Centers for Medicare & Medicaid Services
Medicaid &CHIP All State Call
November 9, 2021

3:00 pm ET

Coordinator: Welcome and thank you for standing by. At this time, all participant lines have been placed in a listen-only mode. After today's presentation, you may ask questions and you may do so at that time by pressing star then 1. Today's conference call is also being recorded. If you have any objections to this, you may disconnect at this time. Now, I would like to turn the call over to your host for today, Ms. (Jackie Glaze). Ms. (Glaze), you may begin when ready?

Jackie Glaze: Thank you and good afternoon and welcome everyone to today's All State Call-In Webinar. I'll now turn to Anne Marie Costello, our Deputy Center Director, and she will provide highlights for today's discussion. Anne Marie?

Anne Marie Costello: Thanks, (Jackie), and hello, everyone, and welcome to today's all-state call. We have a couple of special guests joining us on today's call. First, we'll be joined by Becca Siegel from the Department of Health and Human Services. We can do this COVID 19 Public Education campaign, who will share the latest research about pediatric vaccine confidence.

After Becca's presentation, we'll open a few minutes taking your questions for Becca. Then we'll hear from Dr. Lee A. Fleisher, the Director of CMS' Center for Clinical Standards and Quality. Dr. Fleisher will provide an overview of a new emergency regulation issued on November 4th that requires COVID-19 vaccination of eligible staff at healthcare facilities that participate in the Medicare and Medicaid program.

After Dr. Fleisher's presentation, we'll open the lines to your questions on the new vaccine requirements or any other topic. We'll use the Webinar for both

presentation on today's call. So if you're not logged in to the Webinar platform, I suggest you do so now.

But before we jump into today's presentations, I wanted to give one update on the maintenance of effort requirements in Section 9817 of the American Rescue Plan in response to some questions we received from states. As outlined in the State Medicaid Director Letter published on May 13, 2021, CMS expects states to demonstrate compliance with Section 9817 of the American Rescue Plan beginning April 1, 2021, and state funds equivalent to the amount of federal funds attributable to the increased FMAP are fully expended.

To demonstrate compliance with the requirement not to supplant existing state funds expended for Medicaid Home and Community-Based services, states must not impose stricter eligibility standards, methodologies or procedures for home and community-based services programs and services that’s in place from April 1, 2021 to the recovered HCBS services, including the services themselves and the amount, duration and scope of those services in effect on April 1, 2021 and maintain HCBS provided payments at a rate no less than those in place as of April 1, 2021.

Recently, CMS as you see some questions in states on implementing the maintenance of effort requirements in a managed care delivery system to provide some general guidance.

Specifically, some states have asked if the MOB requirements require a state to implement state directed payment. We wanted to clarify today that a contractual requirement on a managed care plan, specifically the maintenance of effort to Section 9817 purposes is not a state directed payment because it is statutorily required.

Regulations of 42 CFR, 4386 explicitly clarified that the state may not direct managed care plans expenditures under the contract, except as specified in its specific provision of Title 19. However, states that seek to require the managed care plan to increase HCBS have provider payments, such as with state funds equivalent to the amount of federal funds attributable to increased FMAP. My associates the federal requirement for state directed payments and according to the regulations at 42 CFR 4386c, including prior approval as required. And this is all outlined in the State Medicaid Director Letter published in May.

I know we just gave you with a lot, so if you have questions, please email our safe directed payments mailbox at statedirectedpayments@cms.hhs.gov for technical assistance. As a reminder, states providing an assurance of the maintenance of aftercare compliance when they submitted their initial HCBS send the plan projection in narrative.

To managed care program monitoring, states have the same obligation to serve compliance with the maintenance of effort as they do for all of the managed care requirements. Additionally, as if all requirements of a state imposes on managed care plan, any (MOB) requirements must be documented in the Managed Care Plan contract and submitted to CMS for review and approval.

With that, I'll turn things over to Becca to start her presentation. Becca?

Becca Siegel: Thanks so much, and thanks all for letting me join. I want to just - my name is Becca Siegel. I am a Senior Adviser on the HHS Public Education Campaigns for Vaccine Confidence, and I work on strategy, research, data, all of those pieces.

I wanted to share what we've learned over the past many months of research on talking about pediatric vaccines, who is sort of movable on hearing more about pediatric vaccines? What we can say to be most persuasive.

So I'll just start with sort of where things stand now and what we've found from the research. The first thing is that parents are cautious about this and, you know, we have a lot of work to do, which I'm sure is not a surprise to anyone on this call. Just about a third of parents of children in this newly eligible age group, 5 to 11 are sort of ready to run out the door and get their kids vaccinated right away.

Now that has moved somewhat, but it's certainly much, much less than the confidence rate among adults. You know, importantly here we're talking about vaccinated adults who are hesitant to get their 5 to 11-year-old vaccinated. So that's just an important thing to note.

These are people who are not generally skeptical of the vaccine or on vaccines generally, but are a bit hesitant for their child. The good news is these numbers are sort of what we're used to seeing when we make a vaccine available to a new group.

So this is the rate that we saw with parents of those 12 to 17 and frankly, with adults in general before the vaccine was available. So we know that opinion can move on this, but we're in a really important time because this is where a lot of people are making up their minds.

About a third of parents are persuadable, which is a massive number, and not too many parents are sort of strongly opposed to getting their child vaccinated, which is also very important. You know, one in four is not great, but all things

considered, given that about a third are ready to go right now, one in four is not bad and we obviously can do more to move that.

The thing that I would say that is sort of unique to this audience and this work is that short and long term side effects are sort of the beginning and end of concerns for parents. That's it. That is what concerns parents. And so when we think about how we address and talk about this vaccine, that has to be at the forefront.

The other thing I'll just say on the research is that we know parents are sort of most eager to get their kids vaccinated at their child's doctor's office. But as many on the call know, that's sort of not possible to do at scale and at speed to only get kids vaccinated at their pediatrician now because many kids don't have doctors.

So what we want to do here is expand the pool of places where parents trust and are willing to get their child vaccinated to include pharmacies, hospitals, health clinics, big community sites, schools, all of those other places where we can reach children.

So if we go to the next slide, this sort of is when we look at all of that research. What that leads us to is sort of this messaging framework, which is that we need to sort of do two things at once. Parents are weighing the pros and cons of getting their child vaccinated, and our argument for them is that the pros outweigh the cons.

When it comes to their child's safety, COVID-19 is a much greater threat than the vaccine. Now, I want to be very clear this is - this language itself is not necessarily the message we want to use. That sort of implies there's a threat of the vaccine, which we don't want to do, but broadly speaking, we do want to

acknowledge that parents have these safety concerns and we want to make them feel safe and make them feel comfortable and explain all of the information about the vaccine, you know, and the side effects and the long term studies and all the testing.

But we also want to talk about the benefits of the vaccine as we do that that COVID-19 is really risky for children that we don't know the long term side effects of COVID-19. So we're sort of doing both things at once.

The other thing I'll note is in terms of what to address proactively and what to sort of address when asked, because they don't want to give airtime to some of the sort of misconceptions that are out there. We don't want to give them additional airtime if we don't need to. But certainly there are, unlike previous, as mentioned, previous campaigns being parents, that is their concern is vaccine safety.

So things like the long term side effects, testing, the short term side effects that, you know, or the reaction that an adult might have some vaccine may be too much for a child. All those things are important for us to address head on.

We have some materials, I just mentioned this now. We have lots of materials on this, on how to address these things on our We Can Do This Website right at the top. So all of this is sort of written down. The final thing I'll say is just about sort of tone and this, obviously, this has been the case the whole time, but this is an especially important time to show empathy to parents.

We know that this is a very complex decision and we want to show that we are being extremely transparent and will answer any questions, stay in the room until all of their questions are answered. So that's sort of the tone.

On the operational side, like how do we actually get this message out? The first important thing is we want to expand the pool of people that parents trust on this issue. So of course, the most trustworthy person many parents cite is their child's doctor. But as mentioned, not every child has a doctor. And that's sort of too much burden to put on this one set of providers, so we have, you know, we need them to do a lot. But we want to encourage providers at any place where a child can access care, whether that's a doctor's office or the YMCA or a school.

Any place where there are people caring for children. We want them to also provide this pro-vaccine messaging.

And then when we're thinking about outreach, we are trying to sort of replicate what kind of conversation a parent might have with a doctor if they have one. So that means getting fresh faces, getting pediatricians out there, non-governmental doctors, all these folks who can sort of say this is the conversation that I'm having with my patients now so that everyone gets to watch it.

The final thing I will say is that, you know, there is a small amount of work to do to all always to increase access, to let people know about where the vaccine is available, that it is available at no cost. All of those things but I will note, you know, for this group, most of these parents are themselves vaccinated, so they've successfully figured out how to get the vaccine once. So it's a little bit less on access and more on persuasion for them.

On the next - the next slide sort of goes through who then specifically we are talking about here and I don't want to - I want to be clear, these are not the only people who are important to get vaccinated, of course, but these are the

people who right now we can have the most impact on their decisions. You know, we as messengers.

So the most important thing to sort of take away here is when we're talking about target audiences for outreach, we are mostly talking about parents who themselves are vaccinated. As mentioned before, nearly half of vaccinated parents are hesitant to get their 5 to 11-year-old vaccinated.

That's a huge audience of people who again were successfully and safely vaccinated themselves and generally believe in vaccines. Their children are vaccinated for other - with other routine vaccines. So this is the group who is most persuadable.

Now unvaccinated parents, you know, that is obviously going to be an important group. It's not one that we have historically been the best messengers for. That doesn't mean we're not working to make - to get messages out there to this group, but we are not always the best messenger.

So we're really focused on this movable group, which tend to be the sort of half of parents who themselves were most skeptical but then did get vaccinated. There's a few groups that over indexed these demographics. The over index in this group, mothers, those without college degrees, Latino parents, lower income parents most likely to be part of this audience.

But as you can imagine, when we're talking about half of vaccinated parents, that's a massive audience. So they are in every media market, every county, every city, every state they are in every demographic, urban, little suburban, all groups are represented here. So it really is a broad audience.

I want to drill down on just a subset of this audience that we have a particular

duty to and can have a particular impact on, which is parents without easy access to medical services. And we've been focusing on this group, of course, the whole time. But this is particularly important for pediatric vaccines.

From what we've seen in the research, we know that these parents are most concerned about vaccine safety for their children. They have the least - they report that they don't have a person they can trust to get information on the vaccine or a place they trust where they can get their kid vaccinated. But they also are most worried of any group about their children getting COVID.

So the pros for this group are really high, and the cons are really high. So it's a group that doesn't have the answers to these questions, and we need to do particular work to reach out to this group specifically.

The final thing I'll just say on audiences for our work and I think most work we are talking about parents here. When we're talking about 5 to 11, we are not reaching out to children directly; for older adolescents, we are. But we're talking about how do we reach parents here?

Okay, so then the final slide is just sort of our takeaway message that we have found for testing and this is sort of what we're using for our outreach. And it's very simple. It's that the COVID-19 vaccine is the best way to keep your child safe. The long term effects of COVID can be very serious. We don't know all of them.

The common side effects of the COVID vaccine are a sore arm. So when you're thinking about the pros and cons, you're - the pros of getting vaccinated outweigh the cons, especially with the Delta variant with the risks that COVID-19 poses to children right now.

The other thing that's useful to say is that and actually I'll just go back to those briefly, you know, there's - we tested many other messages here. We've tested things like this is the best way to keep your kid in school and have them play with their friends. We've tested this is the best way to keep your community safe, to keep your family safe.

The standard for parents is too high for those of messages, frankly. This is about over - this is about the safety of their child, right? They'll say, "Oh yes, I think it's important to protect the community, but not at the risk of my child. I think it's important for kids to be in school, but not at the risk of my child."

So we're really talking about safety here, and I want to just be clear that some of those other messages, which at first glance seemed like they would make sense, did not really show to be effective. So this is the one that really is important.

The other thing that has worked, I'll note, is that, you know, these are people for the most part who are not skeptical of getting their children other vaccines. So when we talk about how this vaccine is like other vaccines, that can be really helpful.

And then the final thing is you always want to be empathetic. So if you have any questions, we are here to answer them.

So that is it for me, but I am happy to take any questions. (Jackie), I will turn it back over to you if there are any questions.

(Jackie Glaze): Thank you, Becca, so much for your presentation. So we would like to take a few minutes to take any questions you may have for Becca on the information

she shared today? So we'll start with the chat function. So if you'd like to go ahead and answer any questions and then we can move to the phone lines and then we'll move on to the next presentation, so we'll see if we receive a couple of questions.

Coordinator: For phone questions, please press star then 1 and record your name at the prompt.

(Jackie Glaze): Operator, are you seeing any questions in the queue?

Coordinator: We have no phone questions that have come in.

(Jackie Glaze): Okay, and then I'm not seeing any questions in the chat, so we will certainly have time at the end of the next presentation, so if others have questions, we can certainly take them at that time.

So now we'll move to Dr. Lee Fleischer. He's the Director of the Center for Clinical Standards and Quality, and he will provide an overview of the new vaccine regulations. So, Dr. Fleisher, I will now turn to you.

Lee Fleisher: Thank you so much. Good afternoon, everyone, and thank you for inviting myself and my team to today's call to discuss the CMS omnibus COVID-19 healthcare staff vaccination rule.

We recognize that this requirement may not impact you directly, but it could affect the healthcare facilities within your state. I want to start by acknowledging that patient safety is the foremost priority of CMS. This regulation and the requirements within promote this system-wide approach to protecting anyone seeking care by ensuring that healthcare staff are vaccinated for COVID-19.

I also note that the CMS role was part of a whole government approach and coordinated with several of our other requirements you've seen released recently. Importantly, and I'll talk more about this momentarily, is that facilities regulated by CMS should look to our rule first.

Finally, we want to make sure that everyone understands the rules prior to some of the key deadlines we'll discuss shortly. That's why we are taking the opportunity to speak with you all directly today and we are hosting a second national stakeholder call tomorrow at 3:30 PM for additional information if facilities in your state are interested.

Next slide. The staff vaccination requirements apply to the Medicare and Medicaid Services certified facilities that are regulated under the foundational Medicare health and safety standards known as the conditions of participation or COPs, the conditions for coverage or the requirements for participation. The COPs, conditions for coverage, and requirements for participation were established by CMS to protect individuals receiving healthcare services from Medicare and Medicaid Services' five facilities.

As we've discussed to this point, patient safety is a fundamental principle to this regulation, and protecting individuals from COVID 19 across a variety of healthcare settings is the most important factor. The COPs help us ensure these protections and if facilities want to participate in the Medicare and Medicaid programs, they must abide by the COPs.

You see on the screen the 15 provider and supplier types regulated within this regulation. There are certain provider and supplier types that are not included in the staff vaccination requirements, including religious, non-medical

healthcare institutions, organ procurement organizations or OPOs and portable X-ray suppliers.

And could you go to the next slide, please? For OPOs and portable X-ray suppliers, both of these entities likely have staff who are indirectly included in this vaccination requirement who service agreements with applicable facilities. Additionally, CMS statutory authority does not extend to some other kinds of facilities like assisted living facilities, group homes and physician offices.

Again, these requirements only apply to facilities regulated under the COPs. This is a key element to remember when determining whether the staff vaccination requirements apply to a facility within your state. We'll talk about staff who made work between settings and our expectations based on the regulation momentarily.

While I've mentioned that authority does not extend to assisted living group homes, I'll also note, given the interest on the line that entities like Medicaid home care services, home and community-based services and schools receiving Medicaid funding are not included in this regulation as we do not regulate these under the conditions of participation.

Next slide. There are three basic requirements that facilities must complete. They must have a processor plan for vaccinating all eligible staff. That is to say, those who do not qualify for a medical or religious exemption or are considered full-time health workers, which we'll discuss shortly. They must have a process or plan for providing exemptions and accommodation for those who are exempt.

Accommodations could include, but are not limited to, testing, source control,

physical distancing, and they must have a process or plan for tracking and documenting staff vaccination.

Next slide. Great. The regulation establishes two important phases. Phase one requires that within 30 days after the regulations published or by December 6, 2021 facilities have all processes and plans in place for vaccinating staff, providing exemptions and tracking staff vaccinations. It also requires that staff at all healthcare facilities included within the regulation must have received in a minimum the first dose of a primary series or a single dose COVID-19 vaccine prior to staff providing any care, treatment or other services for this facility and or its patients.

And Phase 2 requires that within 60 days after the regulation is published or by January 4, 2022, staff must have received the shots needed to be fully vaccinated, with the exception of those who have been granted exemptions, of course, from the COVID-19 vaccine, for those staff and for whom the COVID-19 vaccination must be temporarily delayed, as recommended by the CDC.

We believe the 30- and 60-day timeframes are reasonable and allow for facilities to implement staff vaccination plans while expeditiously getting healthcare staff vaccinated as quickly as possible.

The vaccination requirements apply to all eligible current and new staff. Again, those who are not exempt or full time teleworkers working at facility, regardless of whether they have direct or indirect patient care. The basic rule of thumb is that any staff member who's onsite in the facility, including this requirement, so who could potentially interact with others who provide direct patient care, must be fully vaccinated.

This includes individuals who are on site full time, staff who may move between facilities. For example, a nurse who shifts between a nursing home and an assisted living facility and may have interactions with others who may provide direct patient care.

Individuals who may be on site part time, but who have full time responsibilities in a facility not regulated by CMS, for example, the independent physician with privileges in a hospital who was admitting or treating patients on site. A physician's office is not regulated. But being on site at a facility included in this regulation means the physician must be vaccinated.

Next slide. We consider fully vaccinated when it's been two weeks or more since they've completed a primary vaccination series for COVID-19. We do know the staff who have received all shots by January 4, 2022 are considered to have met our requirements, even if they have not completed the 14-day waiting period required for full vaccination.

A primary vaccination series can be seen on the slide. The single dose vaccine like the Johnson & Johnson, the multi-dose vaccine like Pfizer or Moderna, as well as the vaccine listed by the World Health Organization for Emergency Use in accordance with CDC guidelines.

At this time, we are not requiring staff to receive additional doses beyond the primary vaccination series, the boosters to be considered fully vaccinated.

Next slide. CMS requires facilities to allow for both medical and religious exemptions in accordance with federal law. Facilities must have a process or

plan in place that permit staff to request either a medical or religious exemption. This is one element that the surveyors will seek to review.

There are specific requirements as it pertains to what level of documentation is needed for either a medical or religious exemption. Facilities should review the Equal Employment Opportunity Commission Compliance Manual on religious discrimination for more information on the religious exemptions.

We want to be clear that we are requiring facilities to have a process for handling vaccination exemption requests for staff as required under federal law, including medical condition for which vaccines are contraindicated for other reasons, like sincerely held religious beliefs.

However, providers and suppliers are not required to grant exemptions to staff who are not eligible, and no exemptions should be provided to staff who are simply trying to avoid vaccination. Additionally, staff who previously had COVID-19 are not exempt from these vaccination requirements.

The available evidence is demonstrated by recent CDC reports and others indicates that COVID-19 vaccines offer better protection than natural immunity alone, and that vaccines, even after prior infection, help prevent re-infection. CDC recommends that all people be vaccinated regardless of their history of symptomatic or asymptomatic SARS, SARS-CoV-2 infection.

Next slide. This regulation requires that facilities develop a process for implementing additional precautions for any staff who are not vaccinated in order to mitigate the transmission and spread of COVID-19. For those staff who are exempt, facilities should provide for accommodations, which could include, but it's not limited to testing physical distance source control,

assigning unvaccinated individuals to non-patient care areas with low risk to patients as well as others.

Importantly, this is ultimately up to the facility to decide how best to handle. In all cases, the facilities must ensure that they minimize the risk of transmission of COVID-19 to at risk individuals.

Next slide. There are a few other important elements. Vaccination is the only option this regulation does not allow for testing as an alternative to vaccinations. And there are no new data reporting requirements at this time. CMS expects facilities, specifically hospitals in nursing homes, to continue complying with the facility's specific data reporting requirements set forth in emergency regulations issued by CMS in May 2020, August 2020 and May 2021, respectively.

Additionally, facilities participating in several of our inpatient and outpatient quality reporting programs must collect data on the new COVID-19 vaccination coverage among healthcare professionals measure quarterly with the first collection period for many programs beginning on October 1st and running to December 31, 2021.

Next slide. CMS has established survey and enforcement process that will use to ensure compliance with the staff vaccination requirements. Test for compliance with the requirements will be conducted by the state service agencies during two periods: recertification; and complaint surveys. While on site, surveys will review the facility's COVID-19 vaccination policies and procedures. That is to say, a plan for vaccinating eligible staff, providing exemptions and tracking staff vaccinations, the number of resident and staff COVID-19 cases over the last four weeks and a list of all staff and their vaccination status.

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This information, in addition to interviews and observations, will be used to determine the compliance of the provider or survivor with these requirements. Finally, the accrediting organizations will be required to update their survey process to assess facilities they accredit in compliance with vaccination regulations.

Next slide. Providers out of compliance will be cited based on the level or severity of noncompliance with an opportunity to return to substantial compliance. For example, for hospitals, immediate jeopardy. The most severe and indicative of serious noncompliance would lead to termination within 23 days if the deficiency is not resolved.

Condition level would be substantial noncompliance and the standard level of noncompliance is the least severe and indicative of minor noncompliance. CMS has a variety of established enforcement remedies for nursing homes, home health agencies and hospitals beginning in 2022. This includes civil monetary penalties, denial of payment and even termination from the Medicare and Medicaid program as a final measure.

The remedy for noncompliance among hospitals in certain other acute and continuing care providers is termination. Importantly, it is not our goal to terminate facilities from the Medicare and Medicaid program. In fact, we want to work with the facilities in your states to bring them back into compliance as quickly as possible so that every person benefits from safe and quality care. Termination is the absolute last resort. And after all, other levers have been exhausted.

It is important to note, however, that we will not hesitate to use our full

enforcement authority to protect the health and safety of patients when requirements are not met.

Next slide. Finally, CMS recognizes that there are several vaccination-related requirements for healthcare workers. So we've established a hierarchy by which the facilities will follow. Healthcare facilities are generally subject to the new federal requirements based on primacy. If the facility is Medicare or Medicaid certified and subject to the CMS conditions of participation, then they should adhere to the requirements outlined in the CMS omnibus COVID-19 healthcare staff vaccination regulation.

The CMS rule takes priority above other federal vaccination requirements, and CMS' oversight and enforcement will exclusively monitor and address compliance for provisions outlined in the regulation. There are rare situations where the executive order on ensuring adequate COVID safety protocols for federal contractors or the OSHA COVID-19 Health Care Emergency Temporary Standard may also apply to staff who are not subject to the vaccination requirements outlined in the CMS omnibus staff vaccination rule.

Finally, we have received many questions on the interaction of this regulation with state law. The bottom line is that this regulation preempts state law and or state issued executive orders under the supremacy clause of the US Constitution.

Thank you for the opportunity to present today, and I and the team look forward to answering any questions.

(Jackie Glaze): Thank you, Dr. Fleisher, for your presentation, so at this time, we're ready to take your questions about today's presentations or any other questions that you may have. So we will start with the chat function so you can begin entering

your questions at this time and then we will move to the phone lines so that we can open those later at a later time. So we'll pause for a moment and see if we can get some questions from you all from the chat function.

Coordinator: And once again, as a reminder for questions over the phone, please press star 1 and record your name at the prompt.

Becca Siegel: Actually, I see a few questions I'll turn to you.

(Jackie Glaze): Yes. So what it looks like our first question for (RTT) new colleagues because consumers clarify what situation it believes that a facility may be covered by both the CMS rule and the OSHA June ETS.

Lee Fleisher: If the facility is covered by the CMS conditions of participation, in total, then it would be covered by the CMS rule. But I'm also going to have my colleague Lisa Parker provide any additional details.

(Lisa Parker): Sure. So we definitely would defer to OSHA and their resources for any specific (effect) scenarios. But one example could be if the facility is co-located where and there's a facility that is covered by the CMS regulations and a facility that is not covered by the CMS regulations, then perhaps those - so, for example, a nursing home that also has in the same building an assisted living facility could be possible that certain employees will be covered by the OSHA requirement.

(Jackie Glaze): Okay, thank you. Thanks. Then we have a question that says, can you please expand on how the requirements apply to individuals who enter the facility? For example, would it apply to people who are not employed by the facility, such as case management entities, visitors and others who may come in from the public?

Lee Fleisher: The - it is not covered by the public, but I will defer again to Lisa about any contrast to individuals, right?

(Lisa Parker): Right. So it doesn't apply to members of the public. We don't have the authority to regulate those individuals. It does not apply to visitors, but it would apply to individuals who provide services to the facility under contract or other arrangements.

So the example of that would be the physician who has privileges there. And so while we don't cover physician's offices, we would cover a physician who is entering the facility to provide his services there. I would also note that it does apply to volunteers at the facility, so they would have an arrangement with the facility to volunteer, and they would be subject to the requirements as well.

(Jackie Glaze): Okay, then we have one other question currently for CCFQ, and it says are only Medicare certified providers required to adhere to the vaccine mandate? And if not, our state Medicaid agency is going to be responsible for enforcing the mandate.

Lee Fleisher: So the mandate will be enforced through our survey and certification process and through the state agencies, but I don't know if (Karen Trits) or (David Wright) is on to discuss this in more detail.

(Karen Trits): Hi. This is (Karen Trits); I'm on. I'm the director of the survey and operations group. Lee is correct. It would be enforced through the State Survey and Justification Agency, which is usually part of the State Department, but different than the state Medicaid agency.

And so they routinely go on site to survey providers for the minimum quality standards or conditions of participation that Lee and Lisa have described. And that's the mechanism that will be used to enforce these requirements. There would not be a direct role for the state Medicaid agency unless there were concerns or enforcement actions in those cases, per our usual process, the state service agency would be working closely with the state Medicaid agency.

Lee Fleisher: As well, (Karen), if you want to mention the accrediting organizations like the Joint Commission and other entities and...

(Karen Trits): Right. And they would be - I specifically mentioned, they're being asked to update their processes to ensure that there's also the - that they would also be serving for the compliance with the vaccine.

Becca Siegel: (David), anything you'd like to add on that?

(David): No, I think you've got it and there will be a little bit of a lag for the accrediting organizations. They have some formalized timeframes in which to update their own standards to reflect any new conditions that we put out. But overall, right, it'd be both the case of agencies and the accrediting organizations and to (Karen's) point too, some states, do have that component of their Medicaid agency that might do the surveys for the ITF IDs or for the protest.

But again, it's folks that we normally work and coordinate with who receive the guidance and be doing the enforcement.

Becca Siegel: Okay, and then let me help - go ahead. So, a number of question just came in for CCFQ it says if clients residing in the ICF facilities attend any outside day

programming not associated with the facility, do those day programming employees need to be vaccinated?

Lee Fleisher: I'm going to throw that into the team, I don't know if (Lisa), (David) or (Karen) want to comment.

(Lisa): Yes. No. Only if those providers are Medicare certified providers, so they would not be covered. The ICF employees must be vaccinated, but not the day programs that the clients would go through unless they are on our list of providers or if the day program is a contractor to the ICF and they provide services to the ICF, then they would need to be vaccinated if they have a relationship with the ICF such that they provide services by arrangement or contract.

So, for example, a transportation provider, if they use the bus company to go from one place to another, then that individual would need to be vaccinated.

Becca Siegel: Thank you. Would now like to switch to the phone lines. Operator, could you provide instructions once again and then open the phone lines, please?

Coordinator: Certainly, once again, if you would like to ask a question over the phone, please press star then 1. Please unmute your line when recording your name. If at any time your question has been answered while waiting, you can remove your request by pressing star 2. Once again that is star 1 for questions over the phone at this time. Please stand by. Once again, star 1 for questions on the phone. And we've had no responses on the phone at this time.

Becca Siegel: Thank you, so, (Ashley), I'll turn back to you, I know you have a few questions from last call, so let's go through those, please.

(Jackie Glaze): Okay, great.

Ashley Setala: Yes. We had a few questions that came in on the last call that we weren't able to answer. Our subject matter experts were not able to attend. And we wanted to make sure and revisit.

So the first question is for our (children) and (adults) health programs group. And it says, “Why is the (FDX) interface treated differently from Paris? Why can they not terminate a member for being out of state based off of (FDX), even if they take the additional steps that they do from Paris, according to the guidance in CMS 9912?

(Jessica): Thanks, (Ashley). And this is (Jessica). The primary reason is that there was a there was a narrow exception that was made for Paris in the IFC. And so generally under the continuous enrollment provisions during the public health emergency, the policy that we discussed with respect to the (FDX) and not being able to terminate based on information from there, if you don't have a response from an individual applies to all data sources, right, that you wouldn't be able to terminate coverage based on that information.

We did craft a narrow exception in the IFCs specifically for Paris, in part based on some of the questions and concerns that we identified at the time. We would need to have new regulations to specifically exclude the (FDX) as well, because even outside of the context of the PHE, there would be - there would need to be a reach out to the individual first to verify that information that has come back about either residency or death, which I know the two things that we've talked about are accurate prior to terminating eligibility and because you can't act without that confirmation in the context of their continuous enrollment provisions, a state would not be able to terminate coverage.

Ashley Setala: Okay, thanks, (Jessica). Then we have one other question around (FDX) and it says regarding (FDX) information as a valid source for out-of-state residency, could you also clarify why a state cannot rely on (FDX) information as confirmation of death and basis for termination of Medicaid benefits?

Anne Marie Costello: Yes, so that I think maybe go one step further than the explanation that I tried to provide just now that even for out of state residents during the PHE, the (FDX) is not on its own a reliable source.

So let me just talk through the process briefly, whether it's for out of state residency or death. During the public health emergency if you receive information from (FDX), the state treats that information as a potential change in circumstance with respect to the either death or residency, and then would be required to reach out to the individual to confirm the accuracy of the information that you have.

If the individual responds and says, “I no longer live in the state,” or you have - you received a response and say from a family member confirming that an individual is deceased, then yes, those are two exceptions to the continuous enrollment provisions: lack of residency and death. And so you would be able to terminate the individual.

In the absence of a response from the individual, the state would not have sufficient information to terminate eligibility. And so that would be the case going back to the question for out of state residency and/or death.

(Karen Trits): So if I could just add and maybe our colleagues from if anybody from the managed care division is on (DHPT), right, I think what a state could do, this is shared alone, I think what if they could certainly do in those situations is to

have somebody who might be in managed care to a fee for service. You know, if your state is capable to do that because then you're not going to be paying a capitation fee for that person if they in fact are deceased. They certainly won't be drawing down services and likely if they're out of state, they also would not be actually accessing services. So you wouldn't be, you know, out of pocket.

Ashley Setala: Okay, thank you, both. And then we have a question around our PHE unwinding work and it says for cases where the state needs to make a disability determination and knows that the individual under review doesn't meet the disability criteria, but the state could not close them due to continuous coverage requirements under the (FSCRA). Will states need to conduct a full disability review again for these individuals before their cases can be closed?

Becca Siegel: Yes. So if as part of the renewal redetermination process, the state would ordinarily need to conduct a disability review, all of those requirements would be - would remain for any renewal or redetermination that the state would do for the renewal conducted in the unwinding period.

Certainly, an individual's status may have changed or there might be additional information that the state would need to consider. The short answer is yes.

Ashley Setala: Okay, great. Then we have a few questions that have come in around the - what we call the treatment show that CMS released a few weeks ago. And the first one says with regards to providing the new mandatory coverage for treatment of a condition that may seriously complicate the treatment of COVID-19, is this new mandatory coverage subject to medical necessity?

In other words, can the state deny claims for treatments of a condition that

may seriously complicate the treatment of COVID-19 for lack of medical necessity?

Secondly, will CMS be providing any guidance on making medical necessity decisions for these treatments?

(Kirsten Jensen): Sure. This is (Kirsten Jensen) from the Division of Benefits and Coverage. The coverage for conditions that complicate COVID-19 is coverage that you all already have in your state planners otherwise covered in your state plan and services, you know, should be individuals should receive services according to that coverage.

Medical necessity criteria are established by states. CMS does not review those criteria. Those are at state discretion. I can't say whether or not a claim could be denied based on medical necessity, because that would be according to what the criteria that states have established and how they are applied in their program.

So because CMS does not review those criteria or how they're implemented in the state, I can't really weigh in on that question. I don't know if anyone else on my team has anything to add there.

(Melissa Harris): (Kirsten), this is (Melissa Harris). And the only thing I would add is that I believe in the letter itself, both in the discussion of services to treat a condition that could seriously complicate the treatment of COVID-19 and for services to treat COVID-19 itself, we did include language indicating that while hard limits on the amount, duration, and scope of services were prohibited under the ARP, states were still able to implement utilization management techniques, and we would include medical necessity as one of those utilization management examples.

So, yes, medical necessity continues to be a foundation of service provision. And as (Kirsten) said, that that criteria is developed at the state level. I think there was also a mention in the letter about states being encouraged to work with their clinical communities in developing medical necessity criteria.

The coverage mandates in the American Rescue Plan are particularly in the requirement to cover services that might - services for a condition that might seriously complicate the treatment of COVID-19. That's a little bit of a different territory from where Medicaid usually is.

And so, you know, we certainly encourage states to be in collaboration with their clinical community in deciding implementation techniques. We included a couple of examples of conditions that could seriously complicate the treatment of COVID 19, but certainly that is not an exhaustive list, but the medical necessity criteria that you are using today.

And any criteria that you use to implement the treatment mandates under the ARP would be state developed criteria that would not appear in the state plan and would not be, you know, based on any kind of CMS guidance. So I hope that's helpful.

(Jackie Glaze): Thank you, (Melissa) and (Kirsten).

In closing, I'd like to thank Becca and Dr. Fleisher for their presentations today. Looking forward, we will meet with you again on Tuesday, November the 23rd. The topic and the invitations will be forthcoming. If you do have questions before the next call, you know that you can reach out to us, your state leads or bring the question to the next call.

If you'd like to pre-submit the question in advance for the open Q&A portion of the next call, please email it to medicaidcovid19@cms.hhs.gov by 1:00 PM Eastern Time on the day of the call. We thank everyone for their participation and hope you all have a good afternoon. Thank you.

Coordinator: Thank you all for your participation on today's conference call. At this time, all parties may disconnect.

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