HHS-CMS-CMCS
February 27, 2024
3:00 pm ET

Coordinator: Welcome and thank you for standing by. At this time, I'd like to inform all participants that today's call is being recorded. If you have any objections, you may disconnect at this time. All lines have been placed in a listen-only mode for the duration of today's conference. I would now like to turn the call over to Ms. Jackie Glaze. Thank you, ma'am. You may begin.

Jackie Glaze: Thank you. And hi, everyone, and welcome to today's All-State call. On today's call, we will be discussing two important topics. We are very pleased to have the Center for Medicare and Medicaid Innovations team joining us today to provide an update on the newest state-based models open to state Medicaid agencies, including the Making Care Primary Model, the States Advancing All-Payer Health Equity Approaches and Development Model, the Transforming Maternal Health Model, the Innovation in Behavioral Health Model, and the Cell and Gene Therapy Access Model.

Next, Dr. Jessica Lee, the Chief Medical Officer for the Center for Medicaid and CHIP Services, will provide an update on the Medicaid and CHIP coverage of new treatments and opportunities to improve care for sickle cell disease. Before we get started, I want to let folks know that we'll be using the webinar platform to share slides today. If you are not already logged in, I

would suggest that you do so, so that you can see the slides for today's presentation.

You may also submit any questions you may have into the chat at any time during the presentation. With that, I'm pleased to introduce and turn things over to Tequila Terry from the Center for Medicare and Medicaid Innovations team to walk you through the newest state-based innovations model. So Tequila, I'll turn to you now.

Tequila Terry: Thank you so much. Well, good afternoon, everyone. My name is Tequila Terry, and I'm delighted to be with you. I am with the CMS Innovation Center. I direct the state and population health group portfolio for the center, and our team couldn't be happier to be here with you today. As you just heard, we are going to give you an overview of the newest CMS Innovation Center state-based models, which we hope you have heard about at some point. But in case you haven't, this will be an opportunity for you to hear the latest on what those models are and some of the key milestones coming up related to each model. Then we will talk a bit about state participation options and how these models can work together.

So, with that, let's get started. If we could go to the next slide. So, for those of you who may not be as familiar with our work, the CMS Innovation Center was established in 2010 as part of the Affordable Care Act with a statutory mandate to test new approaches to care delivery and payment reform with the goal of improving the quality of care provided to Medicare and Medicaid beneficiaries while holding or even lowering program costs. And this is mostly achieved through the development and implementation of innovative service delivery and payment models.

Next slide. So, as we think about how we approach our work, we use this visual depiction of our vision, which is something that we developed in the fall of 2021, where we released the white paper on our renewed vision to really build a health system that achieves equitable outcomes through high-quality, affordable person-centered care. And to realize this vision, the work of the Innovation Center and what you will hear across all of these models are the five strategic objectives that you see listed here.

First, we want to drive accountable care that really promotes the delivery of whole-person integrated care. Second, we want to advance health equity. We're really committed to embedding equity in all parts of our models, from design to through evaluation, and really focusing on making sure that we are serving underserved populations as part of our work.

Third, we want to support innovation that really enables the delivery of person-centered integrated care. Fourth, we want to ensure that our statute, as our statute directs us, that we are really thinking about affordability in the context of program savings. And so, we're committed to that goal.

And then finally, partnering to achieve health system transformation. We recognize we cannot do this alone. We have to collaborate with many of you that are on the line, states, payers, commercial insurers, employers, really to achieve this vision. And so, we hope that today's session will be a helpful overview of all of the models that we are working on and that you should have hopefully seen announcements about over the last few months. So, with that said, I am going to now turn it over to the teams, starting with the Making Care Primary team, Nick Minter, who's going to give you that model overview. Nick, you have the floor.

Nicholas Minter: Thank you so much, Tequila. We can go to the next slide. Thanks a lot, Jackie. So, really quickly, and again, we announced this model back in June of 2023. So, this may not be new to many of you all on the call, but the Making Care Primary model is a 10.5-year model being tested in eight states, as you see here in the upper right-hand corner, that being Washington, Colorado, New Mexico, Minnesota, New Jersey, New York, Massachusetts, and North Carolina.

It provides additional resources to the primary care organizations in those eight states that apply to the model. It starts in July, 2024, and it is really intended to test whether or not, we can successfully bring primary care organizations into value-based payment in a sustainable way that furthers and broadens their care delivery capabilities, allows them to provide interprofessional care in the definition of the National Academy's report on providing high-quality primary care in 2021, and in the process of doing so, improve patient outcomes and reduce total cost of care. This model seeks to meet primary care organizations no matter where they are.

We have three tracks. One that is for the least advanced and changes payment the least at first, but over time, gradually builds upon that as they progress into across tracks, into track two and track three, where we shift their payment to being more prospective, less encounter-based and more population-based, and provide more reimbursement to them based on the improvement that they show in patient outcomes over time. Next slide.

The benefits of participating in MCP for primary care organizations are myriad in nature. But to touch on a few of them, we are offering upfront infrastructure payment for those organizations that have historically not had the resources to engage in value-based payment. It is not a downside model. We are providing only upside payments to promote primary care, which is

already underpaid. We are introducing new payments and mechanisms to improve specialty integration because that's an area where primary care often gets left out and isn't responsible for doing more.

Health equity is at the heart of this model. We risk adjust to make sure that those primary care organizations that are caring for more modules, more folks facing both social and clinical risk are paid higher so that they can sort of bridge the gap that we know exists in patient outcomes where health inequities have previously existed.

And finally, we are sort of - look, we are working on this model in a collaborative fashion, both internally and externally with other payers, which we'll talk about in a second, as well as practices to make sure that as we are sharing that back with our participants. So, the idea being that even though the model is ten years long, the lessons that we learned will be shared far before its conclusion.

Let's keep going to the next slide. Primary care transformation, which is a really a side product of what we're trying to achieve here in Making Care Primary, requires that Medicare fee-for-service, which is where this model is providing the majority of its changes, that it doesn't act alone. So, initially we reached out to the state Medicaid agencies in the eight states in which we're working, and we partnered with them. We said, look, we believe primary care can do more. Do you believe the same thing?

And we are doing the same thing with other private payers to build a multi-payer community in each of the eight regions so that even though we all may be supporting primary care slightly differently, there are certain goals that we share amongst all lines of business and all payers in these regions. Things like moving primary care payment away from fee-for-service and toward a

population-based payment, to join our quality measurement strategies as much as is possible, to reduce the barriers of entry and the ability to participate in this model for our providers, and to combine data over time so that providers have one set of data in one location as opposed to ten or has many sets of data and formats as they do payers themselves.

We want to make sure that these powerful tools are usable and that they're not barriers to entry. And the last thing I'll note is, by working with other payers at a regional level, we ensure that New Mexico and New York don't necessarily look the same in terms of the primary care interventions we focus on. Care is local, and we've designed Making Care Primary to be the same way.

Next slide. So, where are we? Unlike some of the other models that you'll see today, we have already designated where we are testing the model. We cover those eight states. And in late December, we actually closed our application period for providers. So, as of this past Monday, we have notified providers in each of the eight states that apply, whether or not they are accepted and able to sign a participation agreement. We will be working with them between now and April to increase their education on the model and to onboard them after April ends, and the model will start on July 2024.

Again, we are looking forward to changing the way we pay, to providing more support and more resources to primary care in the interest of showing that we can change outcomes downstream if we focus our resources at primary care where the patient enters the healthcare system. And with that, I will pass it to Laura Snyder to talk about the AHEAD model.

Laura Snyder: Great, thank you so much, Nick. Good afternoon, everyone. My name is Laura Snyder. I'm Co-Lead of the AHEAD model, and I have the privilege of

providing you an overview today. Let's go ahead and jump right in. Go to the next slide, please. Thank you.

So, I'm going to work closely from top to bottom, and I'll point out the pretty central role of the state Medicaid agency for participating states throughout the overview. So, based on CMMI's experience with other state models and understanding that no two states have exactly the same priorities, political or healthcare environments, et cetera, AHEAD was designed with this flexible framework approach that can be tailored to each state's unique context to achieve the goals of the model.

I do want to point out that the state Medicaid agency must be the applicant or a joint applicant responding to the AHEAD's Notice
of Funding Opportunity, because of their important role in the model. So, as part of the multi-payer alignment strategy, the state Medicaid agency is responsible for designing and implementing Medicaid alternative payment models with aligned goals, recruiting providers to participate in the voluntary hospital global budgets and primary care head program, and creating policies for state financial targets.

Now, all of that work aims to achieve the AHEAD model goals, which are to improve population and health, advanced health equity by reducing disparities in health outcomes, and curbing health care cost growth. So, to achieve these goals, states have to achieve a pretty significant restructuring of health system activities and spending in their state or sub-state region, if that's how they choose to participate, while also controlling the total cost of care as measured by three categories of targets that we have in the model.

The first is the primary care investment targets. We have one for Medicare fee-for-service, one for all payers, because strong primary care is the

foundation of a high-quality healthcare system. We also have equity and population health outcome targets to sort of track progress on long-term population health impacts of that primary care investment as it's guided by a health equity plan that each state designs and commits too in their state agreements.

And finally, we have the total cost of care growth targets, one for Medicare fee-for-service and one for all payers. Those first two goals create that shift upstream in spending and intervention that aims to prevent the more expensive downstream care in acute hospital settings. So, these total cost of care targets aim to ensure that, that shift is happening and that total cost of care growth is, in fact, constrained.

I will note that Medicaid spending does contribute to all payer targets. However, because of Medicaid's unique population and the model's focus on improving population health and increasing access for at-risk populations, CMS will hold Medicaid harmless within the all-payer total cost-of-care target for growth that is considered good or neutral. So, essentially, spending resulting from state actions taken to promote and ensure access to Medicaid services and supports.

Now, the model helps states to move toward these goals through three key components. The first is the cooperative agreement funding. That's that initial investment from CMS to support transformation in the early years of the model and perform the pre-implementation work that's necessary to be successful over the ten-year model. Then we have the hospital global budgets, the predetermined fixed annual budgets for participating hospitals.

The participating states will be required to implement an aligned Medicaid hospitals global budget by performance year one. The state Medicaid agency

will be responsible for developing that Medicaid-specific methodology with CMS's guidance. So, I'll just point out that there is Medicaid alignment criteria, and more information on that outlined in the Notice of Funding Opportunity.

I'd also like to mention that CMS recently released our Medicare fee-for-service Hospital Global Budget Methodology, resources, which are now available on our model website, available in one of the next slides. But before we move forward, just want to touch on the third component, which is Primary Care Head, and that aims to facilitate the development of the advanced primary care services and infrastructure that are essential to achieving model goals.

Now, Primary Care Head is a Medicare fee-for-service program, but it's designed to align with existing innovations in the state Medicaid primary care patient-centered medical home program or alternative payment model, and states can adapt the Medicare Primary Care Head care transformation requirements and quality measures to align with Medicaid priorities.

Finally, across the bottom of the slide are strategies that are sort of foundational to the design of and success within the model. Next slide, please. So, I will keep it short here and just in the interest of time note that, you know, because system transformation takes time, AHEAD is a ten-year model, and we are currently accepting applications for Cohorts 1 and 2 through March 18, and there will be a second application period for Cohort 3 closing in August.

Next slide please. Okay. And there is a wealth of information available on our model website. I encourage you to explore more there, and we will also have direct links to all of the resources listed in the slide. So, I will hand it over to Linda for the next model.

Linda Streitfeld: Terrific. Thank you so much. I'm Linda Streitfeld, and I'm very proud to share an overview of the Transforming Maternal Health Model. You can see our acronym is TMaH, and we like to refer to that as Team MaH. And our goal is to improve the rather dismal maternal and infant health outcomes in the U.S. and to reduce the racial and ethnic disparities that clearly exist in those maternal health outcomes. Our goals are reflected in the blue box on the right, including improved outcomes, a better experience of care, and overall expenditure reductions.

TMaH also is a ten-year model. And over that time, we're going to be testing the impact of targeted technical assistance for up to 15 state Medicaid agencies, supported by up to $17 million in funding for each SMA that is awarded. We will help them develop a payment model and work with them to implement and expand evidence-based, whole-person maternity care delivery approaches. And that technical assistance will be delivered over a three-year pre-implementation period, after which states will have seven years to test the payment and care delivery model.

Next slide. The SMAs will be expected to partner with the entities that actually provide care, so with Medicaid, with managed care plans, and with providers in the chosen test region. So, the provider types may include Obgyns, maternal-fetal medicine specialists, midwives, doulas, and others, and there will be in lots of settings, including hospitals, birth centers, FQHCs, and physician offices.

Next slide. TMaH is implementing this model through initiatives across three pillars, which you see here. The first, access to care, infrastructure, and workforce, includes such things as covering doula services and increasing access to midwifery care and birth centers. In the center, quality improvement

and safety includes implementing some of the patient safety protocols, as well as our birthing-friendly hospital initiatives. And under the third pillar, whole-person care delivery will include screening and follow-up for depression and health-related social needs, among other things. We have additional specific elements under each pillar with more information on our website and, of course, all of this will be further detailed in the Notice of Funding Opportunity.

Next slide. And here's the timeline. We expect to release that Notice of Funding Opportunity this spring. We'll be looking at applications after the deadline later this summer, making our selections in the fall and then launching at the start of 2025. And this slide also includes our website address and instructions for joining the Listserv. So, that is TMah. Thank you so much. And I will hand off to Isaac Devoid.

Isaac Devoid: Thanks, Linda, much appreciated. Hi there, my name is Isaac Devoid. I'm the Co-Model Lead of the Innovation in Behavioral Health, or IBH model for short. We're really excited to have the opportunity to share more about our model with you today. So, the IBH model focuses on the opportunity to leverage both CMS and state Medicaid agencies, authorities, to help facilitate a new approach to behavioral health that is aligned with the HHS behavioral health roadmap.

The IBH model aims to improve the quality of care and health outcomes for adults with moderate to severe behavioral health conditions, which includes mental health conditions and or substance use disorders. The model supports community-based behavioral health practices to provide person-centered care in a behavioral health setting. Behavioral health providers will work as part of an interprofessional care team coordinating with other providers to best serve beneficiaries.

Next slide, please. We'll now learn a bit more about the structure of the IBH model, starting with the model participants. So, the award recipients will be state Medicaid agencies, and we will select up to state - eight state Medicaid agencies to participate in the model through a cooperative agreement. The application period will open in the spring so that the model can begin in selected states this fall.

Moving on to behavioral health practices. So, within selected IBH states, community-based behavioral health organizations and settings will be eligible to participate in the aligned Medicaid and Medicare payment models as practice participants. These practice participants will be community-based behavioral health organizations, including safety net providers who are licensed by their state to deliver behavioral health services and provide outpatient behavioral health services to adult beneficiaries with moderate to severe behavioral health conditions.

Examples of practice participants include but aren't limited to, community mental health centers, opioid treatment programs, CCBHCs, safety net providers, and other public or private practices that provide outpatient mental health and or substance use disorder services. Practice participants must at a minimum participate in their state's Medicaid model and can voluntarily enroll in the aligned Medicare payment model.

And now on to beneficiaries. So, the IBH model will focus on adult Medicare and Medicaid beneficiaries with moderate to severe mental health conditions and substance use disorder who receive care from an enrolled practice participant that we just mentioned. Now, on to our care delivery framework. IBH states and practice participants will collaborate to implement

the IBH model care delivery framework. The care delivery framework includes three main components.

The first is care integration. This is where practices will screen, assess, and refer beneficiaries as needed for the services they require. This includes behavioral health, physical health, as well as health-related social needs. The second is care management. This is where an interprofessional care team will provide that ongoing care management to monitor each beneficiary's needs, treatment, and outcomes.

And then lastly, we have health equity. This is where practices will screen for health-related social needs and refer patients to appropriate community-based services. And then lastly, onto our payment approach, the IBH model aims to be a glide path to begin behavioral health providers on the progression from fee-for-service to value-based payments. And through an aligned Medicare and Medicaid payment for these integrated services, the IBH model seeks to bridge the gap between mental and physical health by connecting patients with all those behavioral, physical, and social supports that are ultimately needed to manage their care.

In the IBH model, Medicaid and Medicare will align on key model design elements, thinking about things like payment and quality to allow state partners flexibility while designing and implementing a Medicaid alternative payment model for their unique state context. State Medicaid agencies will receive cooperative agreement funding to prepare for and implement the model, including things like statewide health IT infrastructure, convening key partners, developing the Medicaid APM, and collecting, analyzing, and sharing model data.

Practice participants enrolled in the Medicare component of the model will receive an aligned Medicare payment. This will be called the integration support payment to implement the IBH care delivery framework. And then a really foundational component of the model is infrastructure funding. Practice participants will receive infrastructure funding from CMS and states to support health IT, electronic health record, and ultimately practice transformation and staffing.

Next slide, please. So, the IBH model team is still fine-tuning our timeline, and any changes will be made to our upcoming Notice of Funding Opportunity. Right now, we anticipate releasing the Notice of Funding Opportunity for state applicants later this spring. The model will launch this fall in up to eight states selected through that Notice of Funding Opportunity, and we anticipate operating the model for eight years. This includes a three-year pre-implementation period and a five-year implementation period.

Next slide please. Here you can find key links and resources to stay up to date with the IBH model, including our website, email, listserv. And in addition, we'd love for you to attend our model overview webinar this Thursday, February 29, from 2:00 to 3.30 pm Eastern Standard Time. Thank you so much for your time today. We really appreciate it and look forward to talking with you more. And with that, I'll turn it over to Melissa and the Cell and Gene Therapy Access Model Team.

Melissa Majerol: Thank you so much, Isaac. So, good afternoon, and thank you so much for having me here today. My name is Melissa Majerol, and I'm one of the model leads on the Cell and Gene Therapy Access Model, or CGT model for short. Before I dive into the content of this presentation, I just wanted to take a moment to express our model's gratitude for the time and effort that so many

states have taken over the last year in helping us build out the details of this model. We have benefited so much from hearing your perspectives and the experience that some of you all have in this area.

So, now I'll dive into some of the background of this model. This model was born out of an executive order, the U.S. President issued in October of 2022, which directed the Secretary of HHS to propose new healthcare payment and delivery models that could lower drug costs and promote access to innovative drug therapy for beneficiaries enrolled in both Medicare and Medicaid.

The model was briefly described in a report that came out in February of 2023. And between then and a couple of months ago, when we announced the model, CMS has had discussions with states, manufacturers, beneficiary groups, and clinicians. And those discussions have helped us design key aspects of the model. And going forward, we're eager to continue engaging with states to help continue design and implement the model together.

So, how does this model work? At a very high level, the vision-based model is a framework in which CMS would negotiate with manufacturers of cell and gene therapies on behalf of state Medicaid agencies for what we call outcomes-based agreements. And these are agreements that, among other things, tie what the manufacturer receives in payment to the actual clinical outcomes achieved by the therapy in Medicaid beneficiaries.

The goal 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 expenditure trajectory of these patients and improve their health outcomes. The initial focus of this model is on the two gene therapies for sickle cell disease, both of which received FDA approval just this past December.

Next slide, please. Now, I'll describe the model structure in a bit more detail. As I mentioned, CMS will be negotiating outcome-based agreements with manufacturers. And the key terms that will be negotiated include a standardized access policy for the product and a pricing structure which would reflect both outcomes-based components and also other types of discounts. Following negotiations between CMS and manufacturers, the terms will be disclosed to states who then would decide whether or not to join the model and signed on to the negotiated deal.

I want to emphasize that this model is voluntary for both manufacturers and for states. In order for states to participate, a state or territory must participate in the Medicaid Drug Rebate Program, the MDRP, and must meet the requirements of model participation and sign a state agreement with CMS. In order for manufacturers to be eligible to participate, the manufacturers also have to participate in the MDRP, and they have to market an FDA-approved or licensed gene therapy for sickle cell disease and sign a participation agreement with CMS that reflects a negotiated agreement.

CMS will play a few key roles throughout this process, including on the front end. CMS will negotiate the overall set of key terms that reflect the pricing structure that includes discounted pricing and time payment to outcomes. CMS will also offer states optional funding to support activities that promote equitable access to care. And CMS will support states in implementing the model, both through technical assistance to states and by collecting, analyzing, and reconciling data required to adjudicate the amounts owed under these outcomes-based agreements.

Next slide, please. So, this is the snapshot of our model and application timeline. The goal is for states to have the option of beginning participation in

the model as early as January of 2025. Those states are welcome to begin participation on a rolling basis throughout the entire calendar year of 2025, and up until January 1, 2026. So, there are several milestones that will happen between now and then.

First, in early March, we plan to release the manufacturer request for application, which will be due on May 1. This will kick off the negotiation process between CMS and manufacturers. We expect that negotiation process to conclude by no later than late November of 2024, with signed participation agreements with manufacturers by late November or early December.

Second, you have released to states a non-binding letter of intent, which is due on April 1, and which we strongly encourage states to submit to CMS. It's an important way for CMS to engage state interest in the model and for states to engage with CMS on their negotiation priorities. This summer, we'll release the state request for application, which will outline the state requirements for participation in more detail. And then in December 2024, as I mentioned, we'll disclose to states the results of the negotiation process. States that want to participate in the model will be required to respond to the state RFA by February 28 of 2025, and can begin performance in model, again, any time between January 1 of 2025 and January 1 of 2026.

So, third, there will be an optional Notice of Funding Opportunity. And we'll plan to release that this summer as well with applications accepted between December 2024 and February 2025. And we plan to release funding associated with the Notice of Funding Opportunity as early as June or July of 2025. I want to emphasize that the Notice of Funding Opportunity is completely optional. States can participate in the model by simply signing the state agreement, but if states are interested in funding, they should apply to the Notice of Funding Opportunity. So, this whole timeline allows for states and

manufacturers to enter into a supplemental rebate that would go into effect as early as January 1, 2025.

Next slide, please. Okay. So, that is the overview of the model. We encourage anyone interested to go to our website to learn more about our model. The website contains the recording and slides from a model webinar we held on February 6, as well as the model fact sheet and the letter of intent.

I also want to encourage any state that's interested to contact the model team email that you see on this slide, cgpmodel@cms.hhs.gov, to ask questions or set up time with the model team. We are happy to take calls with any interested states. Now, I'll pass it to Allison Marlatt. Thank you.

Allison Marlatt: Thanks, Melissa. And hi, everyone. My name is Ally Marlatt. I am a Senior Advisor in the State and Population Health Group at the CMS Innovation Center. And thanks to all of my Innovation Center colleagues for those great overviews of these exciting new models.

Next slide, please. So, now that we've heard more about each model's goal and structure, we wanted to take a moment to talk a bit about some options for state participation in multiple models. I am sure many of you have questions on whether and how a state may apply for and potentially participate in different combinations of these models. So, in general, states are able to operate multiple models if they have the capacity to do so.

Depending on the combination of models under consideration by a given state, there may be different participation options and exclusions that states will need to think about, such as exclusions or overlapped policies at the statewide, sub-state, or provider level, depending on the combination of models that the state is considering.

Some model combinations, however, cannot work together, as it would make it difficult for CMS to evaluate the effects or could result in duplicative payment. So, because of these nuances, we really encourage states to reach out to us directly if you have any questions about operating multiple models in a particular state, we would be more than happy to discuss what is or is not allowable in different combinations of these models. And as the presenters have noted, all of the model contact information is listed on each model's website.

Our model teams have also been working to develop model-specific policies on overlaps and options for state participations in multiple models. And one example I want to point you to is the AHEAD Model, which recently published an Overlap Policy Fact Sheet on its website, and that's linked here. You can find it on the AHEAD Model's website. This document details the AHEAD Model's policies regarding AHEAD participation overlapping with other current and upcoming models, looking at different levels of overlap, like statewide, sub-state, and provider-level participation. This document offers an example of how the Innovation Center is approaching overlaps policies and additional model overlaps policies as they are available will be shared on the model website.

So, we can go to the next slide, which is just a summary of key dates and resources, as well as links for all five models that we discussed today. We really appreciate the time with everyone today and look forward to hearing from you all and sharing more with you about each of these models in the future. So, that wraps up the Innovation Center portion of today's agenda, and I will now hand it over to Dr. Jessica Lee.

Jessica Lee: Thank you so much. So, exciting to hear about all the different models available now. I'm Jessica Lee, and I'm really excited to talk to you today about Medicaid and CHIP coverage of new treatments and opportunities to improve care for sickle cell disease. Next slide, please. EMS is committed to improving access, quality, and experience of healthcare for individuals living with sickle cell disease. Approximately half of the people nationwide affected by sickle cell disease are enrolled in Medicaid. Individuals with sickle cell disease may experience significant pain and other serious medical problems such as infections, lung problems, stroke, and pregnancy complications.

From our previously published analysis of 2017 data, we know that of Medicaid and CHIP beneficiaries with sickle cell disease, 78% had an emergency apartment visit and 49% had at least one inpatient hospital stay. Next slide, please. Given experiences like pain crises and hospitalizations, the new treatment options for sickle cell disease are an exciting breakthrough. On December 8 of 2023, the FDA approved two milestone treatments, the first cell-based gene therapies for sickle cell disease.

Casgevy and Lyfgenia are both approved for the treatment of sickle cell disease in patients 12 years of age and older with a history of vaso-occlusive crises. I would reference the specific FDA approval notice for more specifics on the approval criteria in addition to the effectiveness data, but very briefly, of 31 patients treated with Casgevy, 93.5% were free from severe vaso-occlusive crises for at least 12 months during the 24-month follow-up period.

And for Lyfgenia, of the 32 patients treated, 88% had complete resolution of vaso-occlusive events between 6 and 18 months after infusion. These products are made from the patient's own blood stem cells, which are modified and given back in a single infusion as part of a hematopoietic stem cell transplant.

Prior to treatment, the patient undergoes myeloblative conditioning with high-dose chemotherapy in addition to other services that I'll briefly describe.

Next slide, please. Reviewing Medicaid coverage of the gene therapy drug itself, outpatient prescription drug coverage is an optional benefit that all state Medicaid agencies currently provide under the Medicaid statute of the Social Security Act, specifically Section 1905A12. State Medicaid agencies that provide outpatient prescription drug coverage are required to cover all covered outpatient drugs offered by any manufacturer that agrees to provide rebates.

Drugs that are administered in an inpatient hospital setting are considered covered outpatient drugs if they are directly reimbursed. As both Casgevy and Lyfgenia are expected to be administered in inpatient settings, they may therefore be covered outpatient drugs and subject to Medicaid rebates if they are directly reimbursed. States do have discussion to establish certain utilization controls, such as prior authorization.

Next slide, please. Turning now to separate CHIP coverage of the gene therapy drug, prescription drugs are an optional benefit states may cover in a separate CHIP. Unlike Medicaid, separate CHIPs that cover prescription drugs are not required to cover all covered outpatient drugs offered by manufacturers that agree to provide rebates. States have the option to seek rebates from manufacturers for prescription drugs covered in separate CHIPs, but they are not best price exempt. Therefore, states have the option to cover both Casgevy and Lyfgenia, and states may also establish utilization controls.

Next slide, please. We want to highlight some state opportunities in value-based purchasing. We encourage states to explore innovative contracting arrangements with willing manufacturers. For example, several states have received CMS approval to enter into value-based purchasing supplemental

rebate agreements with manufacturers. Such arrangements are intended to allow states to collect supplemental rebates for certain drugs when linked to an observed or expected therapeutic or clinical value in a select population.

States that have not yet done so, may obtain CMS approval through a state plan amendment or SPA to enable states and willing manufacturers to enter into such agreements. Alternatively, manufacturers may offer a value-based arrangement to all states, even states without an approved SPA, if they want to report varying best-price amounts.

Next slide, please. As mentioned, this is not a single pill. There's multiple services that are required in order to successfully administer gene therapy. The process includes, for example, an evaluation for gene therapy, preparation during which patients may have changes in medication and transfusion therapy, apheresis for cell harvesting, chemotherapy, and then infusion, both in an inpatient setting, follow-up care and monitoring.

Federal law outlines mandatory Medicaid and CHIP benefits, which states are required to provide, and optional benefits that states may cover if they choose, as many people on this call know. Examples of mandatory Medicaid benefits include inpatient hospital services, laboratory and X-ray services, physician services, and family planning services. And examples of mandatory CHIP benefits include well-baby and well-child visits, mental health and substance use disorder prevention, and age-appropriate vaccines.

Next slide, please. Some beneficiaries will require access to out-of-state providers. For example, if there are no in-state sickle cell disease gene therapy providers. In accordance with 42 CFR 431.52b3, if a state determines on the basis of medical advice that needed medical services are more readily available in another state, then the state must provide for services from the

out-of-state provider, noting that all applicable provider enrollment requirements must be followed.

While there are no similar requirements for separate CHIPs, states may provide access to an out-of-state provider through the Access to Care Assurances in the CHIP state plan, as described in 42 CFR 457.495C. I'll also encourage you, if you're looking for the specific statutory references, so please check out the slides to make sure that I've gotten them right.

The Medicaid Transportation Assurance is a requirement to make certain that every Medicaid beneficiary who has no other means of transportation has access to transportation needed to receive covered care. This includes related travel expenses, such as the cost of travel, lodging, and meals for beneficiaries and their caregivers, as necessary, for the beneficiary to receive the covered service. This requirement generally does not apply to separate CHIPs, except for those that provide EPSDT benefits consistent with Medicaid requirements. For more information, I'll point you to the Medicaid Transportation Coverage Guide that we released last fall.

Next slide, please. I want to highlight the Medicaid optional benefit for sickle cell disease. The American Jobs Creation Act of 2004 created an optional Medicaid sickle cell disease benefit under which states can cover additional services that might not otherwise be covered in a state plan. Under the optional sickle cell disease benefit, states may add new optional benefits, such as genetic counseling for individuals with sickle cell disease, or increase the rates at which they pay for mandatory or already covered optional benefits.

As determined by the state, services may be provided by telehealth. While the American Jobs Creation Act of 2004 did not extend these options to separate CHIPs, states may elect to add sickle cell disease services as a

covered benefit in separate CHIPs. Next slide, please. Continuing about - continuing a description of this optional benefit, states may pay for sickle cell disease services at a different rate than they pay for similar services provided to individuals with other diseases.

For example, under this benefit, if a state wanted to increase payment rates for sickle cell disease-related blood transfusions, it could do so through rate setting for the sickle cell disease benefit without having to increase payment for blood transfusions for all Medicaid beneficiaries.

Payment levels, however, must still be set within federal requirements, including those under Section 1902A, 30A of the Act. States may also use this benefit to establish different coverage limits for sickle cell disease services under the federal amount, duration, and scope provisions that can be found at 42 CFR, Section 440.230, from those that apply to services and other benefit categories in Section 1905A of the Act.

Federal match may be available for Medicaid administrative expenditures related to activities, including certain educational activities that promote Medicaid awareness and access for sickle cell disease, consistent with Section 1903A-3E of the Act. Next slide, please. We have a slide here on exciting cell and gene therapy access model that was just presented by the Innovation Center. I'm going to skip over this over time, but including it here for completeness in terms of the opportunities to improve care that we're providing.

Next slide, please. In addition to what we've outlined, there are many different ways to improve care for children and adults with sickle cell disease. Data show that gaps in recommended care for Medicaid and CHIP beneficiaries for sickle cell disease specifically exist in the rates of

transcranial doppler ultrasound screening and pneumococcal vaccination for children, and in rates of hydroxyurea use among both children and adults. Those data were from 2017 and were published in our sickle cell disease infographic, which can be found online.

I also want to highlight the CMCS quality improvement program, which provides state Medicaid and CHIP quality staff and their quality improvement partners with information, tools, and expert support. Technical assistance is available to help states build QI knowledge and skills, develop QI projects, and implement, spread, and scale up quality improvement initiatives.

You can contact medicaidchipqi@cms.hhs.gov for more information, or check out our quality improvement initiatives page on Medicaid.gov, where you can find resources like how to get started on a quality improvement project for specific areas of focus. Thank you so much for the time and attention and the opportunity to talk to you about ways to improve the care, access, and experience of health care for individuals with sickle cell disease. And with that, I'll turn it back over to Jackie.

Jackie Glaze: Thank you, Jessica. So, we're ready now to take state's questions. So, we will begin by taking your questions through the chat function. So, you may begin submitting them now, and then we will transition to taking questions over the phone line. So, we do have one question now in the chat, and this is regard to the CDT access model. So, there's three questions, so I'll read them slowly, and then if you need for me to repeat them, I will.

It says, can you explain more on the specific ways in which you envision managed care populations entering the model? Will managed care plans be able to sign on SRAs based on the CMS negotiated terms? Or would the

managed care population need to be carved out? So, I think that question might be for you, Melissa.

Melissa Majerol: Yes. And thanks so much for that question. So, as I mentioned, the first year of the model will be a rolling start year. And during that year, we also envision states being able to bring their managed care lives in as would be easiest for them. So, there is a requirement that all states bring their managed care lives in no later than January 1 of 2026.

And in terms of how those lives will be brought in, you know, that's going to depend on each state's relationship with their managed care organizations. But yes, we are absolutely requiring that all states bring all their managed care lives in no later than January 1 of 2020.

Jackie Glaze: Thank you, Melissa. I'm not seeing any additional questions in the chat, so I'll ask if you do have questions about today's presentation or any other questions that you may have, please enter them now. But we'll transition to the phone lines. So, (Missy), if you can provide instructions for how to register the questions, and then if you can open the phone lines, please?

Coordinator: Yes, ma'am. If you would like to ask a question over the phone, please press Star followed by 1. Please make sure that your phone is unmuted and record your name when prompted. If you wish to withdraw your question, you can press Star 2. Please allow a moment for questions to come in. Thank you. I'm not seeing any questions coming in yet.

Jackie Glaze: Thanks. I'm not either, so we'll give it another couple minutes, and then we'll close early. Okay, we do have one additional question in the chat, and it says, when will -- and I may not be pronouncing this right, but it's -- (COAG) amount for the IBH model be announced?

Isaac Devoid: Hi, there. Yes, this is Isaac, the Co-Lead of the IBH model. We'll be providing more information on our cooperative agreement funding in the near future, including on our model overview webinar. That's actually this week. So, if folks are interested in learning more, definitely tune into the Listserv that we had mentioned during our presentation, but also tune in for our model overview webinar. That's this Thursday from 2:00 to 3.30 pm Eastern Standard Time.

Jackie Glaze: Thank you. (Missy), are you seeing any additional questions?

Coordinator: No, ma'am, I'm not.

Jackie Glaze: Okay, then so, in closing, I do want to thank the Medicare and Medicaid Innovation Team for their presentation today, and also thank Dr. Jessica Lee for her presentation. So, looking forward, we will provide the topics and the invitations for the upcoming calls. And if you do have questions before our next call, please feel free to reach out to us, your state leads, or bring your questions to the next call. So, we do thank you for joining us today, and we hope everyone has a great afternoon. Thank you.

Coordinator: Thank you. That does conclude today's conference. You may disconnect at this time, and thank you for joining.

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