HHS-CMS-CMCS All-State Call
8/13/24
3:00 pm ET

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'll now turn the call over to Jackie Glaze. Thank you. 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 just be discussing excuse me. 3 important topics.
1st, Charlene Wong as senior advisor with the centers for disease control and prevention will provide a brief update on fall vaccines. We'd like to remind states about resources in the state Medicaid, children's health insurance program and basic health program vaccine toolkit released in February of this year.

The updated toolkit serves as a comprehensive compilation of vaccine policies, including related flexibilities and coverage and payment requirements and additional considerations states may make to enhance vaccine coverage and access including provider qualifications, immunization registries, and payment considerations.

Next, Kirsten Jensen, a division director in the Medicaid Benefits and Health Programs Group, will share an overview of the four walls provision that was

recently released within the 2025 Outpatient Prospective Payment System Notice of Proposed Rulemaking on July the 10th. And this NPRM CMS is proposing to amend the Medicaid Clinic Services Regulation to authorize federal reimbursement for services furnished outside the four walls of a freestanding clinic by IHS Tribal Clinics. In addition, at the state option, federal reimbursement would be available for services provided by behavioral health clinics and services provided by clinics located in rural areas outside the four walls of the clinic.

For clinics located in the rural areas, CMS is not proposing a specific definition of rural but is seeking public comment on different alternative definitions for consideration and final rulemaking. The public comment period ends on September the 9th. Lastly, Cassie Lagorio, a technical director in the Children's and Adult Health Programs Group, will share an overview of the proposed continuous eligibility provision in the same 2025 outpatient prospective payment system NPRM that was recently released on July the 10th.

As part of this rulemaking, CMS proposes updates to the Medicaid and CHIP regulations to codify the children's continuous eligibility requirements in the CAA 2023. Before we get started, I want to let folks know that we will be using the webinar platform to share slides today. If you are not already logged in, I'd suggest that you do so, so that you can see the slides for today's presentation.

You can also submit any questions you may have in the chat at any time during the presentation. With that, I'm pleased to introduce and turn things over to Charlene Wong from the CDC to get us started. Charlene?

Charlene Wong: Thank you so much, we appreciate the opportunity to be here. Our topic for

today is preparing for the fall winter respiratory illness season, and I wanted to share some key updates and information with this group of Medicaid leaders. Next slide, please. So starting with one question that we continue to get is, you know, how can we best talk about some of the latest information about why immunizing is so important? And, you know, based on research that we and our partners have done, the message that vaccines are the best defense against viruses that can cause serious illness is a great message to use.

And we have included on this slide that you all will have access to a couple of key stats that are really compelling and that we have found to be compelling when talking with patients, communities about why vaccinations are so important. They include that viruses cause - as you all know, many hospitalizations, including, for example, that RSV is the number one reason that babies are hospitalized in the U.S. In the second column, while we do know that there are some people who are at higher risk, we also cannot predict who is going to get severely ill from COVID, flu, and respiratory syncytial virus.

So, for example, while adults 65 plus are four times more likely to be hospitalized for any of these viruses than those under 65. We also see that half of children who are being hospitalized with COVID have no underlying conditions. I happen to be a primary care pediatrician and continue to hear folks say, well, but I don't think my patient, I don't think my child is at that high risk because they don't have any underlying condition. And again, just a reminder that we cannot predict who's going to get really sick with these viruses. And then finally, immunizations being our best defense, You can see here that COVID and flu vaccines cut the risk of hospitalization in half across all age groups, and our RSV vaccines, both for older adults and their 7-AB for babies and young children, are super, super effective at preventing that severe illness. Next slide, please.

So, the other top question that we get is, who should be getting which vaccines this 2024 to 2025 fall-winter respiratory season. We have created this image as an at a glance tool so folks can remember, understand, who should be getting these vaccines. In the first column for the 2024 to 2025 COVID-19 vaccine, still the same recommendation. Everyone 6 months and older should be recommended one of these vaccines, including pregnant folks. Same thing for the 2024 to 2025 influenza vaccine, everyone 6 months and older should be recommended to get 1 of these vaccines and for adults 65 plus, we do recommend if available the use of a higher dose or an adjuvant native flu vaccine for the increased protection.

In the final column, the RFV immunization products, let's start with infants and children. So, we have nirsevimab, which is recommended for all infants under 8 months of age, as well as for children who are 8 to 19 months old with risk factors. They should be getting a dose of the nirsevimab monoclonal antibody immunization. For most of the U.S. That would be between October and March. And that is for infants if their mom did not receive the maternal RSV vaccine. So, for maternal RSV vaccine, the recommendation is women who are between 32 and 36 weeks of gestational age, could get the maternal RSV vaccine. Reminder that this is the Pfizer or Abruzzo product only as the one that's the one recommended for pregnant people.

And administration for the maternal RSV vaccine should be between September and January in most of the continental U.S. Finally, let's talk about the older adult RSV vaccine. You all are likely aware this is where we've had an updated recommendation. So, while last year was shared decision-making, clinical decision-making, this year, we have a universal recommendation for all adults 75 plus should be recommended an older adult RSV vaccine, and an adult 60 to 74 years old who have certain risk factors should also get one

lifetime dose of the RSV vaccine.

On the next slide, we recently released the MMWR, oh, excuse me, I think, oh, sorry, my - okay. On the next slide, I want to go over the timing of when these vaccines are going to be available and when they are recommended to be administered. So, COVID-19 vaccines, we expect to be widely available in September recommendation is to administer as soon as the vaccine is available, though you can see they can be given at any time of the year to folks who are eligible for a COVID-19 vaccine.

For influenza, those vaccines are starting to be available in the market now reminder that the ideal timing for vaccination against flu is in the early fall. The older adult RSV vaccine is also already currently - they are already currently available in the market. And again, ideal to administer in the summer or early fall. And then for maternal RSV vaccine and nirsevimab, you can see there we expect these also to be available starting in September and October and to be administered in those time frames that I just reviewed.

Next slide. So, for the older adult RSV vaccine, we are also getting the question, you know, what are those health conditions that put people at higher risk for getting really sick with RSV? We recently released our MMWR that lists these conditions. They include in the top row some very common conditions that we see in folks ages 60 to 74 years old. So, chronic cardiovascular disease, severe obesity, diabetes with complications, chronic lung or respiratory disease. You can see many of the other body systems are identified here. Also, in the bottom row, anyone living in a nursing home, people who are immunocompromised. And did also want to flag, importantly, that bottom right box, other factors that providers determine would increase the risk of severe disease. So, for example, if they know that their patient is particularly frail, but maybe doesn't have one of these specific diagnoses.

Next slide. We also wanted to make this group aware that, you know, we are really encouraging and working to support vaccine providers to order immunizations for the respiratory season. On this slide, we have a new tool that we have made available that we collected data from all the different vaccine manufacturers to make it easier for providers to know how and when to order vaccines, also includes details on the different products like, you know, how do we need to store these vaccines, what are the return policies for unused product. And this is really in service of wanting to encourage and support more practices in ordering and offering immunizations in their clinics, because we know that that is one way that we know works to increase protection from these vaccinations.

Next slide. We also wanted to share some updates on the Vaccines for Children Program. Again, this has been a great partnership between CDC and Medicaid programs. The one thing I wanted to highlight here is one of our focus areas for this year is increasing access to nirsevimab in birthing hospitals. Obvious benefit here is immunizing newborns before they are discharged from the hospital. It's such a critical opportunity to protect the most vulnerable infants, because the smaller, younger the babies, the higher they are at risk of getting very sick and being hospitalized with RSV.

Currently, we have about 25% or a quarter of birthing hospitals are enrolled in VFC, and so the opportunity here is we wanted to make sure that this group of Medicaid leaders is aware that VFC does have a program for specialty providers if approved within your jurisdiction's VFC program, meaning that in these programs, they only are required to offer their 7-Ab and hepatitis B vaccine because those are the ones that are recommended at birth, as opposed to needing to offer all of the ACIP recommended vaccines. The team has worked to make enrolling easier, doing things like virtual enrollment,

allowing a vaccine order replacement model, as well as noting here that VFC providers are not currently required to meet the private inventory requirement for COVID-19 vaccine and or nirsevimab during this respiratory season, but note that those will go back into effect August of 2025.

Next slide. We also wanted to highlight the importance of pharmacies. Again, I'm sure that many of you all are quite aware of this, but wanted us to remind everyone that particularly for the fall winter respiratory vaccines, It is very common for adults, as well as children, but particularly adults over 60% of getting their vaccines in pharmacies each fall winter. They're very convenient. Over 90% of U.S. residents live close to a pharmacy. There are obviously the extended hours.

We also know that there are some variability as well as opportunities when it comes to pharmacies, opportunities for pharmacies to participate in VFC, variability in what pharmacists' scope of practice is, and we'll just share with this group is we have been engaging with pharmacy associations. One of the things that we continue to hear from them are questions or concerns about reimbursement in pharmacies and, you know, just wanting to take additional steps so that they can offer vaccines to more of the patients that come into their pharmacies. For those of you who are already working with pharmacies, another thing that they have asked is for all of us to help remind patients that they should be checking whether the pharmacy to your provider, they are going to get their vaccine at is an in-network provider or pharmacy.

Next slide. Also wanted to flag, as you all may be aware, that COVID-19, right now we are seeing a little bit of the summer wave that we have gotten used to over the last several years. So, we are seeing emergency department visits increasing in the U.S. right now. And this is a great opportunity as my last slide, Next slide, to remind you all also about the importance of treatment,

we continue to see underutilization of some of our really great treatment tools like Paxlovid. And for our clinicians, some of the things that we are continuing to remind them of, for example, with Paxlovid is that there is not a requirement to do lab testing for most patients. And also, there are some drug-drug interactions. And it's very possible to adjust other medications, like taking a pause on a patient's statin so they can take Paxlovid to keep them from getting very sick. This is particularly important, again, for those patients, folks that we see who are at higher risk for severe COVID-19, and you can see, again, those risk factors in the blue box.

Thank you so much. I think that was my last slide, and I will turn it over - oh, I'm sorry, one last one. I did want to flag that we do have a wonderful campaign that we'll be kicking off later this month. It's called Risk Less, Do More. You'll hopefully see some ads. There'll be social media, other items, communications items. And you can see the audiences targeted there include older adults, particularly folks who are living in long term care facilities and health navigators, so the people who help influence the decisions made by particularly other older adults. And I think with that, these are some opportunities and have put some key resources here on this slide, and really thinking about some of those coverage and reimbursement policies that you all are always thinking about to increase access to vaccines and treatment. And with that, I will turn it over to Kirsten. Thank you.

Kirsten Jensen: Thank you. Hi, this is Kirsten Jensen, and I'll be talking today about the four walls provision related to our clinic benefits and some provisions that are in the 2025 Outpatient Prospective Payment System, or OPPS, Notice of Proposed Rulemaking. I'd like to note, as mentioned on this slide, that the policies presented in this deck are not final and are subject to change in the final rule. All comments must be received using the instructions in the published Federal Register document, which is the 89FR59186, and

comments must be received by September 9, 2024. So, given that this is a notice of proposed rulemaking, I will be sticking to the language in this slide deck fairly closely. Next slide, please.

Some background about the clinic services benefits for those that don't know, it is an optional benefit category. The Clinic Services Benefit is defined as Section 1905A9 of the Social Security Act with implementing regulations at 42 CFR part 440.90. The Clinic Services Benefit is a separate benefit category from Federally Qualified Health Centers, or FQHCs, and Rural Health Clinics, or RHCs, and outpatient hospital services benefit categories. Each of these benefit categories are similar but are distinct and discreet in the Medicaid benefit package. Under the current regulation, clinic services are defined as preventive, diagnostic, therapeutic, rehabilitative, or palliative services furnished by a facility that is not part of a hospital, but is organized and operated to provide medical care to outpatients. The services must be furnished by or under the direction of a physician, and they must, in the current clinic benefit, they must be furnished within the four walls of the clinic, except for services furnished to an individual who is unhoused.

Next slide, please. In 1987, Congress amended the clinic benefit to provide the exception to the four walls requirement for individuals who are unhoused. In rulemaking that we undertook in 1991, CMS explained that clinic services have always been limited to the four walls of the clinic or a satellite location, and the exception added by Congress for individuals who are unhoused represents an exception to the four walls requirement. CMS, at that time, interpreted this legislative change as ratifying that the four walls requirement - I'm sorry, CMS interpreted this legislative change as ratifying the four walls requirement by establishing an explicit exception for individuals who are unhoused.

Next slide, please. In 2017, CMS discovered that Indian Health Service and tribal clinics were providing services outside of the four walls, including to individuals to whom the existing statutory and regulatory exception does not apply, so people who were not only unhoused, and that states were paying for these services at clinic services rates. So, in a 2017 FAQ document, CMS announced a 4-year grace period to January 30th of 2021 to allow states and IHS tribal clinics to come into compliance with the four walls requirement. And subsequently, CMS issued a different additional information bulletin extending the grace period in two in 2021 and one in 2023. And right now, the grace period is currently scheduled to end on February 11th of 2025.

Next slide, please. During this time, CMS has heard from tribes, the Tribal Technical Advisory Group, or TTAG, and the HHS Secretary's Tribal Advisory Committee, or STAC, that the four walls requirement will create barriers in access for beneficiaries to receive care from IHS and tribal clinics after the grace period ends. Tribes, the TTAG, and STAC have asked CMS to eliminate the four-walls requirement for IHS and tribal clinics, and CMS has also received requests from some states to allow exceptions to the four walls requirement for clinics that serve vulnerable populations such as behavioral health clinics.

Next slide, please. So, what are the changes that we are proposing in this Notice of Proposed Rulemaking? CMS has included a proposal to add additional exceptions to the Medicaid clinic four walls requirement. CMS is proposing a mandatory exception to the four walls requirement for IHS and tribal clinics, and this applies in states that have IHS and tribal clinics, and optional exceptions for behavioral health clinics and clinics located in rural areas. And I'll go through some details in just a moment on these. Again, comments are due September 9th, and we are proposing these exceptions after hearing from tribes, the TTAG, STAC, other interested parties. We have three

executive orders that we are fulfilling with these changes, and we also want to be consistent with our strategies, goals, and objectives to advance health equity and improve health care access for tribal behavioral health and rural populations.

Next slide, please So, now I will discuss the criteria used to determine which population served by certain clinics have similar health care access issues as the unhoused population and therefore should be exempt from the four walls requirement. CMS continues to believe that the statute does not authorize a broad exception to the four walls requirement that have no relationship to the current exception or that we have authority to completely eliminate the four walls requirement.

We are reinterpreting Section 1905A9 of the Act, which is the clinic statute, as permitting additional exceptions to the four walls requirement for populations served by clinics if those populations have similar healthcare access issues as the unhoused population. The exceptions outlined in the proposed rule follow four criteria that mirror the needs and barriers to access experienced by individuals who are unhoused. So, those four criteria are, number one, the population experiences high rates of behavioral health diagnoses or difficulty accessing behavioral health services. The population experiences issues accessing services due to lack of transportation.

Next slide, please. The third criterion, the population experiences a historical mistrust of the healthcare system and the population experiences high rates of poor health outcomes and mortality. So, if finalized, the exceptions would authorize states to pay for services furnished under the exceptions as facility-based clinic services payment.

Next slide please so the 1st this exception is related to IHS and tribal clinics.

This exception would be mandatory for all states that cover the clinic services benefit. It would only apply to clinics that are owned and operated by IHS. Clinics that are owned by IHS and tribally operated is authorized by the Indian Self-Determination and Education Assistance Act or by tribes and tribal organizations as authorized under that same act. The exception would apply to any Medicaid beneficiary who receives services from an IHS or tribal clinic. CMS is not proposing to include facilities operated by urban Indian organizations in this proposed exception.

Next slide, we are proposing this exception based on advice and input received through tribal consultation and evidence that the population served by IHS tribal clinics tends to meet the four criteria more than any other population. CMS is proposing that the IHS tribal clinics would be a proxy for the patient population they serve because the entire patient population is likely to meet some or all of the four criteria that I just recently described, and they serve a clearly identifiable group of Medicaid beneficiaries under IHS statute and regulations.

Next slide, please. The second clinic exception will be for behavioral health clinics. This exception would be optional for states that cover the clinic service benefit. It would apply to clinics that are primarily organized for the care and treatment of outpatients with behavioral health disorders, defining behavioral health as mental health and substance use disorders. It would apply to any services furnished outside the four walls of the clinic by the behavioral health clinic, and it could include behavioral health clinic types recognized nationally such as community mental health centers and other behavioral health clinics organized in a state. If this proposal is finalized as described, states that choose to adopt this exception would describe the types of behavioral health clinics in their Medicaid state plan, and, you know, that'll be something that comes later once we finalize the particulars of this rule.

So, behavioral health clinics, we are proposing this exception for behavioral health clinics based on evidence that indicate that an exception to the four walls requirement might be useful based on state specific circumstances as these clinics serve a patient population that they'd be more likely than other groups to meet the four criteria I described earlier. CMS is proposing that the behavioral health clinics would be a proxy for the patient population they serve because clinic services we believe it would be two operationally burdensome to require that to qualify for the exception, clinic services be provided specifically to individuals with a behavioral health disorder. And it's our understanding that behavioral health clinics generally serve a patient population that consists primarily of individuals with behavioral health disorders.

Next slide, please. The third clinic type that we are proposing to add the exception to the four walls requirements for are clinics located in rural areas. So these are clinics operating under our clinic benefits that are located in rural areas. And we are distinguishing these from our rural health clinics that are covered as their own separate benefit category. And this type of clinic also would be optional for states that cover the clinic service benefits to elect to allow them to be able to provide services outside the four walls.

Next slide, please. Again, here, we're proposing that exception based on evidence that indicates that the exception to the four walls requirement could be warranted based on state-specific circumstances for clinics located in rural areas. Because these clinics might primarily serve a patient population that might be more likely than other groups to meet more of the four criteria that I described earlier, CMS is proposing that clinics located in the rural areas would be a proxy for the population that they serve. And it's mostly because clinics in rural areas likely are generally serving a patient population that

consists primarily of individuals who reside in rural areas.

Next slide please. As we were doing our research we uncovered that there are lots of definitions, federal and state definitions of rural, and there's no single definition that precisely identifies all rural areas. So, therefore, we did not include a definition of rural in the proposed rule, but we are seeking comments on several options here to try to get a sense of what - you know, what makes sense for defining rural.

Next slide please. We are also making some - we're proposing to make some changes in codifying our regulation text and in terms of making our long-standing interpretation of the existing clinic regulation that certain components of the benefit are mandatory for states that cover the benefit. We're deleting eligible in this particular context, and we are - as we've just discussed, we're proposing to make the IHS tribal clinic exception to the four walls requirement mandatory and the exceptions for behavioral health clinics and clinics located in rural areas as optional.

Next slide, please. This is just a little bit more detail here about why we chose to make those exceptions, and CMS is not proposing any additional exceptions to the Clinic Services four walls requirement. And again, we welcome comments on our proposed rule. Comments are due September 9th, and please submit those comments following the instructions in the Federal Register Notice. So, with that, I will turn it over to Cassie.

Cassie Lagorio: Great, thank you. Good afternoon, everyone. I will be sharing a brief overview of the Medicaid and CHIP Continuous Eligibility Policy changes CMS is proposing through the Medicare Outpatient Prospective Payment System, or OPPS, Notice of Proposed Rulemaking.

Next slide, please. The changes we are proposing are in response to the Consolidated Appropriations Act of 2023, or the CAA 2023. Prior to the CAA 2023, states had the option to provide up to 12 months continuous eligibility to children enrolled in Medicaid & CHIP. States also had the option to limit continuous eligibility to a time period of less than 12 months or to limit continuous eligibility to a subgroup of Medicaid or CHIP enrollees. However, the CAA 2023 made this previously optional continuous eligibility policy mandatory effective January 1 of 2024. The CAA 2023 also eliminated the options to provide continuous eligibility to only a subgroup of enrollees or for a time period of less than 12 months.

Therefore, through the OPPS proposed rule, we are proposing updates to the Medicaid and CHIP regulations to codify the requirements of the CAA 2023 related to continuous eligibility by first requiring that states provide 12-month CE under the state plan or waiver of a state plan for children enrolled in Medicaid & CHIP, two, removing the option to limit CE to a time period of less than 12 months or to a subgroup of Medicaid or CHIP enrollees, and three, for CHIP, we are proposing to remove the option to disenroll children during the CE period for failure to pay premiums. Thanks, everyone, and I will turn it back to Jackie Glaze.

Jackie Glaze: Thank you, Cassie, for your update. So, we're now ready to take state's questions. So, we'll begin with the chat function. So, please begin submitting your questions now, and then we'll follow by taking your questions over the phone lines. So I'm not seeing any questions at this point. So, I'll turn to you (Krista) and we'll see if we get some questions. Kirsta, no questions so far?

(Krista): I'm not seeing any questions in the chat no.

Jackie Glaze: So, why don't we start with the phone line, so we'll see if we can get some

questions there. So, (Ted), if you could please provide instructions for how to register the questions, and if you can open the phone lines, please.

(Ted): Yes. 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. 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.

Jackie Glaze: Okay. (Ted), no questions for the phone lines?

(Ted): I'm showing no questions at this time.

Jackie Glaze: Thank you, thank you. And (Krista), I'll check back with you. I'm not seeing any, are you?

(Krista): I'm not. No. Jackie.

Jackie Glaze: I think I just saw one question for you.

(Krista): I did just see one come through. Is there an expected date to codify former foster care updates due to the Support Act? I'm not sure that we have the right folks on the line to answer that question, (Megan), but I can take note of it and we can circle back.

Sarah Litchman Spector: Sorry, (Krista), this Sarah Litchman Spector. Can you repeat the question?

(Krista): The question is, is there an expected date to codify former foster care updates due to the Support Act?

Sarah Litchman Spector: I think we don't have a particular date for rulemaking on that issue right now. This is Sarah Lichtman Spector from the Division of Medicaid Eligibility Policy.

(Krista): Okay. Great. One more comment from that same person, which I will read here is, I believe it would be beneficial to define any state for FSC.

Sarah Litchman Spector: Okay. This is Sarah. Thank you for that comment. I appreciate that.

(Krista): All right. I'm not seeing any additional questions in the chat at this time. If folks have additional questions, feel free to type them in.

Jackie Glaze: Thank you, Kirsten. So, I'll circle back to you, (Ted), if you could again provide instructions once again and open the phone line.

(Ted): Yes. As a reminder to ask a question over the phone, please press star one and record your name. Thank you. And I'm currently showing no phone questions at this time.

Jackie Glaze: Thank you, Ted. So, back to you, (Krista). I believe there's one additional question.

(Krista): Yes. That's right. We did see one more come in. Is there any consideration about adding clinics that serve individuals with developmental disabilities in the four walls exception?

Kirsten Jensen: This is Kirsten, we have not considered those types of clinics for inclusion in the proposed rule but again, the comment period is open so, please follow the instruction in the Federal Register Notice if you'd like to provide a comment.

Jackie Glaze: Thank you, Kirsten. We are going to wait another couple minutes and see if we receive any additional questions, and then we'll just probably wrap up early today.

(Ted): As a reminder, to ask a question over the phone, please press star 1.

Jackie Glaze: (Ted) no additional questions on your end?

(Ted): I'm showing currently no phone questions.

Jackie Glaze: Okay. And I'm not seeing any questions. (Krista), correct me if there is anything.

(Krista): None here either.

Jackie Glaze: Okay. So, we're going to wrap up then. So, I do want to thank you all and again thank the team for their discussion and presentations today. Our next call will be next month so we will provide the logistics for that. If you do have any questions that come up before the next call, please still reach out to us, your state leads, or bring any questions to the next call. So, we do thank you for joining and we hope everyone has a great afternoon. Thank you.

(Ted): This concludes today's call. Thank you for your participation. You may disconnect at this time. Speakers, please stand by.

END