFO. This section explains how applications will be assessed. Next slide, please.

Applicants must submit all the required standard and additional forms in the required format by no later than February 28th, 2025, at 11:59 PM Eastern Standard Time. As Gabe said, we strongly recommend that you do not wait until the application due date to begin the application process. 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*, the applicant risks not being eligible for or awarded the Cooperative Agreement funding.

As you can see from this slide, the CGT Access Model NOFO application will require standard forms, a Budget Narrative, and a Project Narrative. In the subsequent slides, we will cover the forms necessary for an eligible application. There are five standard forms as well as four additional documents. Next slide, please.

These next two slides describe the CGT Access Model NOFO application's standard forms, including a Project Abstract Summary, SF-424, SF-424A, SF-LLL, and Project Site Location Forms. The first required standard form is the Project Abstract Summary. This one-page summary is used to provide a concise description of the proposed project and includes the purpose and outcomes, the total budget, and a description of how the funds will be used. CMS will use this document for information sharing and public information requests for states that receive the CGT Access Model Cooperative Agreement award.

The SF-424, Official Application for Federal Assistance, is used to apply for Federal grants. Federal awarding agencies and the Office of Management and Budget use information reported on this form for general management of federal assistance awards programs. The AOR completes and signs this form. Guidance on how to submit a strong award description is provided in the CGT Access Model NOFO.

The SF-424A, Budget Information Non-Construction form, is used to budget and request grant funds for non-construction programs. Federal awarding agencies and OMB use the information on this form for general management of federal assistance awards programs. Next slide, please.

The next standard form for submission is the SF-LLL, Disclosure of Lobbying Activities. All applicants must submit an 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.

The final standard form is the Project Site Location form. This form is used to report the primary location and any other locations at which the project will be performed. It is important to note the application kit available online in Grants.gov is used for many programs and may designate the SF-LLL and Project Site Location forms as optional. However, both of these forms are required as part of the CGT Access Model NOFO application package, and must be submitted for the application to be considered eligible for review. Next slide, please.

The next two slides describe the CGT Access Model NOFO application's additional forms. CGT Access Model applicants must provide a Project Narrative, Budget Narrative, Program Duplication Assessment, and Business Assessment of Applicant Organization, which we will describe on the next slide.

The Project Narrative articulates in detail the proposed goals, measurable objectives, and milestones in accordance with the NOFO, Section D2.4 specifically. It should offer a clear and concise description of your proposed project, should be double-spaced, and should not exceed 80 pages in length. This Project Narrative should include a description of the applicant's Model Implementation Plan, organizational capacity of the applicant organization, existing collaborations with community-based organizations, participation of CHIP enrollees and applicable activities, optional Medicaid benefits, Milestone Funding project proposals, and Medicaid and CHIP Authorities.

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 each Budget Period. Applicants include a clear description of the proposed costs for each activity within the line item. There is more information to

support applicants as they prepare their Budget Narratives in Appendix I: *Guidance for Preparing a Budget Narrative and Request.* This form may not exceed 10 pages in length. Next slide, please.

The Program Duplication Assessment includes questions to consider an applicant's understanding of program duplication risks 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. Applicants will respond to questions and provide CMS with sufficient information to avoid program duplication related to the CGT Access Model. This assessment may not exceed 5 pages in length. Sample questions with program duplication implications are included in Section D2.6 of the NOFO.

The Business Assessment of Applicant Organization form helps CMS to evaluate the risk posed by an applicant before they receive an award, as required by 45 CFR Part 75.205 for Cooperative Agreements. The applicant will be expected to review, answer, and submit business assessment questions outlined in Appendix III. Business Assessment of Applicant Organization, which includes items such as financial stability, quality of management systems, internal controls, and the ability to meet management standards, as prescribed in 45 CFR Part 75. This document should not exceed 12 pages in length. Next slide, please.

Before we open up for Q&A, I'll review additional details related to federal award administration and share more about the process. Next slide, please.

The Notice of Award, or NoA, is the legal document authorizing the Cooperative Agreement award and issued to the applicant as listed in the SF-424. If the application is successful, the NoA is available to the applicant organization through the online grants management system used by CMS and recipients, called GrantSolutions. Any communication between CMS and applicants 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 via the email address listed on its SF-424, within 30 days of the award date of the program. Next slide, please.

The HHS Grants Management Process is displayed on this slide. The HHS Program Management Office will identify program priorities and timelines in coordination with their respective grants management office. Next, we develop the Funding Opportunity Announcement which reflects program goals, requirements, and timetables.

The Grants Management Office then oversees the review and evaluation of grant applications to ensure outside reviewers and agency personnel comply with management policies and regulations, along with sound business management practices. Next, negotiation, which may be minimal or may involve negotiating all aspects of the award with the applicant. It may involve explaining to the recipient that the budget must be changed to comply with regulations.

The award is officially obligated through the Notice of Award process, which describes all the terms and conditions of the award, including reporting requirements. In this step, the Grants Management Office prepares and signs the grant award, certifying that the award complies with all legal, regulatory, and internal policy requirements and that it is a sound business agreement.

Post award monitoring of recipient performance, which is the next step here, includes reviewing financial and progress reports, maintaining all communications, conducting site visits, and responding to

requests for amendments. Finally, closeout involves reviewing expiring grants to ensure all requirements are met, obtaining certification from the Program Management Office that objectives have been met, resolving any known issues, and ensuring the grant file is complete. Next slide, please.

All award recipients receiving the Cooperative Agreement funding from CMS must comply with the administrative and national policy requirements, the HHS Grants Policy Statement, and reporting requirements related to SAM.gov. Please reference Section F of the NOFO for additional information on these requirements. Next slide, please.

I'll now pass it to Jason Petroski, who will moderate the Q&A section of the webinar. Next slide please.

>>Jason Petrosky, CMS: Okay, thanks so much, Makaria. I'm also looking at the time, and I think I'm going to ask everybody on the webinar to multi-task with me, so that we can actually have a little bit more time for Q&A.

Two things before we get to the question and answer session. We have a poll that you should see on your screen right now. Please take a minute if you're from the states or you're working with states, and please respond to this poll with your feedback. We'll leave that up while we go through the Q&A. So thanks again for taking a look at that and your feedback.

The other request that we'll make, is to give us feedback. We'll also put in the chat, and we'll provide a link to a survey that gives us feedback on the webinar today. We would really appreciate your feedback there.

We're going to jump right into the Q&A because we only have about two minutes here. You can always reach us at our model mailbox as well. So with that, let's jump right into one of the questions that we received prior to the webinar, but also a couple of questions came up on this during the webinar.

Let me read one of them verbatim. The proposed funding for the NOFO is up to 9.55 million for each state over the duration of the model, however, total funding available to all recipients through the cooperative agreement is 95.5 million. The question is: How many states does CMS plan to award the NOFO funds to? And I'm going to direct that one to Melissa Majerol.

>>Melissa Majerol, CMS: Thanks Jason. So yeah, all 52 possible applicants, including the states, the District of Columbia, and Puerto Rico, can all apply and receive NOFO funding. The maximum is 95.5 million. So if more than ten states apply, then each state would get less than 9.55 million, and we'd have to allocate that between as many states that applied and were awarded funding, not all states will necessarily receive the same amount of funding, but no state is eligible for more than 9.55 million dollars.

>>Jason Petrosky, CMS: Okay, thanks, Melissa. I'm going to throw another question to you quickly. We received this one during the webinar: I see February 28th, 2025 deadline for the application, but when will states be required to commit to the CGT Access Model? Can you help with that one Melissa?

>>Melissa Majerol, CMS: Sure, so states will have to commit by that deadline of February 28th, 2025. However, they don't need to begin participation in the model until January 1st, 2026. But that commitment will have to be made by that application deadline date.

>>Jason Petrosky, CMS: Thanks, Melissa. And Melissa just following on to that question, another question about timing here. When and where will, where can the public find out what states have applied to the model? And will this information be made publicly?

>>Melissa Majerol, CMS: Sure. So like with all of our models, we will post model participants on our model website. We will know who all the model participants are by June of 2025, when all the State Agreements need to be signed. So that will be when we have all that information. And that State Agreement is the document that governs state participation in the model, so that's when we will actually know definitively which states are participating.

>>Jason Petrosky, CMS: Okay, thank you much, so much, Melissa. I think we're going to try and slip one more question in.

So we received a couple of questions about the types of, what can be used for, what can the NOFO funding be used to pay for? One of the, one of the responders or folks asking the question said: The Implementation Funding for optional model activities, Co-OP funding, can be used for reimbursement of behavioral health services and fertility preservation services not otherwise paid for by manufacturers? So that was a question.

Someone else asked: Access to behavioral health, chronic pain management, etc., are a major stumbling block to the implementation of gene therapy, can states propose to use funds to directly pay psychologists, therapists, PT, OT, acupuncture, chronic pain clinic for patients undergoing gene therapy? So we had a question on this, or we had a question and response on this. I think this is another one for you, Melissa. Can you talk briefly about basically what the NOFO funding can be used for and what it cannot be used for?

>>Melissa Majerol, CMS: Sure, and I should say we're going to run till 3:05 for the folks who can stay on.

But this is a really important question. As a reminder, Cooperative Agreement funding cannot be used to pay for state share of any benefits, not expanded benefits under the model, not the gene therapy, not to increase reimbursement rates. So that's a very important thing to know. What Implementation Funding can be used for, is to pay for staff or contractor time related to implementing those expanded benefits, any infrastructure costs related to implementing these benefits and services. It can also be used to pay CBOs to provide certain direct services allowable to individuals with sickle cell. So, for example, childcare is not an allowable Medicaid benefit, so states can pay CBOs to provide childcare services consistent with certain requirements set out in the NOFO. Section A6.8.1 of the NOFO describes a lot of this in a lot more detail.

>>Jason Petrosky, CMS: Okay, thanks, Melissa. And then I'm going to turn this next question to Caroline, and then we'll probably need to wrap up after this last question. Caroline, can you please speak more to how the choice to include research projects in the application will impact scoring and funding awards?

>>Caroline Horrow, CMS: Sure. Yeah, so the states that choose to seek Milestone Funding are going to propose their research projects in advance, and they have to propose any Milestone Funding projects they plan to conduct during Budget Period 1 in the NOFO application, specifically in that Project Narrative section. So for more information on how the applications will be reviewed, we encourage you to read Section E of the NOFO.

In general, merit panelists, merit review panelists will assess and score applicants' responses in accordance with the criteria in Section E.1 of the NOFO, and that will be on a scale of 130 total base points. So the proposals for the Milestone Funding research projects to be conducted during the first Budget Period are worth up to 20 points out of that 130 point total. So that's about 15% of the scoring total.

>>Jason Petrosky, CMS: Okay, thanks so much Caroline. Okay, I think with that, we're going to try and conclude here. We obviously didn't get time to go through all of the question and answers that we had liked to. But, we will make sure that we update our model information on our website and other materials, taking into account the great questions that were raised here, both on this call, but prior to the call. So we'll make sure we, we follow up with information on our website. Next slide, please.

Okay, so a big thanks to all our presenters today and really to everyone that attended this webinar. Thanks again for staying on a little bit later with us. We did want to call your attention to the plethora of model resources that are available. Please take advantage of these, again, on our, at our model website. There's a bunch of information that will be helpful if you're really considering the NOFO. Next slide, please.

Okay, and just one last final thanks again to everyone for attending. We really appreciate all the engagement, all the interest in our model, and, you know, appreciate the time spent with us today to learn more about the Notice of Funding Opportunity. And we look forward to this partnership going forward. So thank you everyone and have a good day.

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