HHS-CMS-CMCS

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2:00 pm CT

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode. During the Q&A session, if you'd like to ask a question, you may press star 1 on your phone. Today's call is being recorded. If you have any objections, please disconnect at this time. I will now turn the call over to (Jackie Glaze). Thank you. You may begin.

(Jackie Glaze): Good afternoon and welcome everyone to today's all state call-in webinar. I'll now turn to Sara Vitolo, our Deputy Center Director for opening remarks. Sara?

Sara Vitolo: Hi, everyone. Welcome to today's all state call. On today's call we'll have several timely presentations. Meg Barry from our Children's and Adult Health Programs Group will provide an overview of some of the key Medicaid and CHIP provisions of the Consolidated Appropriations Act, or CAA, of 2023. This will be followed by a deeper dive on the new continuous eligibility requirement, which is effective this coming January, led by Stacey Green from our Children's and Adult Health Programs Group.

And lastly, Anna Bonelli from our Financial Management Group will provide a quick overview of the CAA of 2023 unwinding reporting requirements and the FMAP reduction for failure to meet those requirements. But before we dive into the CAA, (Kathy Traugo) from our Division of Medicaid Benefits

and Health Programs Group will provide a brief verbal update on coverage requirements for LEQEMBI, the monoclonal antibody medication used for treatment of Alzheimer's disease. The drug was originally approved in January, but just received full traditional approval this week.

I want to remind folks that we'll be using the webinar platform to share slides today. So if you're not already logged in, I suggest you do so now so you can see the slides for today's presentation. You can also submit any questions you have into the chat at any time during the presentation. With that, I'm pleased to introduce and hand things over to (Kathy Traugo) to discuss today's updates regarding LEQEMBI.

(Kathy Traugo): Thank you, Sara. As Sara mentioned, I'm going to provide a quick high level synopsis of the coverage requirements for LEQEMBI. Before I do that, though, I do want to provide just a little background about the approval for LEQEMBI, to set the stage. So many of you are probably aware, but just again, to kind of set the stage, on January 6, 2023 FDA approved accelerated approval for LEQEMBI, the brand name for Lecanemab, which was developed by Eisai.

As a part of the accelerated approval pathway, FDA required Eisai to conduct a confirmatory study to verify the anticipated clinical benefits of LEQEMBI. Efficacy was evaluated using the results of Study 301, which was also known as Clarity AD, which was the Phase III randomized controlled clinical trial. On July 6, 2023, FDA converted LEQEMBI to traditional approval following FDA's determination that the confirmatory trial verified clinical benefit. It is the first amyloid beta-directed antibody to receive full traditional FDA approval. It is approved for patients with mild cognitive impairment or mild dementia stage of Alzheimer's disease.

Regarding Medicare coverage, Medicare released a National Coverage Determination, or NCD decision memo on April 7, 2022 regarding Medicare coverage of FDA-approved monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease. This NCD applies to (Atrahelm) and now also applies to LEQEMBI. There are a lot more details in the NCD, which can be found on CMS's Web site. But in summary, Medicare coverage criteria changes upon traditional approval of one of these products by FDA.

Specifically related to LEQEMBI, to receive Medicare coverage beneficiaries need to one, be enrolled in Medicare Part B; two, be diagnosed with mild cognitive impairment or mild dementia stage of Alzheimer's disease; and three, have a physician who participates in a qualifying registry with an appropriate clinical team and follow-up care. Clinicians participating in the registry will only need to complete a short, easy-to-use data submission.

Upon traditional approval by FDA of LEQEMBI, CMS disseminated information to the Medicare Administrative Contractors, or MACs, to manually upload a new HCPCS code, J0174, for claims processing. And this code must be used on LEQEMBI claims. The effective date of this code is July 6, 2023. The MACs have been given until July 25th to load the code, and providers have been asked to hold their submitted claims until July 25th for dates of service beginning July 6th.

Regarding Medicaid coverage, Medicaid coverage of LEQEMBI began upon approval in January. Medicaid coverage is governed by Section 1927 of the Social Security Act. That was the case when LEQEMBI was approved through an accelerated approval process, and it's still true with the traditional approval. In other words, the Medicare MCV does not establish a controlling policy for states or territories in the Medicaid program. Instead, Section 1927 governs Medicaid programs.

So with that, states must provide coverage of LEQEMBI as it meets the definition of a covered outpatient drug when it is prescribed for a medically accepted indication. While states have the discretion to establish certain limitations on the coverage of these drugs, such as preferred drug lists or use of prior authorization processes, such practices must be consistent with the requirements of Section 1927D of the Act. States should note that the registry requirement that I mentioned previously does not apply to Medicaid; that applies to Medicare only.

And finally, regarding crossover claims - so regarding Medicare/Medicaid dual-eligible individuals, as is standard for Part B drugs, Medicare is the primary payer and states are liable for any applicable Medicare cost sharing. Operationally, Medicare will process the Part B claim and then the claim will be sent to the Medicaid program for secondary coverage. The state will process the claim and the standard cost sharing requirement as established by the state for full dual-eligible beneficiaries will apply.

If the state pays any of the Medicare cost sharing, the state must invoice manufacturers for applicable rebates on the drug. And manufacturers would be required to pay rebates under this scenario as appropriate. Now, specifically related to LEQEMBI, for claims that cross over from Medicare for dual-eligible beneficiaries, those claims will have the new HCPCS code that I mentioned, on them. And those claims may start crossing over as soon as July 25th. CMS will use its normal file transmission process to send an updated file to states with this new code.

States should take appropriate action to ensure they can process these claims. Any questions about anything that I just talked about, can be sent to

CMSMDR Operations at MDROperations@CMS.HHS.gov. Thank you very much. And now I can turn it over to (Jackie).

(Jackie Glaze): Thank you, (Kathy), for your update. And we also have time at the end of our discussion today to take questions, so we may have some questions later on. But next, our CMS team will provide guidance on the CAA 2023, the Medicaid and CHIP provisions. And so I'll now turn to you, Meg.

Meg Barry: Thanks, (Jackie). And thanks for going to the next slide. Since our main presentations today are about the provisions of the Consolidated Appropriations Act of 2023, we want to take this opportunity to remind you about the Medicaid and CHIP provisions in that bill. So this first slide describes Section 5101, which makes some funding adjustments for the territories. And the details are here for those for whom this is relevant. Let's go on to the next slide, please.

This slide describes the various coverage provisions in the CAA 2023. In Section 5111, CHIP funding was extended through fiscal year 2029. Section 5112 is the main topic of our call today, continuous eligibility. So more to come on that soon. Section 5113 made the option to extend postpartum coverage permanent. Previously, it expired in 2027. Section extended 5114 the money follows the person demonstrations through fiscal year 2027. And it provided some additional money for research, evaluation, and technical assistance related to that program. Next slide, please.

The next set of provisions Congress put under the heading mental health or behavioral health, although arguably they are much broader than that. Section requires 5121 states to provide certain services to eligible juveniles just before and just after a release from a public institution. This provision will also require states to align their coverage suspension policies and CHIP with

Medicaid. The provision will be effective in January 2025. And I know that there is a lot more to come on this provision. Next slide, please.

Section 5122 gives an option for states to receive federal financial participation to cover services provided to eligible juveniles or those in the former foster care children eligibility group who are pending disposition of charges. This provision is also effective in January of 2025. Section 5123 requires Medicaid and CHIP fee-for-service and managed care plans to publish public searchable provider network directories that are updated quarterly and must indicate whether the provider accepts telehealth. This provision will also be effective in July of 2025.

And finally, something that's just a requirement for CMS and not for you, Section 5124 requires us to issue guidance to states regarding crisis response services in Medicaid and CHIP and establish a technical assistance center to help state Medicaid and CHIP programs design, implement, or enhance their continuum of crisis response services. And it requires us to develop and update a publicly available compendium of best practices for the successful operation of a Medicaid and CHIP continuum of crisis response services.

Not mentioned on these slides are the unwinding reporting requirements and FVAP reduction for failure to meet those requirements, which Anna Bonelli will talk more about later in this call. And so with that, I am going to turn it over to Stacey Green to tell us more about the continuous eligibility requirements that's in Section 5112 of the CAA 2023.

Stacey Green: Thanks, Meg, and good afternoon, everyone. Next slide, please. I'm going to start our presentation today with a quick overview of continuous eligibility for children under the CAA, as Meg just highlighted. Next, I'll spend a little time talking about the existing CE state plan options and then move on to some of

the finer details of what CE will look like when it's mandatory. And lastly, I'll talk about submissions of CE related to Medicaid and CHIP spas.

The CAA makes amendments to Medicaid statute at 1902 E-12 and CHIP statute at 2107 E-1 to make it mandatory for all states to provide 12 months of CE for children under age 19 with limited exceptions. The effective date, as mentioned earlier, of this provision, is January 1, 2024. In terms of the (SPA) submission in Medicaid and CHIP, it's required for all states that will be newly implementing CE and for some states that already have CE. Next slide, please.

Since many states have experience with CE for kids, research on the impact of this policy is readily available. Today we're sharing just a few of the findings from the literature. The research has shown that children who are disenrolled for all or part of the year are more likely to have fair or poor healthcare status compared to children who have health insurance continuously throughout the year. We also know that guaranteeing ongoing coverage helps ensure that children can receive appropriate preventive and primary care as well as treatment for any health issues they experience.

Stable coverage also enables doctors to develop relationships with children and their parents, track health and development, and avoid expensive emergency room visits. CE has also been shown to reduce financial barriers to care for low-income families, to promote improved health outcomes, and to provide states with better tools to hold health plans accountable for quality care and improved health outcomes. Next slide, please.

Turning to the existing authority, CE for Children has been a longstanding state plan option in both Medicaid and CHIP. The statutory and regulatory citations that are listed here on this slide are just an easy point of reference for

states. I want to take a moment to flag an important point, though, which is that these regulations will continue to apply to mandatory CE in 2024 except where inconsistent with the CAA. For example, we think it's important to note that under the existing state plan options, states may provide CE to a subset of the Medicaid and CHIP population, such as to kids under age 19.

States may also provide CE for a period of less than 12 months. These options will no longer be permissible under the CAA. As of June of 2023, 22 states have implemented CE in both Medicaid and CHIP, and additional nine states have implemented CE in at least one program. The fact that we have a little over 30 states that have experience with implementing CE means that in addition to CMS, these states can serve as a valuable resource for other states newly implementing this provision in 2024. Next slide, please.

Under the existing state plan option, children determined eligible at application or during an annual renewal, remain eligible for a 12-month period regardless of most changes in circumstances, such as changes in income or household composition, loss of SSI for children that are eligible for Medicaid, or obtaining health insurance for children enrolled in CHIP. There are limited exceptions when a change in circumstance can result in termination of eligibility during a CE period under current Medicaid and CHIP regulations, such as when a child turns age 19 or ceases to be a resident of the state.

In addition to the examples that you're viewing on this slide, our existing Medicaid and CHIP regulations have exceptions for when there are requests for voluntary termination of eligibility, when the agency determines that eligibility was erroneously granted, and when a child dies. And for CHIP specifically, there are exceptions for when a child becomes eligible for Medicaid and a state option when a family has not paid a premium. And I'll talk more about these exceptions relative to the CAA statute in a few minutes.

Next slide, please.

Moving ahead to the CAA, we know that this legislation requires one year of CE for kids, but I want to take a moment to talk about who is eligible in more detail. For Medicaid, CE applies to all children under age 19 who are enrolled under the state plan in a mandatory or optional Medicaid eligibility group. The citation for this is 1902A-10A, which we're happy to share after the presentation, if helpful. So I think many of you are familiar with it.

For CHIP, mandatory CE applies to all targeted low-income children enrolled in a separate CHIP under the state plan. This includes targeted low-income children covered from conception to end of pregnancy, which is also known as the unborn option. States are also required to provide CE to children enrolled in Medicaid or CHIP under a Section 1115 demonstration. And as you can see from the language under the second bullet of this slide, the CAA explicitly includes exceptions to CE for children turning age 19 and those that are no longer state residents.

In addition, the legislation specifies that a child in CHIP who becomes Medicaid eligible and transfers to that program must remain in Medicaid for the duration of the 12-month period. Next slide, please. If you take a look at this slide, you can see that the CAA does not explicitly include the voluntary termination, erroneous eligibility, or death of child exceptions that are currently in Medicaid and CHIP regulations. But we want to highlight today that we consider these regulatory exceptions to be consistent with general program integrity principles. So states will very likely be expected to continue to apply these exceptions to CE.

In addition, the CAA does not include the current state option to consider failure to pay premiums and CHIP as an exception to CE. We consider this

exception to be different from the program integrity-related exceptions. Failure to pay premiums and CHIP can serve as a barrier to continuity of care for kids, and we do not consider it consistent with the intent of the CAA. So it's very likely that failure to pay premiums will not be permissible, a permissible exception to CE starting in January 2024.

We caveat this guidance around exceptions with the fact that these policies still need to work their way through our clearance process, which they're doing right now, before being finalized. Next slide, please. There's nothing in the CAA that changes current rules related to the start date of the CE period in Medicaid and CHIP. So nothing has changed on that front. So, with application, the CE period for new applicants begins on the effective date of eligibility. For Medicaid, it's the date of application.

For the first day of the month, the application was submitted depending on the option the state has elected. For CHIP, it's the date of application or another reasonable methodology, again, depending on date option. And at renewal, a new CE period begins for individuals whose eligibility is renewed at a periodic renewal. So the effective date rules related to renewals, are in Medicaid regulations at 435.916, and those are applied in CHIP at 457.343. Next slide, please.

Okay. Let's talk a bit about how the effective date of CE works for new applicants and existing enrollees. So at this point in the presentation you've heard me say many times that this provision is effective January 1, 2024. So because the CE period is based on the effective date of the child's last eligibility determination, and that could be either at initial application or the last renewal, children under age 19 currently enrolled in Medicaid and CHIP, when a state first implements CE will receive CE for the remainder of their eligibility period based on the date of their last determination.

This is important and will likely require eligibility system changes for some states. So let's go through an example. Let's say that (Mary)'s most recent determination of eligibility was completed in September 2023, and her current eligibility period began on October 1, 2023, effective January 1, 2024 the state must provide (Mary) with CE for the remainder of her 12-month eligibility period. So that would be through September 30, 2024. Of course, there's the caveat, unless she experiences one of the required exceptions to CE, that we discussed a few minutes ago, such as a change in residency. Next slide, please.

Okay. Let's talk about when a SPA is needed in Medicaid and CHIP. All states that are newly implementing CE for children in Medicaid and/or CHIP will need to submit a SPA. In addition, states that currently have CE will need to submit a SPA if they impose restrictions that are no longer permissible under the CAA, such as only applying CE to a subset of kids, such as children at an age younger than 19, where the CE period is shorter than 12 months. Or in the case of CHIP, if the state has an exception for nonpayment of premiums.

In order to meet the January 1, 2024 effective date, states will need to submit a SPA in Medicaid no later than March 31, 2024, and in CHIP no later than the end of the state fiscal year in which January 1, 2024 falls. We also just want to emphasize that we encourage states to adopt CE prior to the timeframes I just mentioned, so that we can provide any needed technical assistance in advance of the provision becoming mandatory. And if the state doesn't want to submit a SPA in advance we can still certainly provide TA in advance.

CMS is also planning to provide updated templates in both Medicaid and CHIP. I also want to mention there will be more to come on whether any additional action is needed for states that currently have CE and are already in

compliance with the CAA. Next slide please. Okay. Here are some of the key takeaways for states. Currency regulations will continue to apply to CE after January 1, 2024, as well as the effective date rule, unless inconsistent with the CAA.

As I just mentioned, when we say inconsistent we mean states that are, for example, only applying CE to a subset of kids shorter than 12 months. Or in the case of CHIP, a state that has an exception for nonpayment of premiums. SPA submission in Medicaid and CHIP, again, is required for all states that will be newly implementing CE, and for some states that already have CE. So we do encourage you to reach out to your Medicaid state lead or your CHIP project officer, with questions on SPA submissions.

CMS will be releasing more detailed guidance this year on the CAA. This guidance will contain information on what we talked about today. And in addition, it will discuss the relative to specific populations, such as children who are incarcerated and the from conception to end of pregnancy option in CHIP. So please stay tuned on that. I will now hand it over to Anna Bonelli. Thank you very much.

Anna Bonelli: Thanks. Hi. This is Anna Bonelli. I'm with the Financial Management Group. (Jackie), you can go to the next slide, please. So as you all just heard, the Consolidated Appropriations Act passed in December. It required states to report a number of data points related to unwinding. States were required to start submitting these data on April 1st. Starting July 1st, CMS is required to impose a penalty on states that don't submit these data timely. And that's what I'm going to focus on today.

Just to release guidance, we released a new Frequently Asked Questions on June 30th that reiterates information that we provided in previous guidance.

Specifically, all the data that states are required to report remain the same. States should keep using the same data reporting processes that they have already been using. They should be very familiar to states. CMS will collect the data using the processes that states have been using for many cases years, in some cases many months.

We're talking about TMSIS. That's the Transformed Medicaid Statistical Information System, the performance indicator data and unwinding data report, which also has been known as renewal data. So the FAQs also say more about timeliness. States must meet the deadlines associated with these different data reporting processes or make a good faith effort to do so. If any state thinks that they will have difficulty in meeting the deadline for these different data reporting processes, they should reach out to CMS as soon as possible via our unwinding mailbox.

So that's the mailbox we put on everything. It's CMSUnwindingSupport@CMS.HHS.gov. The FAQs also say a little more about the mechanics of the penalty. The penalty grows if states fail to report in multiple quarters. So for the first quarter, the penalty is a quarter of a percentage point of the state's default FMAP rate. So for those of you who like citations, that's the 1905B state-specific FMAP rate.

The penalty then grows by a quarter of a percentage point for each quarter that the state is not in compliance. And the maximum penalty is a full percentage point. If a state fails to meet the data submission requirements in one month during a quarter, the FMAP penalty will still apply to the entire quarter. Those are really the key takeaways from the FAQs, again, that we released on June 30th. But we are working on further guidance on this topic and plan to issue a rule in the fall. So with that, I will turn it back over to you, (Jackie).

(Jackie Glaze): Thank you, Anna, Stacey, and Meg, for your presentations today. We're ready to move into the state questions. So we ask that you begin submitting your questions through the chat function. If you have general questions or any questions about the presentation today, go ahead and put those in. And then we will follow by taking questions over the phone lines. So I'm looking now at a question we received, and it says, can you repeat the HCPCS J code CMS is using for LEQEMBI? So I think that one's for you, (Kathy). Thank you.

(Kathy Traugott): Oh, yes, I most certainly can. It is J0174.

(Jackie Glaze): Thank you, (Kathy). We received another question that says, will the FMAP reduction apply to the state Medicaid agency if the state-based exchange fails to submit reports timely? I think that was for you, Anna.

Anna Bonelli: Yes. Thank you for the question. That's something that we can talk about with each state as these issues come up. But it is true, and we spell out in the FAQs, that we will be using data from the state-based exchanges, as well as from the federal exchanges, in order to match that data to Medicaid data to produce information that's needed for the required reporting.

So it is important that all of the state-based exchanges continue to meet their obligations under the CAA to continue to report data, because yes, the FMAP penalty, you know, cannot be assessed against a federally-facilitated exchange, a or marketplace a state-based marketplace. So yes, any penalties that are incurred would be incurred on the Medicaid program.

(Jackie Glaze): Thank you, Anna. (Ted), I think we'll transition to the phone lines. I'm not seeing any additional questions through the chat line. So if you could provide instructions for registering their questions and then open the phone lines, please.

Coordinator: Yes. So the phone lines are now open for questions. If you would like to ask a question over the phone, please press star 1 and record your name. If you'd like to withdraw your question, press star 2. Thank you. And again, if you would like to ask a question over the phone, please press star 1 and record your name. I'm currently showing no phone questions at this time.

(Jackie Glaze): Thank you. And let us know if you do. We did receive one additional question. It says, will CE begin with each eligibility period when a renewal is completed? Stacey or Meg?

Woman: Sorry about that. Yes. The answer to that is yes, that is correct.

(Jackie Glaze): Thank you. The following question says, can you please provide the link to the FAQ of 6-30-2023? I guess we can follow up afterwards. Yes. Okay. And the slides will be available. We will post those, I believe it will be I think, within the next few days that the slides will be posted. But we do post them on Medicaid.gov. (Ted), can we switch to you one more time and see if there are any calls through the phone?

Coordinator: Yes. As a reminder, if you would like to ask a question over the phone, please press star 1 and record your name. Thank you. I'm showing no phone questions at this time.

(Jackie Glaze): Thank you. We did receive an additional question. It says, what is the difference between unwinding flexibility number 20 for review reconsideration? What is the difference for unwinding versus normal policy and state options? Let me know if you want me to read that one more time.

(Suzette): Hi. This is (Suzette). I'm pulling up - can you maybe repeat the question, (Jackie)?

(Jackie Glaze): Yes. It says, what is the difference between the unwinding flexibility number 20 for review reconsideration? What is the difference for unwinding versus normal policy and state options?

(Suzette): I'm pulling it up right now. Option 20, which is to reinstate eligibility effective on the individual's prior termination date for individuals who are disenrolled based on their procedural reason and are subsequently redetermined eligible during the 90-day reconsideration period. I think this option allows the state, during a reconsideration period, to make the effective date of the new eligibility period the date that they were terminated.

The difference is that using regular Medicaid rules, an individual who is terminated for procedural reasons, so for failure to return information at renewal, that person would be made eligible - if they return their information or are found eligible, would be made eligible prospectively. And then the state would use our retro rules at 435.915 to make that individual eligible in the three months prior to the date they are found eligible. Yes. They could use the retro rules to retro that person in the intervening period between when they were terminated and when they returned their renewal form.

And that is because during the reconsideration period, the return of a renewal form is considered a new application. So the reconsideration period allows

states to consider a renewal form, a renewal, a new application without requiring that the person submit a whole new full application.

(Jackie Glaze): Thank you. Okay. I'm not seeing any additional questions. (Ted), one more time, any questions that you're seeing through the phone lines?

Coordinator: I'm showing no phone questions at this time.

(Jackie Glaze): Okay. And I'm not seeing any additional questions either, so I think we will close early today. So I do want to thank our team for their presentations. Looking forward, the topics and invitations for our next call will be forthcoming. If you do have questions that come up before the next call, feel free to reach out to us, your state lead, 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: This concludes today's call. Thank you for your participation. You may disconnect at this time.

[End]