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'll now turn the call over to Jackie Glaze. Thank you. You may begin.

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, for opening remarks. Anne Marie?

Anne Marie Costello: Thanks, Jackie, and hi everyone, and welcome to today's all-state call. On today's call we'll be discussing four important topics. First up, Ryan Shanahan, from our Medicaid Benefits and Health Programs Group, will share an overview of the State Medicaid Director Letter released last week on the extension of 1915C HCBS Waiver Appendix K expiration date.

Following Ryan, Kirsten Beronio, our CMCS Senior Behavioral Health Policy Advisor, will provide an overview of the Mental Health and Substance Use Disorder Action Guide that we released on July 25. Next, Mary Beth Hance, from our Children and Adult Health Programs Group, will share updates

regarding the impact of COVID-19 vaccine commercialization on state Medicaid and CHIP programs. We are hoping this, and our final presentation, will help with state planning related to COVID-19 vaccines. Lastly, Evelyn Twentyman, from the Centers for Disease Control and Prevention, will discuss the COVID-19 Vaccine Bridge Access Program related to the commercialization of the vaccine.

Before we get started, I wanted to let everyone know that we will be using the Webinar platform to share slides today. If you are 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 our presentation.

With that I'm pleased to turn things over to Ryan Shanahan for an update on the extension of HCBS Waiver Appendix K exploration dates. Ryan?

Ryan Shanahan: Thank you, Ann Marie. On August 2, CMS released a State Medicaid Director Letter to facilitate the continuation of HCBS waiver flexibility requested by states during the COVID-19 PHE. Specifically, the guidance announces an update to CMS's policy regarding the end date for flexibility approved in state Section 1915C HCBS Waiver Appendix K amendments.

Under our prior policy these flexibilities were set to expire six months after the expiration of the PHE. Given the end of the PHE on May 11, 2023, that Appendix K authority would have expired on November 11, 2023.

The new guidance, however, stipulates that COVID-19 Appendix K flexibility currently approved to end six months after the expiration of the PHE may be extended if the state takes action by November 11, 2023, to incorporate desired Appendix K provisions into underlying HCBS programs.

So this means that in order to ensure continuation of a flexibility beyond November 11, 2023, states must incorporate that flexibility into a formal submission of an amendment to or renewal of each underlying waiver to which that flexibility will apply. Each amendment, or renewal request, must be submitted to CMS by November 11, 2023, otherwise the Appendix K authority for that flexibility will expire on that date.

The purpose of the extension is to prevent lapses in approved Appendix K flexibility if the state wishes to extend beyond November 11, 2023, particularly those that are substantive in nature and would require public comment in respect to the approval date. The extension is intended to also minimize disruption and flexibility for beneficiaries, and providers if the state wishes to implement on a more long-term basis, including, for example, rating increases for HCBS providers, supplemental recruitment and retention payments, and allowing payment for family care (unintelligible).

CMS still strongly urges states to submit any waiver actions incorporating appendix case flexibilities as early as possible. In addition, although not a federal requirement, CMS advises that states provide their stakeholders with adequate notice of any flexibilities impacting beneficiaries and providers if the state does not wish to extend beyond November 11, 2023.

We also note that the policy update in the (FMVL) extends the circumstances where a state authorizes Section 1915C like services through a Section 1115 demonstration and has comparable COVID-19 Appendix K attachment case flexibility currently authorized under that demonstration. We note that no state action is required to effectuate the extension in the Appendix K, or Attachment K. The extension is automatically effectuated by the issuance of the (FMVL).

Finally, if you have any questions you can reach out to me. My contact, my email is ryan.shannahan@cms.hhs.gov. Again, that's ryan.shannahan@cms.hhs.gov or you can go ahead and contact your state (HPDSMS). So with that I will hand things off to Kirsten Beronio, our CMCS Senior Behavioral Health Policy Advisor.

Kirsten Beronio: Thanks, Ryan. Hello, everyone, happy to be with you today. As Anne Marie mentioned last month on July 25, CMCS issued a Mental Health and Substance Use Disorder Action Plan outlining major goals and prioritized strategies for how we work with the states to improve care for Medicaid and CHIP enrollees with mental health and substance use disorders.

A full description is, and an overview, is also available on medicaid.gov. We can go to the next slide, (Krista). In that first bullet there's a link to the plan itself, and I'll just provide an overview today.

So as the introduction to the action plan points out improving access to high-quality mental health and substance use disorder treatment is integral to our partnership with you all, with states and state Medicaid agencies. As we all know, Medicaid and CHIP can provide a full - coverage for a full array of services and supports for people with mental health conditions and substance use disorders, including services and supports that are generally not covered by health programs and plans - other health programs and plans.

And this is critical since we know that people with more serious mental health and substance use disorders are more likely to be enrolled in Medicaid and CHIP. It's also important to note that certain special protections in Medicaid and CHIP help to ensure access to coverage for these enrollees, including the

EPSDT benefit, the Early Periodic Screening, Diagnostic, and Treatment requirement.

As we outlined in a recent informational bulletin some - offers some critical protections for young people enrolled in programs with mental health and SUD conditions. We noted in that bulletin that that requirement does apply to the EPSDT benefit does include and incorporate mental health and SUD conditions and services and treatments.

Also important to note that the Mental Health Parity and Addiction Equity Act requirements do apply to Medicaid and CHIP and are critical for ensuring access to care for people, including people newly enrolled under, well not so newly now, but under the expansion population in most states under the Affordable Care Act. And as we know those folks in that population group are at heightened risk of mental health and substance use disorders, so the MHPAEA protections applying to them is very important.

And another key hallmark of the Medicaid and CHIP programs includes coverage of home and community-based services. That is particularly important for people with more serious mental health conditions and substance use disorders.

And we recognize that these kinds of services are, one way they're really important, is that they promote engagement and treatment that is really fundamental for supporting recovery and include things like social support and linkages to stable housing and food. They're really how - and services that help people pursue self-identified goals and support their recovery.

So next slide. We also - this introduction section also highlights another key - important issues that inform the strategies and actions included in our plan.

We note that people with mental health and substance use conditions often experience high rates of co-occurring physical health conditions that drive much of the elevated cost of care for treating these individuals and also interfere with that treatment. And so support for integrated care is really important for improving, you know, the ability to address those co-occurring conditions as well as integration being a key way to help, again, engage individuals in treatment by offering a more familiar setting.

Provider workforce shortages, we know, are a big issue across the US, particularly in certain workforce shortage areas, and rural areas are especially affected. As we've noted, we can see in the data, that also that some of those areas are areas that have high rates of mental health and SUD conditions, so kind of a double whammy there.

We also note that children and adolescents are particularly affected by COVID-19, and that the effect seems to, you know, have really affected mental health and substance use. So we are very mindful of that as we're pursuing these strategies and activities.

And we note that adolescents and adults with serious mental illness, or SUD, are particularly those from marginalized groups have high rates of involvement in the criminal justice system. So those are just some of the issues that we were - have been mindful of as we've, you know, been pursuing these goals and activities.

So next slide, please. So in terms of the action plan it really summarizes CMCS actions to improve access to treatment and support. And these actions align with three overarching goals that are outlined below along with prioritized strategies.

So the three big goals, that we have in mind as we're working on these issues, include increasing access to prevention and treatment by improving coverage of mental health and SUD screening and therapies and promoting parity, supporting integration and coordination of mental health and SUD treatment with other care, improving engagement in care by increasing treatment and support for HCBS and also supporting access through non-traditional settings. And finally, enhancing quality of care is our third major goal, and we do that by encouraging implementation of evidence-based practices and enhancing quality measurement and analyzing and publicizing data on key topics.

So next slide, please. The one, you know, big area of focus is increasing access to prevention and treatment. And in support of that goal one key strategy is improving coverage and promoting parity. So one way we're doing that is by supporting strong connections to health care coverage through engagement with states on Medicaid renewals.

As we're leaving, you know, as the Public Health Emergency has ended, we've been working very proactively with our state partners on that issue. Also, we have the Connecting Kids to Coverage campaign, which is a national outreach and engagement enrollment initiative. It includes a radio tour that this year focused on mental health as well as providing materials for schools and community organizations and states on getting kids connected to coverage.

Another key activity aimed at improving coverage focuses on improving network adequacy and participation by behavioral health treatment providers, including through the managed care access - managed care and access rulemaking that - where we propose some national standards for maximum wait times focused on mental health and SUD as well as improving provider reimbursement transparency.

We also work with states through Section 1115 demonstrations on this issue. And certain types of those demonstrations have encouraged states to make progress on ensuring that their reimbursement rates for certain types of providers are in line with Medicare rates. We also are continuing our work on a demonstration to increase substance use disorder provider participation in Medicaid and SUD that was enacted, or authorized, under the SUPPORT Act.

We also do a lot of work around ensuring compliance with MHPAEA and parity. We are also working with states on ensuring CHIP covers a broad array of services as required under the SUPPORT Act. And we recently also, or in this document, we announced that we will be issuing a request for comment on how we may improve our processes for ensuring compliance with MHPAEA.

And then finally, we do have a new set of activities around EPSDT. It's called for by the Bipartisan Safer Communities Act. We're reviewing state compliance with EPSDT, and there's a required report to Congress in 2024. This is, as I pointed out, a very key protection for ensuring access to mental health and substance use disorder services for young people.

Next slide, please. Another strategy for increasing access to prevention and treatment focuses in on supporting integration and coordination and care. And some of the actions we have underway in the - or that fall under that strategy includes support for use of health information technology among mental health and SUD providers.

It's part of our work with states on Section 1115 demonstrations focused on serious mental illness. We have required states to develop plans for how they're going to use HIT to improve mental health and SUD care. HIT is also a component of the new reentry 1115 focused on helping people transition out

of jails and prisons. And we've encouraged states to make HIT improvements there.

And then finally, we are developing new guidance, technical guidance, on the enhanced match for Medicaid IT to support improvements for mental health - how mental health and SUD providers can access technology to improve care (unintelligible) and integration.

We also are continuing our work in support of coverage of telehealth and developing additional guidance on using telehealth to provide services that are coverable by Medicaid and CHIP. This new guidance was mandated by Congress.

And then finally, we are - we have recently issued some really important guidance around interprofessional consultation. And that's a really important way to think about leveraging existing mental health and SUD specialists to support integration and into primary care, emergency departments and schools by reimbursing directly for those consultations and those other more mainstream non-specialized settings to really leverage the capacity for - of those mental health and SUD specialists to provide care.

Next slide, please. The second big area of focus, and key goal that we have in working on these issues, is around improving engagement in care. And some of the strategies there including - include increasing treatment and support in home and community-based settings.

One way we do that is by we're encouraging states to support a continuum of crisis stabilization services including mobile crisis, crisis stabilization settings and call centers to respond to the new national hotline 988 for mental health

and SUD crises. And one key activity has been helping states access the enhanced federal Medicaid match for mobile crisis through planning grants.

We issued a state health official letter in September of 2021, and planning grants in December of 2021, for about 20 states. And then seven of those states have been approved for the enhanced match, and we're working with a host of other states to help them access that additional support.

We are working on new guidance around crisis services and partnering with SAMHSA on that new guidance as well as establishing a technical assistance center around Medicaid and CHIP support for crisis services. And we're also using our work on the certified community behavioral health clinic demonstration to encourage states to think about those clinics as key providers of both mobile crisis and stabilization setting kind of service as well as connections with 988.

And in that vein we are working with SAMHSA on a big new expansion of the CCBHC demo that was enacted in the Bipartisan Safer Communities Act with planning grants going out to 15 states in March of this year, and our work on the payment policy side is ongoing. We are also continuing our support for state efforts to strengthen HCBS services through the enhanced match that was available under the American Rescue Plan Act.

CMCS issued a really important State Medicaid Director Letter that helped states draw down significant additional funding for those services. And we have seen many states use that additional funding to increase availability of mental health and SUD services and address workforce challenges. And finally, we're continuing our work to increase awareness of the fact that Medicaid can cover peer support.

Next slide, please. In this area of improving engagement and care, we also are working with states to support access to mental health and SUD services through nontraditional settings, including by improving connections to support for people leaving jails and prisons. In general, as you know, services for incarcerated individuals are not covered by Medicaid and CHIP with some limited exceptions.

We did issue guidance this April that outlined a new 1115 opportunity for covering certain short-term services in the period before people are released from jail or prison. We've approved a couple of states for those 1115 demonstrations, and we are working with 14 additional states that have indicated interest. As you may know incarcerated populations have high rates of mental health and substance use disorder issues, so this is really a key new initiative.

We are also working to implement new provisions that require coverage or require maintenance of enrollment in CHIP and Medicaid and covering certain services for youth while incarcerated. And we're also promoting school-based services, including mental health and SUD prevention and treatment with guidance that was really important, new guidance issued earlier this spring. And also work with Department of Ed on a TA center to encourage more Medicaid and CHIP support for school-based health services.

And finally, we are also improving connections to supports to address health and related social needs through our Section 1115 opportunities and through managed care in lieu of services policies. And these are really important opportunities to engage people with mental health and SUD.

Our last area of focus is around ensuring and enhancing quality of care. One of the primary strategies we use for that is encouraging implementation of

evidence-based practices. And one example of that, of how we do that, is through informational bulletins including the one listed, sorry we need to move to the next slide, the one listed here around leveraging Medicaid and CHIP to improve behavioral health services for children and youth, that was the informational bulletin issued last August on the EPSDT benefit, as well as highlighting a number of evidence-based practices that states should consider.

And we also encourage implementation of evidence-based practices through our 1115 demonstrations focused on SMI and SUD. And an example of an evidence-based practice that we are very actively working to encourage and support states interested in improving access to is around contingency management.

That's an evidence-based SUD treatment that incorporates therapeutically focused incentives aimed at promoting recovery including through abstinence and engaging in treatment. And those SUD and SMI 1115s have encouraged a number of improvements in service delivery and implementation of evidence-based practices that I won't go into because I'm almost out of time, or I am out of time.

But the other way we work on improving quality of care is through our learning collaboratives that focus on pressing issues and support peer-to-peer learning, as well as providing expert resources. And finally, this is my last slide, the next slide please, other ways we work on improving and enhancing quality is through improving quality measurement or implementing mandatory reporting on the core mental health and SUD measures that are part of the child core set and also the behavioral health measures in the adult core set and the health home set, that includes significant mental health and SUD performance measures.

And then finally, we are working on analyzing our data to really highlight key issues including by looking at the data we're getting through our 1115 demonstrations and posting reports. A really interesting rapid stakeholder reports around the SUD 1115s are currently on the Web site, that show some really interesting findings around, for example, increasing availability of medication assisted treatment in residential settings.

We also develop and post an SUD data book that includes - is a really important resource for assessing access to SUD treatment among the Medicaid population. And then finally, we are working on new products that focus on enrollees with mental health conditions. So with that I will turn it over to Mary Beth Hance. Thank you.

Mary Beth Hance: Great. Thank you so much, Kristen, appreciate it. As Ann Marie mentioned earlier I will be talking about the commercialization of COVID-19 vaccines. While I'm going to go through the slides, I do have a number of colleagues from different places within CMCS, the Division of Benefits and Coverage, the CHIP program, the Financial Management Group, as well as colleagues from CDC on as well in case there are questions.

So thank you for the opportunity to talk about this today and, (Krista), can I have the next slide? Thank you. The Food and Drug Administration, FDA, advised COVID-19 vaccine manufacturers to develop an updated vaccine that more closely aligns with the current COVID-19 variant.

The updated vaccines are expected to be available this fall. And the American Medical Association is developing codes for these vaccines. These updated vaccines will be available for all ages and will, with some exceptions, generally not be federally purchased and distributed, like previous COVID-19

vaccines have been, instead, they will be commercially available similar to how other routinely recommended vaccines are available.

Commercialization is the transition of COVID-19 medical countermeasures including vaccines, treatments, and test kits previously purchased by the federal government to establish pathways of procurement, distribution, and payment by both public and private payers. Providing medical countermeasures in the commercial market is something that manufacturers, logistics companies, and payers do every day.

Next slide, please. HHS began phasing down federal distribution of federally purchased COVID-19 vaccine doses in early August 2023. You may have received a letter from CMS Administrator Brooks-LaSure about this, which was sent on July 13, addressing this transition.

The Centers for Disease Control and Prevention, CDC, will support the vaccination of uninsured children through the Vaccines for Children's Program and the vaccination of uninsured adults through a temporary Bridge Access Program, which you will hear about shortly. Both programs will provide public purchased COVID-19 vaccines to uninsured persons after commercialization occurs.

Next slide, please. Vaccine purchased after commercialization, with commercialization vaccine purchased for COVID-19 vaccines will align with vaccine purchase for other traditional vaccine. Specifically, for most children enrolled in Medicaid, the vaccine doses will be subtly purchased and distributed through the Vaccines for Children's Program like other routine pediatric vaccines, which means that states and VSD providers will not incur costs with respect to vaccine doses for those children. States with separate

CHIP programs will have the same option to purchase COVID-19 vaccine doses through the Centers - through the CDC.

For other, next slide please, for other Medicaid populations, and for beneficiaries enrolled in CHIP, states will need to determine if - will need to determine their process for covering COVID-19 vaccine doses which could be the same as for all other vaccine. As mentioned earlier states with separate CHIP programs can purchase COVID-19 vaccine doses through the CDC contracts, similar to other pediatric vaccines. Interested CHIP programs are encouraged to contact their state immunization programs.

Next slide please. The ARP coverage period for COVID-19 vaccines, under statutory amendments made by the American Rescue Plan Act of 2021, state Medicaid programs are currently required to cover COVID-19 vaccines and their administration without cost sharing for nearly all Medicaid beneficiaries, including most eligibility groups receiving limited benefit packages under the state plan or a Section 1115 demonstration for a specific period of time which is referred to as the ARP coverage period.

This coverage requirement began on March 11, 2021. And as you are probably aware the last day of the ARP coverage period will be September 30, 2024. For all separate CHIP enrollees similar to the Medicaid ARP coverage requirement, states must cover COVID-19 vaccines and their administration without cost sharing during the ARP coverage period.

Next slide, please. Are we on the, let's see, okay. The ARP also established a temporary Medicaid FMAP, and child enhanced FMAP, of 100% for amounts expended by a state for medical assistance for COVID-19 vaccines and their administration. This 100% FMAP and eFMAP period - the eFMAP period began on April 1, 2021, and will also end on September 30, 2024.

The ARP also adjusted CHIP allotments to account for the increase in expenditures due to the temporary increase in eFMAP for COVID-19 vaccines and their administration. After the commercialization of COVID-19 vaccines, and through the end of the ARP FMAP period, states will begin to claim the temporary 100% FMAP for their expenditures on COVID-19 vaccine doses and COVID-19 vaccine administration.

Next slide, please. After commercialization, states and providers will need to negotiate the price for the vaccine directly with COVID-19 vaccine manufacturers for purchase of the COVID-19 vaccines. As previously noted state Medicaid and CHIP programs will be responsible for covering COVID-19 vaccine doses for eligible beneficiaries with their expenditures on COVID-19 vaccine doses, and COVID-19 vaccine administration federally matched at 100% until September 30, 2024.

After that date, state expenditures on COVID-19 vaccine doses and vaccine administration services will be matched at the applicable state FMAP. This does not include COVID-19 vaccine doses for most children enrolled in Medicaid as COVID-19 vaccine doses will be purchased and distributed through the VFC Program for VFC federally eligible children.

The VFC Program does not cover vaccine administration, so Medicaid programs must cover vaccine administration for VFC eligible beneficiaries who are eligible for vaccine administration under Medicaid. Since COVID-19 vaccines are included in the VFC Program, the VFC administration fee schedule will apply.

Next slide, please. State Medicaid programs would also be responsible for covering both vaccine doses and administration for anyone who is not eligible

for VFC, but who is eligible for this coverage under Medicaid. Individuals enrolled in separate CHIP are not eligible for VFC, so separate CHIP programs will be responsible for covering both vaccine doses and administration for eligible beneficiaries.

States have significant discretion in how they set payment rates and pay for vaccine products and their administration, provided that the rates are consistent with efficiency, economy, and quality of care. States should check their state plans to determine whether they need to change payment rates for COVID-19 vaccine products and submit a state plan amendment for any needed changes.

Next slide, please. Ongoing coverage of COVID-19 vaccines and administration, beginning October 1, 2023, under amendments made by the Inflation Reduction Act, or the IRA, most adults enrolled in Medicaid and CHIP will have mandatory coverage of all FDA approved ACIP recommended vaccines and the administration of those vaccines without cost sharing. This would include all FDA approved ACIP recommended COVID-19 vaccines.

When this IRA coverage becomes available most children and adults in Medicaid and CHIP will have coverage of FDA approved ACIP recommended COVID-19 vaccines and their administration without cost sharing beyond the ARP coverage period. Benefits for adults and children enrolled in a basic health program include mandatory coverage of all vaccinations recommended by ACIP for routine use, including COVID-19 vaccinations, generally without cost sharing. For additional information on Medicaid and CHIP coverage of vaccines, including COVID-19 vaccines, please refer to the state health official letter and fact sheet which we issued on June 27.

Next slide, please. So key takeaways, in order to be prepared for the availability of updated COVID-19 vaccines, this fall through the commercial market, states should start planning for the transition now. States should determine how COVID-19 vaccine doses will be purchased and distributed within their states, as well as Medicaid and CHIP payment rates for vaccine doses.

This could include working directly with vaccine manufacturers to order vaccine if that is how the state chooses to purchase COVID-19 vaccines. For most children in Medicaid, COVID-19 vaccine doses will be provided through the VFC program.

Federal match is only available after the vaccine is administered to an eligible beneficiary. States with separate CHIP programs should determine if they want to purchase vaccines through the CDC contract. If interested, states should contact their state immunization program.

The American Medical Association, or AMA, is developing new codes for the updated vaccines and CMS will share them once they are available. CMS is available to provide technical assistance with this transition.

And I will turn this over to Evelyn Twentyman to talk about the Bridge Access Program. Thank you very much.

Dr. Evelyn Twentyman: Thank you so much, Dr. Hance, and all. Hi everyone. I am Dr. Evelyn Twentyman. And I serve as senior advisor for vaccine strategy for immunization services division at Centers for Disease Control and Prevention. And I'm here today to share a brief update on the Bridge Access Program for

COVID-19 vaccines that you may have heard initially announced at the end of April.

Next slide, please. So let's speak first to what the Bridge Access Program is. So this program is serving as a temporary measure to prevent the loss of cost free access to COVID-19 vaccines for underinsured adults and uninsured adults after commercialization.

This is a public-private partnership. It will provide continued cost free access to vaccines, both to those without health insurance at all and to those whose insurance does not provide zero cost access, and that's what we mean by underinsured.

This program is set to run from fall in 2023, when we expect that these products will transition to the commercial marketplace as just discussed in depth, and it will run to the end of 2024. And this program will not only help maintain broad cost free access in the near term, it will also help to improve equity in communities that are often underserved by our existing structures.

And I do want to take a moment to say that this program is really important for adults and for equity. With COVID-19 vaccines transitioning to the commercial market about 25 to 30 million adults that are uninsured or underinsured are expected to lose cost-free access to vaccines. And as you heard, from the speaker before me, children are covered by the Vaccines for Children Program, but this is meant to cover adults.

This is not a super long-term solution. The White House has proposed a Vaccines for Adults program in the FY 2023 and 2024 presidential budget. That would be a permanent, more comprehensive, program modeled after the successful Vaccines for Children Program to cover vaccination at no cost for

underinsured adults and uninsured adults, but that program has not yet been enacted into law, so we are standing up the Bridge Access Program as a necessary but temporary measure to cover these adults in the near term.

Next slide, please. So let's speak to how uninsured adults will be able to find COVID-19 vaccines. And this will also serve to speak to the public-private partnership aspects of this program.

So we'll go by location, three locations, one, adults will be able to find vaccines at their local healthcare providers. Existing partnerships with state and local health departments will facilitate distribution of these vaccines through providers in existing networks. And in this side of the program CDC will manage purchase and distribution of COVID-19 vaccines and provide some oversight and technical assistance.

Now moving to local health centers, federally qualified health centers can partner with state and local health departments and state immunization programs to ensure access to vaccines through uninsured adults. And this will occur through HRSA, who will be providing funding to a network of FQHCs to support these services toward equitable access.

And then lastly, on the far right of the slide, getting into the real like public-private partnership side, pharmacies, or some pharmacies, will ensure continued access to cost free COVID-19 vaccines using extensive footprint and community partnerships. The vaccines are expected to be provided to CDC contracted pharmacies by vaccine manufacturers, so by Pfizer, Moderna, and Novavax while cost of administration will be covered by CDC.

Next slide, please. So I know that the writing on this slide is awfully small, but this is to say we are making good progress toward our launch. We do

expect the public health infrastructure side of this program to launch about two weeks after ACIP.

We're thinking maybe that's September of 2023, so after the vaccines are approved and the 317 notice of awards have gone out to state and local awardees, that can get started. And then in October you'll see our pharmacy component stand up.

And then we will be doing some close monitoring and evaluation across the course of the program. I'll speak to that in a second. And the program will be completed by December 31, 2024.

Next slide, please. So here is what I mentioned about monitoring and reporting and ultimately evaluation. So awardees, and enrolled providers, and contracted pharmacies will all be reporting data to the CDC that will be used for multiple purposes.

So first let's speak to the awardees and enrolled providers side. Through state IISs and (VTRAC)s we'll be receiving vaccine administration and demographic data. We'll be receiving evidence of patient eligibility verification, number of insured persons expected and actually vaccinated, participating vaccine locations, and then funded partners and partnership activities to get those vaccines out to low access areas and where they're needed most.

And then on the pharmacy side, that public-private partnership side, through HHS Protect we'll be receiving detailed vaccines and therapeutics and actually even testing encounter data. We'll be receiving patient level demographic data, patient eligibility verification, participating vaccine locations, and again

funded partners and partnership activities on that side to extend the reach of these free COVID-19 vaccines to those who need them most.

And all of this data will be used to track program impact, update lists of low vaccine and low access areas to get us closer to where we need to go to improve equity, ensure patient eligibility, prevent fraud, provide technical assistance, and track use of vaccines and program funding to ensure adequate resources to all that need them. And that is actually my last slide. The next one is just for questions. Yes, thanks very much all.

Jackie Glaze: Thank you so much, Dr. Twentyman. So now we're ready to take the state questions. So please ask any questions that you may have about today's presentation or any other general questions.

We will begin by taking your questions through the chat function, so you may begin submitting those now. And then we will follow by taking your questions over the phone lines. So I will now turn to you, (Krista).

(Krista): Awesome, thanks so much, Jackie. The first question that I'm seeing here is for Ryan on Appendix K's. So Ryan, "If a state is planning to submit a formal waiver renewal request, continue a flexibility authorized under an existing Appendix K, does CMS have to complete its 30-day federal comment period by 11-11 as well, or is it permissible for the state to complete its portion/state public notice process for formal submission to CMS by the prescribed deadline 11-11? We plan to follow up with our state lead, but thought you might be able to clarify."

Ryan Shanahan: All federally required public comment, which they would normally be expected to complete prior to submission of a waiver renewal or an amendment with specific changes, would need to be completed prior to

submission to CMS which means that in order for the changes to be approved, to continue that activity needs to take place prior to submission, i.e., prior to November 11. So we can definitely touch base if there's more questions around that in the state's specific circumstance, and we would encourage you to reach out to your state lead.

(Krista): Thank you, Ryan. We now have two - so shifting gears a little bit, we now have two questions on eligibility for the unwinding team, for (TAP) if you guys are here. The first question is, "Could you provide further guidance on - could you provide further guidance on what would be considered a change in circumstance? Would an interface update, such as through the FSA, be considered a change in circumstance or must it be exclusive to a member reported change?"

(Suzette): Hi, this is (Suzette), maybe I can start us off. So if the state receives information, whether it be from an individual who reports a change in circumstance, or information from any third party, the state, and that change may affect an individual's eligibility, the state should act on that change.

(Krista): Thank you, (Suzette).

(Suzette): So (unintelligible) example if the state receives information from SSA that might indicate a change, the state should reach out to, and that change affects eligibility, the state should treat that as a change in circumstance and reach out to the beneficiary to verify that change or verify continued eligibility, but the state cannot terminate just based on that information.

(Krista): Thank you, (Suzette). We have another question here around eligibility and non-MAGI beneficiary renewal. So the question is regarding the asset waiver

disregard for non-MAGI beneficiaries at renewal. "Does this waiver apply to individuals that may have aged out of MAGI during the PHE, due to turning 65, or are - and are now being renewed during the unwinding period? For example, can the state apply the waiver to individuals that will not be renewed under MAGI and must be determined under a different pathway?"

(Suzette): So I think the question then is, if an individual was, for example, in the adult group they're aging out of the adult group can the state - when the state redetermines eligibility at renewal for that individual, and they have an asset waiver, do they take into account the assets at that point or not? Actually, why - let us take that back to make sure we give clear guidance on that. So we will take that one back.

(Krista): Thanks, (Suzette). Shifting gears a little bit, we do have a question about the COVID vaccine. And the question was, "Can you repeat how state IT systems will know which COVID vaccine is already paid for by the federal government and which will be needed to pay for by the state?"

Mary Beth Hance: So this is Mary Beth Hance. (Jeannie), is that something that you can talk about, the distinctions between the existing COVID vaccines and the future COVID vaccines?

(Jeannie): I can. Thank you, Mary Beth. So there's actually - the answer to this is actually, I think, a pretty fortunate change that's going to happen when we go to commercialization. And I think Mary Beth commented that the FDA had recommended a new strain for the fall.

And so the vaccines that with which we go to commercialization those will actually be new vaccines, same manufacturers, but new products and new national drug code numbers for the purposes of commercialization. We won't

be going commercial with the same vaccines that we've been using as part of the response.

And in fact, what we anticipate is that when the new vaccines are authorized, which as Mary Beth had said expected sometime in the fall, that the existing vaccines will no longer be authorized or recommended for use. So there'll be sort of a switchover between the vaccines we've been using, that have been paid for as part of the large government response, and the vaccines that will be administered to people following commercialization.

(Krista): Thank you so much. One additional question here around the COVID-19 vaccine is, "Will there be a published Medicare rate for the COVID vaccine once it is commercialized?"

Mary Beth Hance: So this is Mary Beth. Let us make sure that we have - let us take that back to our Medicare colleagues and not - I think that would be a better bet than to try and answer that today. So we'll follow up.

(Krista): Sounds great. And one more question here about COVID, "How does a member qualify for the Bridge Access Program?

Dr. Evelyn Twentyman: This is Evelyn Twentyman. Eligible persons are those adults, i.e., age 18 or older, who attest to having no insurance or insurance that is shown to be associated with cost of the COVID-19 vaccine. So that's actually very rare for multiple reasons, but in other words those adults who are underinsured or uninsured. And I don't know if this is a question, but there is no citizenship question in patient eligibility verification. Thanks.

(Krista): Great, thank you. And I just see one additional question here in the chat, and then we'll turn things over to the phone, this question is back on Appendix K

for Ryan. "Regarding the Appendix K extension if we don't have all the details ready to submit an amendment prior to 11-11 can we add to an existing amendment? Is it enough to add the intent in the purpose of the amendment and submit a subsequent amendment once all details are finalized?"

Ryan Shanahan: The SMDL is pretty specific in indicating that the change needs to be incorporated into, you know, the formal amendment submission. You know, but I think we would like to perhaps discuss this further and take this one back as well. Thank you.

(Krista): Thank you, Ryan. We're ready to transition to the phone lines. So (Ted), could you please provide instructions on how to register the questions, and then if you could open the phone lines, please.

Coordinator: 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. 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 one and record your name. I'm currently showing no phone questions at this time.

(Krista): Thank you, (Ted). So we'll give it another minute or two and see if we get another question, and then we'll close out for the day.

Coordinator: There is a question over the phone that just came through from (Jason McGill). Your line is open.

(Jason McGill): Oh, hello. Thanks all. Great presentation today, really appreciated the behavioral health work. Question about any partnership or work with the

Medicare side of the house in terms of further coverage and improving behavioral health coverage.

Of course, lots of state coverage there, state-only coverage, because Medicare doesn't cover many services. I know we're making some progress, but would like to see more. Thank you.

Kirsten Beronio: So this is Kirsten Beronio. I did just want to let you know that we do coordinate closely with the Center for Medicare Services on a number of behavioral health issues, and I know they're doing a lot in the context of their payment rules that they issue every year. Physician fee schedule rule in particular has some new proposals, so I would encourage you to take a look there.

Jackie Glaze: Thank you, Kirsten. And in closing I would like to thank everyone for the questions today. I also would like to thank our team for their presentations.

Looking-forward the topic and invitation for our next call will be forthcoming. If you do have questions before the next call, please feel free to reach out to us, your state leads, or bring the questions with you to the next call. So we thank you all for joining us today, and we hope everyone has a great afternoon. Thank you.

Coordinator: This today's concludes call. Thank you for your participation. You may disconnect at this time.

[End]