

Centers for Medicare & Medicaid Services
COVID-19 Medicaid & CHIP All State Call

January 7, 2021

3:00 pm ET

- Operator: Greetings, and welcome to the CMCS All-State Medicaid and CHIP Call Webinar. During the presentation, all participants will be in a listen-only mode, and we will conduct a question and answer session. You can submit questions in the chat box in the bottom left of your screen or on the phones by pressing one four on your telephone. If at any time during the conference you need to reach an operator, please press star zero. The conference is being recorded Thursday, January 7th, 2021. And now I'd like to turn the conference over to Jackie Glaze. Please go ahead.
- Jackie Glaze: Thank you. Good afternoon, everyone, and welcome to today's All-State Call and Webinar. I'll now turn to Anne Marie Costello, our Acting Center Director, and she will provide highlights for today's discussion. Anne Marie.
- Anne Marie Costello: Thanks, Jackie. Welcome to our first All-State Call of 2021, and let me wish you all a happy new year. Thanks for joining us today. We have a really packed agenda. And as you may have noticed, we've extended today's call by 15 minutes so have planned to go from now until 4:15. We have three major topics that we plan to cover today. The first is our "Unwinding" State Health Official (SHO) Letter. The second is the Drug Utilization Review and Value-Based Purchasing final rule. And our third topic for the day is an update on our vaccine toolkit.
- Anne Marie Costello: First, we'll hear from a few of our CMCS staff about a state health official letter that we released on December 22nd. This SHO letter provides guidance to States on transitioning back to regular state operations when the COVID-19 Public Health Emergency ends. We refer to this letter as the "Unwinding" SHO letter. We recognize that it will take time and a significant amount of planning for states to transition back to normal operations given the number of changes made when responding to the pandemic.
- Anne Marie Costello: Ashley Setala, from our Center Director's office, will orient you to the letter and what's included in it. We hope that this will be helpful because it's a long letter, just shy of 55 pages. Melissa Harris from our Disabled and Elderly Health Programs Group will provide an overview of the Appendix K provisions, in particular the ability to extend existing Appendix K approvals.
- Anne Marie Costello: Then Jessica Stephens from our Children and Adults Health Programs Group will discuss highlights of the eligibility and enrollment provisions outlined in the letter. On a future call, we'll have a more in-depth presentation focusing on transitioning back to regular eligibility and enrollment operations when the Public Health Emergency ends.

- Anne Marie Costello: After their presentations, we'll then take your questions on the "Unwinding" SHO letter. Then, John Coster from our Disabled and Elderly Health Programs Group will provide an overview of the Medicaid drug utilization review (DUR) and value-based purchasing final rule that was published on December 21st. After John's presentation, we'll open the lines for your questions on the DUR Rule.
- Anne Marie Costello: Finally, we'll hear from Jeremy Silanskis in our Financial Management Group about updates to the Medicaid and CHIP vaccine toolkit released on December 17th. After Jeremy's updates, we'll open the lines for a general question. I will note that for our first and second presentations, we are going to be using slides so if you're in front of your computer, please log into the webinar if you haven't done so already.
- Anne Marie Costello: But before we jump into our first presentation, I want to get some updates and another State Health Official Letter that CMS released on December 30th. Yes, we were very busy over the holidays. This letter outlines requirements for states related to a new Medicaid mandatory benefit established by Congress. Section 1006(b) of the SUPPORT Act established a new mandatory state plan benefit for medication assisted treatment, or MAT, under section 1905(a)(29) of the Social Security Act.
- Anne Marie Costello: This provision became effective on October 1st, 2020. It will be in effect through September 30th, 2025. The MAT benefit includes all FDA approved or licensed drugs and biologicals to treat opioid use disorder and counseling services and behavioral therapy.
- Anne Marie Costello: As a reminder, MAT drugs are covered outpatients drugs and are eligible for rebates. Under Section 2601 of the Continuing Appropriations Act of 2021 and Other Extensions Act clarified that the rebate requirements in section 1927 of the Social Security Act apply to MAT drugs.
- Anne Marie Costello: States will need to submit a new SPA to cover the new mandatory benefit. Templates for ease of completion have been posted already to [Medicaid.gov](https://www.Medicaid.gov). CMS is aware that most states have been unable to submit a state plan amendment for the new MAT benefit that meets the submission and notice timing requirements because you all have been focused primarily on the COVID-19 pandemic through much of 2020.
- Anne Marie Costello: Therefore, we are given states the opportunity to request that CMS exercise its section 1135 authority to modify the regulatory deadlines associated with state plan effective dates and the public notice requirements of coverage and payments SPAs for the new MAT benefit while the COVID-19 Public Health Emergency is still in effect.
- Anne Marie Costello: States may request this flexibility so that their SPAs adding coverage and payment for the new mandatory MAT benefits submitted in the first quarter of 2021, may be effective back to October 1st, 2020, making you all in compliance with the statutory requirements of the SUPPORT Act.

- Anne Marie Costello: We you want to note that any state requesting this 1135 flexibility, that request must be submitted by next week, January 14th and approved during the COVID-19 Public Health Emergency. The SHO outlines the details for submitting these 1135 requests. You are all very familiar, you need to submit them to Jackie Glaze.
- Anne Marie Costello: The statute also allows for an exception based on provider shortages, and there is a process to make that request as well. January 14th, 2021 is also the deadline for states to submit a request for an exception to comply with the implementation of the new mandatory MAT benefit due to provider and/or facilities shortages. These requests must be submitted through the SPA mailbox.
- Anne Marie Costello: CMS will address the new MAT benefit in more detail on our next week's all-state call on January 12th. With that I'll turn things over to Ashley to start our first presentation.
- Ashley Setala: Thanks Anne Marie, and hi everyone. So as Anne Marie said, on December 22nd, we've released a state health official letter providing guidance to states on planning for a return to normal operations when the COVID-19 Public Health Emergency eventually ends. And as I am sure that you have noticed, if you have looked at the letter, it is luminous and has a lot of content packed into it. And so today we wanted to spend just a few minutes providing an overall orientation to the letter and what's actually included in each of the sections.
- Ashley Setala: So this is the SHO table of contents. The letter is organized into eight sections with four supporting appendices. The section titles are listed in the table of contents on this slide and also included in a hyperlink table of contents at the beginning of the SHO to hopefully make it a little bit easier to navigate.
- Ashley Setala: The SHO starts off in section one with some background information about the effective and termination dates of various authorities that I imagine that many of you have seen before, as well as the key termination dates for the various conditions for the Federal Medical Assistance Percentage (FMAP) increase that was provided under the FFCRA.
- Ashley Setala: I will note that the Families First Coronavirus Response Act (FFCRA) conditions extend past the end date of the Public Health Emergency while our disaster relief SPAs expire on the day that the PHE ends, if not sooner. And so we point out in the background section that one of the things that states will need to think about is whether their state plans needs to be amended to make sure that any changes that were made in a disaster SPA to meet the enhanced FMAP conditions are maintained for the entire period of time that they apply and don't expire on the day that the PHE ends.
- Ashley Setala: In section two, we focus on resuming normal operations before the PHE ends, as well as extending temporary flexibility beyond the PHE. So in the SHO, we recommend that states routinely assess whether individual flexibilities continue to be needed to respond to the PHE. And if not, think about transitioning back to normal operations, as soon as they are no longer needed.

- Ashley Setala: And then in section two, we also provide guidance on the steps that need to be taken if a state wishes to extend any of their disaster SPA authorities, PHE blueprint revision, verification process changes, or Appendix K flexibilities beyond the end of the Public Health Emergency.
- Ashley Setala: In section three, we cover the regulatory requirements that states will need to follow when ending temporary authorities and expiring FFCRA provision. So this will include things like redetermining eligibility and providing advanced notice and fair hearing rights, if the sunset of a flexibility means that a beneficiary will lose coverage or see a reduction in benefits.
- Ashley Setala: In section four, we talk through the requirements for ending other authorities. This is a pretty meaty section and cover things like processes for terminating coverage in the optional COVID-19 testing group, ending flexibilities that were granted via regulatory concurrence, and then section 1135 waivers, and ending a number of other authorities that are listed out on this slide.
- Ashley Setala: In section five, we talked through a number of the operational considerations that states do need to think through when ending flexibilities. So this will include things like notifying providers of changes, updating IT systems and state processes, ensuring accurate financial reporting, as well as considerations for managed care.
- Ashley Setala: And then in section six, we talked through CMS's expectations for returning to routine eligibility and enrollment operations when the Public Health Emergency ends. And you will hear more about this section in just a couple of minutes.
- Ashley Setala: In section seven, we highlight a number of best practices and strategies that states may want to think about adopting to make the transition back to normal operations easier. And then in section eight, the final section, we just flag that CMS will be releasing additional guidance on COVID-19 related program integrity issues for states.
- Ashley Setala: And then we have included four appendices at the end of the letter that summarize some of the key information that's contained in the letter for easy reference. So in appendix A, we provide background information on the emergency authorities that were approved during the PHE. In appendix B, we provide a snapshot of the regulatory requirements that states will need to comply with as they transition back to regular operations, as well as the flexibilities that will be subject to each regulatory requirement.
- Ashley Setala: In appendix C, we outlined the actions that will be necessary to resolve pending eligibility and enrollment actions and end section 1135 waivers, as well as the timeframe within which each action is expected to be completed. And then in appendix D, we summarized the operational considerations related to terminating temporary authorities or changes that were made to comply with the FFCRA provisions that states will need to think through.

- Ashley Setala: So this is a very quick and high-level walkthrough of what's included in each section of the letter. And so now I am going to turn things over to Melissa Harris to talk a little bit more about some of the Appendix K updates in the letter.
- Melissa Harris: Thank you very much, Ashley. This is Melissa Harris, and we are now on slide 11, the extending section 1915, the Appendix K flexibility. We had heard from a lot of states and stakeholders that the flexibilities that they were receiving approval for in their Appendix Ks were so critical and they really needed to continue for as long as possible.
- Melissa Harris: And typically, our past practice had been that Appendix Ks would be in effect for no more than 12 months. And that life span, that 12 months life cycle had been sufficient for the emergencies that had come before the COVID Public Health Emergency. But this is a different experience altogether. And we wanted to provide states with the ability to extend their Appendix Ks beyond the traditional 12 months.
- Melissa Harris: And so you probably read in the "Unwinding" SHO that states now have the ability to extend the flexibilities that are in their Appendix Ks such that they would be in effect until six months after the expiration of the Public Health Emergency.
- Melissa Harris: We're not requiring a particular date. In the states Appendix K, the end date can literally say six months after the end of the Public Health Emergency. And so we recognize that states will need to submit amendments to their Appendix Ks. We're encouraging the states to just really submit that first page that has the effective date, the beginning and end date to CMS for revision. And that will really facilitate a very expeditious review on our part. We should be able to fly those through very quickly.
- Melissa Harris: If you are packaging an extension request in with other amendments to your Appendix K, we're happy to review that as well. Just understand that it might take us a few days longer to work through all of those. And so we're hopeful that this provides the amount of flexibility that states and stakeholders were hoping for and look forward to providing speedy approvals.
- Melissa Harris: One clarification or one specification to make, this extension does not have any implication on the amount of time that retainer payments can be in effect. The retainer payments are still limited to a maximum of three 30-day periods. And so if that timeframe has already passed, the extension of the Appendix K does not open up a new timeframe for additional retainer payments. So I just wanted to make that clear in case there was maybe some confusion on that point.
- Melissa Harris: But we look forward to processing your extensions and please let us know if there's any particular technical assistance that we can provide to you. So with that, I'm going to turn it over to Jessica Stephens. Thanks.
- Jessica Stephens: Thanks Melissa. Many states have asked about expectations and requirements for catching up on eligibility and enrollment actions that they have been unable to do

at the end of the Public Health Emergency and returning to normal operations. As Anne Marie said at the beginning, we will spend more time discussing the details of this aspect of the letter in more detail in future weeks, but wanted to take the opportunity just to highlight a few key takeaways.

Jessica Stephens: First after the PHE, states will need to take actions to complete pending actions in the eligibility and enrollment sphere in four key areas. Catching up on any application backlogs, completing verifications for individuals enrolled based on self at the station, if applicable.

Jessica Stephens: And I'll highlight here that this is something that specifically applies to states that have taken up the action either prior to the Public Health Emergency or during it to complete enrollment based on self-attested information and verify information after the fact after enrollment. The third is redeterminations based on changes in circumstances, and finally renewals.

Jessica Stephens: Due to the FFCRA continuous enrollment requirements, there are aspects of this work that can't be completed until the Public Health Emergency is over and specifically termination. However, during the Public Health Emergency, we expect states to complete as much work as they can. And in particular, to prioritize actions that ensure that eligible individuals are able to enroll in routine coverage.

Jessica Stephens: I think there are a few of these that are specifically worth highlighting. First is making timely determinations of eligibility for new applications. Then completing renewals for individuals whose eligibility can be renewed based on available information, otherwise known as ex parte renewals and initiating verification in those states that have taken up that particular verification option and completing that verification for individuals whose eligibility can be verified based on available information.

Jessica Stephens: I'll note that states are really encouraged to process as many pending verifications renewals, and redeterminations based on changing circumstances as possible. And this will limit the amount of work that will need to be done after the end of the PHE. And in particular, changes that expand eligibility for individuals, for example, a change that might result in greater coverage for an individual.

Jessica Stephens: Now in the letter, which you'll see once you have a chance to dig in, we have laid out a phased approach for states to complete the work that is needed after the end of the Public Health Emergency and laid out the maximum timeframe for each of the four areas that I've talked about already.

Jessica Stephens: Specifically, states may take up to four months following the end of the month in which the Public Health Emergency ends to process any pending applications received during the Public Health Emergency and resume routine timely application processing, and may take six months following the end of the month in which the PHE ends with all other actions related to renewals, redeterminations based on changes in circumstances, and verifications.

- Jessica Stephens: We've noted in the letter that states will need to develop and document a plan to achieve the timelines that we've described. I'll also note that we have a forthcoming planning tool that we will be releasing that will help states develop the plans. But note that that plan does not need to be submitted to CMS though we will request that states provide data, and more information on the specific data points and data template are forthcoming.
- Jessica Stephens: It's important to note that states has some flexibility here, but are expected to use a risk-based approach to complete the work that is needed at the end of the PHE. And that risk-based approach is based on individuals who are likely to no longer be eligible and minimize the extent to which coverage is provided to individuals who no longer meet eligibility criteria.
- Jessica Stephens: There are options here, but includes things like prioritizing cases for individuals who are likely to no longer be eligible or based on individuals who have been enrolled for the longest. For example, conducting renewals and redeterminations for individuals who have been enrolled since March of last year first, and doing those that might enroll in January of 2021, later.
- Jessica Stephens: We outline a number of different options in the SHO, including strategies that many of you are already familiar with to help more efficiently process the actions and we'll certainly be providing more of that information in the near future. With that Jackie I'll turn it back to you.
- Jackie Glaze: Thank you, Jessica. And thank you, Ashley and Melissa for your presentations. So at this time, we'd like to take your questions on the "Unwinding" SHO letter. We will begin by looking at your questions that you've posed in the chat function. We've already received a few, but if you'd like to go ahead and send those questions in now, and then we will follow with opening up the phone lines. So we'll begin responding to the questions that we see right now in the chat function.
- Barbara Richards: Great. Thanks, Jackie. So our first question is for our colleagues in Disabled and Elderly Health Program Group, Melissa and team. If a state is interested in extending their Appendix K, should they send their extension through the SPA mailbox or the COVID-19 mailbox or some other way?
- Melissa Harris: Hey, Barb, this is Melissa. And so they would submit it through the COVID-19 mailbox. There are some states that are participating in kind of a pilot with us on the SPA mailbox and they know who they are, and if they're in that file, they would submit it through the SPA mailbox and otherwise it would come through the COVID-19 mailbox.
- Barbara Richards: Great, thanks, Melissa. And our next question is for Jessica and our colleagues in CAHPG. And Jessica just feel free to also, if you want to defer this one to your EME focused conversations, feel free to do that too, but the question is what does backlogs mean in the context of renewals? If we have allowed for streamlined renewals, do we have to redetermine eligibility, or is it enough just to continue at next renewal period?

- Jessica Stephens: Sure. I think we may ultimately need a little bit more information directly about what you mean by streamlined renewals here. I'll say generally for renewals, there still is an expectation for states to complete a renewal process that includes attempting to renew individuals based on available information.
- Jessica Stephens: If a state can renew an individual's coverage based on available information during the Public Health Emergency, they should and can finish that process. For any other individual consistent with the renewal verification timeframes, which in most cases would be 12 months, the state would need to complete that renewal based on available information, send a form if additional information is needed, and then complete that verification process.
- Jessica Stephens: I think what we're referring to here in the context of a backlog is situations in which the state has neither completed the renewal based on available information or otherwise completed that renewal process. And we expect that there will certainly be a number of those cases in all states, because states have not been able to complete terminations due to the FFCRA continuous enrollment requirements. If that doesn't address your question, I think we may need to have a separate conversation offline just to understand what the state is doing.
- Barbara Richards: Great. Thanks, Jessica. The next question is in a SPA extending a disaster relief flexibility. Do we delineate in the SPA that it is for a limited time period?
- Jessica Stephens: I'm sorry, Barb, can you say that again?
- Barbara Richards: Sure, certainly. And this is sort of potentially cross cutting. So in a SPA extending a disaster relief flexibility, do we delineate in the SPA that it is for a limited time period?
- Jessica Stephens: I'm not sure if there's anybody who can speak directly to that at the moment. I think in this context it would be Anne Marie.
- Anne Marie Costello: So this is Anne Marie. I'll just say without really understanding the full context is the disaster response template expire at the end of the Public Health Emergency. If the state wants to sunset a particular flexibility within a SPA earlier than the end of the Public Health Emergency, they can do that. So if you have something earlier and wants to extend it, I believe you can resubmit a new state plan amendment. But if that is not answering the question, if someone could just email us and we'll follow up with the specific details.
- Barbara Richards: Great. Thanks, Anne Marie. And Jackie-
- Jackie Glaze: Yes, let's move to the phone lines at this point. Great. So operator, can you please provide instructions and open up the phone lines so that we can take a couple of questions?
- Operator: Absolutely. If you'd like to register for a question on the phone, please press one four on your telephone. Then you will hear a three tone prompt to acknowledge

your request. If your question has been answered and you would like to withdraw your registration, please press the one followed by three. Once again, that's one four to register for a question. One brief moment for the first question.

Operator: One brief moment, as a reminder, if you'd like to register for a question on the phones, please press one four. We have a question from the line of Amy Lulich. Sorry, Lulich, please go ahead. The line is open.

Amy Lulich: Hi, my name is Amy Lulich. I'm calling from Illinois. In regards to the end of Appendix K and any kind of flexibility we've included there related to we're working on our actual 1915(b) waiver renewal. So how would you go about suggesting the timing on that? So for example, our waiver renewal would start October 1st, 2021, but let's say, the PHE is continuing through then, and we have our Appendix K continuing through then, which one is the better vehicle for that continued flexibility?

Ralph Lollar: This is Ralph from DLTSS, and I'll tell you that I think it takes a more focused and specific discussion, but what we would tell you is to submit the renewal if the issue is whether you can extend the Appendix K overlay on top of the renewal, the Appendix K will stay in effect even after the renewal is approved, is the timeframe for the Appendix K expires after the renewal is in place.

Amy Lulich: Okay, thank you.

Ralph Lollar: Okay.

Operator: Our next question is from the line of Nicole Silks. Please go ahead, your line is open.

Nicole Silks: Hi. I know we didn't get to the specific part of the SHO letter. So I hope I'm not jumping the gun by asking this question. In one particular section of the SHO letter where they're talking about individuals and determined ineligible for Medicaid within the previous six months that the state must send two notices.

Nicole Silks: We have to notify the individual availability determinations and that their enrollment ends at the end of the PHE. What we would like to clarify is that in our state at the time eligibility is around, we send a notice, are we required to send an actual notice or letter saying that their eligibility ended because of the PHE?

Nicole Silks: Or can we just send an advance notice saying that your eligibility is ending because you no longer meet the criteria, which is in addition to the PHE ending, like you're over income or you're over resources, or whatever you're not meeting your eligibility for, do we have to inform them that it's ending because of the PHE?

Jessica Stephens: This is Jessica. I think there might be two parts to this question. I'll start with the first. And the section of the letter that I believe that you're referring to talks about

an option that we provided to states to minimize the amount of work that needs to be done after the end of the PHE, many states are conducting determinations right now, but in most circumstances cannot terminate those individuals who they find to be ineligible.

Jessica Stephens: If an individual has been determined to be ineligible within the six months prior to the time that that determination is being made after the end of the PHE, the section that you referred to provides an option for states that essentially says if you have notified the individuals at the point that their determination was made, that they were ineligible, but that their coverage would not end until the end of the Public Health Emergency and send a follow-up termination notice, advanced notice of termination after the end of the PHE, then you don't need to complete sorry, repeat the redetermination.

Jessica Stephens: So it doesn't actually speak to the contents of the notice beyond... well, it doesn't speak to the contents of the notice saying that the individual is being terminated because of the PHE. I don't believe that there is a requirement to note that individuals being terminated because of the PHE, but I'm going to pause for a second to see others on the line if there's any more you want to say about that.

Sarah deLone: This is Sarah. I think that's probably right, but I think we ought to just pause and talk about it internally and make sure of that because I'm not sure everybody's aligned right now. We might want to have additional discussions and make sure. I think you're probably right, so let's circle back.

Jackie Glaze: Okay. Thanks, Sarah and Jessica. So we'll circle back on that question. And then we will now move to John Coster and he will provide an update on the DUR Rule, John.

John Coster: Thank you. Good afternoon, everybody. I'm going to ask for my first slide. So what I want to do over the next few minutes is give you an overview of the new regulation that was published at the end of the year that makes some significant changes to the Medicaid Drug Rebate Program so it's going to be a brief overview. Ten minutes won't give it full justice, but we'll try the best we can as to give you some of the highlights of how the rule could affect the pharmacy benefit under Medicaid.

John Coster: So let's go to the next slide for the timeline. You'll see the timeline indicates that the rule was published at the end of December, December 31st. The effective date of the regulation is March 1st, 2021, except there are several provisions that are effective later than that the summer effective on January 1, 2022. Those include a new provision relating to the ability of manufacturers to report multiple best prices for their drugs under a value-based purchasing arrangement.

John Coster: There's also a provision regarding state reporting of drug utilization data which I'll also talk about, and then also a change in the definition of what constitutes a line extension, and then a year after that, there's another provision that becomes effective regarding the provision of how manufacturers include or consider

manufacturer cost sharing assistance in their programs for the calculation of the drug manufacturer's price and best price.

- John Coster: Let's go to the next slide. The goals of the final regulations in general were to make changes to the Medicaid Drug Rebate Program in order to support the ability of states to engage in value-based purchasing arrangements for prescription drugs.
- John Coster: We have heard from many states and manufacturers that they would like to have some more flexibility around engaging in outcome-based contracting for prescription drugs so we made a set of changes, which I'll talk about in a minute that will hopefully facilitate states and manufacturers entering into these arrangements to make it easier for you to engage in outcome-based contracting.
- John Coster: The regulation also implements some of the opioid related provisions of the SUPPORT Act and creates a few new DUR standards relating to opioids, and also makes changes to the rebate program to align recent changes made in statute to the program as well as to make changes consistent with things that we're seeing in the marketplace.
- John Coster: Let's go to the next slide. So the modifications that we made to the Medicaid Drug Rebate Program to support outcomes-based purchasing arrangements. So right now there are nine states that have supplemental rebate agreements, CMS authorized supplemental rebate agreements to engage in outcomes-based contracting with manufacturers. And we're proud of those states for engaging in those types of arrangements and we hope they've been successful.
- John Coster: And what we tried to do in the regulation is facilitate the ability of states and manufacturers to enter into these agreements outside of the supplemental rebate agreement if they choose to do so. So one of the first things we did in order to facilitate such arrangements is we defined what a value-based purchasing arrangement is. And I'll show you that definition on the next slide.
- John Coster: Second, we clarified that a value-based purchasing arrangement is considered a performance requirement under what's known as a bundled sale. So a manufacturer is offering a value-based purchasing arrangement to a payer can average out the successes and the failures when they consider the price to that payer in terms of reporting the best price to us so states may be able to take advantage of the fact that we have now clarified for manufacturers that a value-based purchasing arrangement would be considered a performance requirement under a bundled sale.
- John Coster: The most significant change we make is we allow manufacturers who enter into contracts in the commercial sector with payers for multiple outcomes-based arrangements, multiple outcomes-based price points to report those prices to us and states could then take advantage of those arrangements. Again, I'll talk about a little bit more about that in a minute.

- John Coster: We modify manufacturer reporting requirements for value-based arrangement. Right now, manufacturers can only modify the pricing metrics that we report to us and that we use to calculate rebates that are due to states within a 12 quarter period of the quarter in which the price was paid. We allow for modifications of that outside of 12 quarters, because oftentimes value-based purchasing arrangements changes occur outside of 12 quarters or three years.
- John Coster: And we also specify certain state reporting requirements. States that have EMS authorized supplemental rebate agreements with manufacturers, they would have to begin to report to us certain elements of those agreements or outcomes from those agreements starting next year as well.
- John Coster: Let's go to the next slide. So the definition of value-based purchasing arrangement, we needed to define what this was in order to give guidance to states and manufacturers as to which of these arrangements could have multiple best prices reported for them.
- John Coster: We defined a value-based purchasing arrangement as an arrangement or agreement and tended to align pricing or payments to an observed or expected therapeutic or clinical value in a select population, which could include evidence-based measures, which link the cost of the drug to existing evidence of effectiveness and potential value for specific uses of that product.
- John Coster: So this would be cases where a product might have different uses in different populations or suggested that it's more effective in certain populations compared to others, or for specific uses compared to others or outcomes based measures, which link the payment of the drug, how it actually performs in patients.
- John Coster: So this is the definition of value-based purchasing arrangements which we adopt for prescription drugs. And what this essentially means if we go to the next slide is if a manufacturer has entered into an agreement with a commercial payer for an outcomes-based arrangement and they report those prices to us then states can take advantage of that outcome-based arrangement.
- John Coster: So right now states that have supplemental rebate agreements are negotiating with manufacturers and the prices under those arrangements are exempt from best price. What this does is it allows states, if a manufacturer reports these outcomes-based arrangements to us, to actually take advantage of those arrangements. So you would not have to enter into a supplemental rebate agreement with a manufacturer to do that.
- John Coster: So traditionally, manufacturers have only reported one best price to us for every drug in a quarter. Now if the prices that they're offering in the marketplace are tied to some sort of outcomes-based agreement over time where commercial payers can earn more rebates depending upon how that drug performs and they report those to us, the states can also take advantage of those.
- John Coster: So this new provision will become effective next January, 2022, at least at this point. And we'll be working with states and manufacturers over the next year to

make sure that we can allow the states to know which drugs and we expect that the drugs that most likely will be the subject of these arrangements to be these new high-cost gene therapy drugs.

John Coster: We'll be sure to work with states and manufacturers over the next year to make sure you're aware of which products have these prices reported for them to us. You are not required to participate in any type of outcomes-based arrangement prices that are reported to us.

John Coster: You would still get access to a manufacturer's best price, but this will give states that have interest in doing so, the opportunity to earn additional rebate based on outcomes for a particular high cost drug, where manufacturer has such an arrangement in the commercial marketplace and reports that to us.

John Coster: So we make a set of value-based outcomes changes to the program. The most important, which we think is this opportunity for manufacturers to report multiple best prices to us for an outcome-based arrangement. Again, states can take advantage of this if they wish to do so.

John Coster: On the next slide, you'll see one of the other changes that we made. This is apart from value-based contracting is we created a definition of what a line extension drug is. And that is because the Affordable Care Act, which is now almost close to 11 years old, established an alternative rebate calculation for drugs that manufacturers make line extension drugs of older drugs that manufacturers have.

John Coster: And we know, we all know manufacturers create extended release formulations or other formulations of their drugs as part of their marketing strategy in order to prolong patent life or extend patent life. But one of the other reasons that they have been doing it is to reduce the amount of rebates they have to pay inflation rebates they pay on older drugs.

John Coster: So in the Affordable Care Act, Congress created an alternative rebate calculation for a line extension drug where the manufacturer would have to basically transfer the inflation on the older drugs to the newer drug, if that increased the rebates that they would have to pay on the newer drugs. However, we've never really defined in regulation what line extension is in spite of several attempts to try.

John Coster: But we did in this final rule, define what a line extension drug is. So this definition provides clarity to manufacturers regarding drugs that are line extensions for the purpose of the alternative rebate calculations. So this new definition becomes again effective in a year. So giving some additional time for manufacturers, states and us, frankly, to get our systems ready in order to have manufacturers report these new line extensions to us.

John Coster: Currently, we're doing that now, but we're trying to get this new definition, these modifications into our new MVP system, which we're hoping to come up sometime in the middle of next year. So the definition of line extension includes drugs that are extended release formulations of older drugs, to change in the dosage forms, so like going from 50 to 100 milligrams, a change in route of

administration, for example, an oral to injectable, change in strength, a change in ingredients. So this is how we define line extension.

John Coster: We took out from our proposed definition, combination drugs and drugs that have new indications where the manufacturer markets separately identifiable drug. This issue is important to states because they tend to negotiate with manufacturers for line extension drugs for supplemental rebates.

John Coster: And we wanted to flag this for you now because there may be some need for states to look at their preferred drug list, depending upon the line extension drugs that manufacturers are finding report to us to see whether the manufacturers make any modifications to the supplemental rebates that they are paying to state.

John Coster: So again, we flag this to you as a potential change in the way you structure your preferred drug list or drugs that maybe manufacturers are offering supplemental rebates on depending upon whether the drug would be considered a line extension or not.

John Coster: On the next slide, we did quantify the SUPPORT Act requirements. These went into effect already in October 2019. These are mostly related to opioids. They created standards for prospective and retrospective opioid reviews specifically around subsequent fills, fills of prescriptions that were too soon, around maximum daily morphine milligram equivalents.

John Coster: There were edits on currently prescribed opioids and benzodiazepines, or opioids anti-psychotics, monitoring of anti-psychotic prescribing for children, and identification of potential fraud and abuse by enrolled individuals, prescribers, and pharmacies. Most states had these effects even before the SUPPORT Act, but the final rule codified these particular requirements.

John Coster: And if you go to the next slide, you'll see the additional related opioid standards that we codified around day supply limits for opioid naive patients, quantity limits, therapeutic duplication limits, early fill limitations. There's a new way that states need to have an effect around medication assisted treatment such that if a beneficiary receives an opioid after being prescribed, a drug use for MAT, that should raise a red flag.

John Coster: And then there's another new edit around co-prescribing or co-dispensing of opioid reversal agent like opioid overdose reversal agent to a high risk beneficiaries. So someone who's already on opioids, there's an edit that the states will need to implement regarding potential co-prescribing, the co-dispensing of approved antagonist or reversal agent to those individuals. Again, these become effective March 1st, 2021, many states already have these in place.

John Coster: And the last slide I'll mention is states reporting requirements. States already report to us their data on state drug utilization. This is not a utilization review, this is state drug utilization data, things like payments made, rebates collected. That's due to us now 60 days from the end of the rebate period.

- John Coster: That's going to remain in effect except what we do here is we require that any adjustments made to the data be submitted to the manufacturer also be submitted to us because we oftentimes see states submitting changes to manufacturers that don't make their way to us.
- John Coster: And the data that you submit has to be certified by either the Medicaid director and the deputy or an individual who has the authority to perform the tasks. So again, a quick brief overview of the rule. Hopefully, we're going to have some more in depth briefings over the next few weeks and months and work with you over the next several months to implement under what the current effective dates are. And thank you very much.
- Jackie Glaze: Thank you. Thank you, John. So in the interest of time, we'll now move to Jeremy Silanskis, and he will provide an update on the Medicaid and CHIP vaccine toolkit. And then we'll take questions about the DUR Rule and other questions at the end of the session today. So, Jeremy.
- Jeremy Silanskis: Thanks. Thanks Jackie. So good afternoon. I'm going to provide some information on the recent updates that CMCS has made to the coverage and reimbursement of COVID-19 vaccine, vaccine administration, and cost sharing under Medicaid CHIP and the BHP. And we just refer to this as the vaccine toolkit so that's how I'm going to describe it throughout the presentation.
- Jeremy Silanskis: So we made updates to the vaccine toolkit on December 17th to more fully discuss coverage and reimbursement for adults covered under traditional Medicaid, children covered under Medicaid, and CHIP coverage and reimbursement. Specifically, the updates include language outlining a streamlined state plan amendment approval process for any COVID-19 vaccine administration reimbursement changes, clarity on Medicaid network adequacy requirements, and provider enrollment flexibilities.
- Jeremy Silanskis: The updates are available on [medicaid.gov](https://www.medicaid.gov) on the COVID-19 landing page under Medicaid & CHIP resources, and the December 17th updates are noted within the document. So that it's clear where changes have been made. My focus today is to briefly highlight some of the updates and changes under sections two and four of the toolkit or made regarding the process for submitting vaccine administration SPAs and payment methodologies.
- Jeremy Silanskis: So first under section two on page nine the toolkit, we provide two important verifying guidance on the interaction between coverage and payment under disaster relief Medicaid SPAs, and the Families First Coronavirus Response Act, section 6008 federal medical assistance percentage increase.
- Jeremy Silanskis: So this information is really important for states that want to continue to receive the FMAP increase since disaster relief SPAs expire and may not extend beyond the date of the COVID-19 Public Health Emergency, but the state provides COVID-19 vaccine administration coverage and/or payment under disaster relief SPA.

- Jeremy Silanskis: And once the claim of temporary FMAP increase in the quarter in which the COVID-19 PHE ends, the state would need to prepare to have a SPA in place under the traditional SPA submission process after its disaster relief Medicaid SPA expires. And all of the traditional SPA requirements, including public notice processes would apply for the submissions.
- Jeremy Silanskis: This information is also described in section four of the toolkit. And so we just want to emphasize and encourage states that use the disaster Medicaid SPA process to consider the more permanent coverage and payment for COVID-19 vaccine administration through the non-disaster relief SPA. And again, it's really important to carry forward that FMAP temporary increase.
- Jeremy Silanskis: Under section four of the toolkit, that's where we describe the bulk of the changes that we made in our December update. And that section starts on page 24 of the toolkit. And we described Medicaid and CHIP SPA template BHP blueprints and streamlined review processes for vaccine administration.
- Jeremy Silanskis: Section four is intended to assist states in assessing the need for responses to effectuate coverage and payment of COVID-19 vaccines. And we continue to be available for states for technical assistance and we recommend the states reach out to us to talk about changes you'd like to make related to vaccine administration. I'd encourage everyone to take a look at the updates that we made in section four and come to us with any questions that you have on the information that's presented in that section.
- Jeremy Silanskis: But I'm going to discuss a few key highlights. The first, in an effort to streamline the development and submission of COVID-19 vaccine administration SPAs, we note that applicable state plan language only describes the qualifications of practitioners who may order and administer the vaccine under the benefits where the vaccinations are covered.
- Jeremy Silanskis: And additionally, a reimbursement SPA is only needed to the extent a state pays for COVID-19 vaccinations differently from other vaccination administration for other vaccine products already approved under the state plan. So essentially if you're going to pay for COVID-19 vaccinations differently than you currently do for other vaccine products, you'd have to come in with a SPA and make that update.
- Jeremy Silanskis: So for example, a state might choose to pay the Medicare rates for vaccine administration for COVID-19 or change payment policies related to the administration of multiple doses. We also make some distinctions in the toolkit between the traditional state plan vaccine administration submissions and disaster relief Medicaid SPA templates submissions.
- Jeremy Silanskis: So for disaster relief SPAs, you're probably aware of that we have additional flexibilities that we can use from under 1135 to make modifications around submission being some public notice requirements. However, those SPAs also are temporary and would expire with the PHE. So States may be more interested in using the traditional SPA would have to come and make those vaccine

administration changes more permanent. And we're here to help you with either the pathways that you choose to use.

- Jeremy Silanskis: But quickly, I'll also list a number of important policy considerations for states particularly for key vaccination administration sites. For instance, the toolkit describes options for states to cover and pay for vaccines within long-term care facilities, including nursing facilities and alternative service sites, like drive-through sites.
- Jeremy Silanskis: We do touch on FQHC and RHC payments through the perspective payment rate within the toolkit. We know that a number of states have questions about paying for vaccine administration at the FQHC and RHCs through either alternative payment methodologies or through rates other than PPS.
- Jeremy Silanskis: We're very interested in hearing and discussing those ideas with states, but we would encourage you at this time to separate the FQHC, RHC vaccine administration SPA submissions from other vaccine administration SPA proposals that might be more routine. So that way we can quickly approve the routine proposals while we determine whether there are other options available for FQHC payments.
- Jeremy Silanskis: We just aren't there yet, and we need to go through a process of vetting that. So again, please, if you can split those FQHC SPA submissions out from, for instance, if you want to increase your rates up to Medicare for other service sites, please split those out too, we can take those on a different track.
- Jeremy Silanskis: So then finally, the toolkit suggests are helpful strategies for moving vaccine administration SPAs through a streamlined approach. Particularly, for traditional SPA submissions, we suggest that please submit standalone vaccine administration SPA pages. So those would be the submissions that describe payment changes for vaccine administration on their own. And you can do that at a page that sits at the front of other Medicaid State Plan Attachments, such as 419-A, B and D.
- Jeremy Silanskis: And what that does is it doesn't co-mingle those changes with other state plan pages where we'd have to do reviews of everything that's on that page. They stand alone, we can quickly review those, provide you with feedback, and get them approved so it just separates that out nicely.
- Jeremy Silanskis: And we provide some examples within the toolkit for how that language might be described the state plan and it attempts to make it very easy for you to just pick that language up and put it in the plan. And then we give you some other examples of potential state plan language that you could use for various methodologies.
- Jeremy Silanskis: So I just want to note that we have several states that have already submitted SPAs to modify policies associated with the administration for COVID-19 vaccine products, and we prioritize those SPAs, and we're working quickly to provide feedback to states. And we're also planning some more targeted outreach

to states to help you move forward with updates on vaccine administration payment methodologies, and to work through any policy or logistical questions that you may have.

- Jeremy Silanskis: So you may be receiving information on that outreach effort soon, and we're certainly available to see if any state would discuss vaccine administration changes that you'd like to make within your Medicaid program at your state's convenience and we'd ask that you reach out to your Medicaid state rep to start those discussions. So that concludes my presentation for today and I just want to thank you all for your time.
- Jackie Glaze: Thank you, Jeremy. So we're ready to take questions now. So you may ask questions from any of the presenters that you heard today, or any other questions you may have, so we'll begin with the chat function. So please begin submitting your questions and then we'll follow with taking your questions over the phone line.
- Ashley Setala: Okay. So the first question through the chat is for DEHPG, and it says written guidance for state plan services indicates that states only need to submit a SPA when they are creating differentiated rates for remote versus in-person services. But my understanding is that CMS is not using the same approach for HCBS and would instead require amendments for all remote services. Could you explain whether this is accurate and if so, why the authorities are being treated differently?
- Melissa Harris: Thanks Ashley, this is Melissa. And I'll say a couple of things. We did issue in the telehealth toolkit. That seems like it was a lifetime ago when that was issued. We said that correctly as was indicated in the comments that if the state wanted to use the same methodology and use the same payment amount for service delivered remotely, for that same service delivered in person, then no state plan amendment would be required. That same premise will carry into home and community based services.
- Melissa Harris: I think it's recognized that there are differences in the costs that are incurred when a service is delivered remotely versus in person. When you're delivering a service in person, you've got indirect costs associated with brick and mortar buildings that the service is delivered in. If the service is delivered in someone's home, you might have transportation expenses that are factored into the right methodology. All those things don't occur when you are delivering a service remotely.
- Melissa Harris: On the other hand, there are technology costs associated with remote delivery that typically are not built into the methodology for an in-person service, but we recognize that there are those valid differences there. We did for many reasons say that no state plan amendments, no adjustments to those methodologies with dollar amounts was necessary. And that continues to be the prevailing principle.
- Melissa Harris: Certainly if the state wants to alter their payment methodology to account for those different costs between in-person and remote delivery, we're happy to

provide technical assistance in either a state plan on waiver, depending on what type of HCBS we're talking about, but the overarching principle that was outlined in the telehealth toolkit, and it does apply across Medicaid, and it's not specific just to state plans, and we can certainly reinforce that going forward.

- Barbara Richards: Great. Thanks, Melissa. This is a question going back to the "Unwinding" SHO letter and it's for CAHPG, for the resumption of all other eligibility activities post six months, can you give a bit more clarity on the CMS expectations of how long states will have to address these processes or is the expectation the process will start, and is there a given timeline to the completion of these processes?
- Jessica Stephens: This is Jessica. Let me see if I can clarify. The six month period that we refer to is the amount of times that states will have in order to catch up on all of the three different areas that I discussed earlier, verifications, acting on changes in circumstances, and renewals and resume normal pre PHE operations.
- Jessica Stephens: That six month timeframe begins in the month following the month in which the Public Health Emergency ends. And that's aligned with the end of the continuous enrollment provisions of the FFCRA, and then in six months after that. So it's six continuous months, but all the work is expected to be done by the end of the six month period.
- Ashley Setala: Okay, great. Thanks Jessica. So the next question is for FMG on the vaccine toolkit update, and it says for the recommendation that we separate out the FQHC related COVID vaccine SPA, would we also need to do that for the disaster relief SPA too, or just the permanent SPA? If for the disaster relief, how would we identify or address that we plan to treat vaccine administration for FQHCs differently?
- Jeremy Silanskis: Yeah. So you'd have to submit one amendment first. So you send in one with one transmittal number that describes the changes that you've made, for instance, for other service sites, like if you wanted to read payments within practice offices, you raise those rates all through one transmittal, and then you follow that with one for FQHC changes so that way it's two separate SPAs.
- Barbara Richards: Great. Thanks, Jeremy. And the next question goes back to our friends in CAHP on round the "Unwinding" SHO letter. Two things promised in the December 22nd letter are additional guidance on how to handle the increased appeals guidance after the PHE and guidance on how to establish future renewal dates. If we expected to renew most of our populations in six months, when will this additional guidance being released?
- Jessica Stephens: Great question. I will start by just flagging with respect to the second point about renewal date is that there is a little bit of guidance already in the letter about one option, but I know that we did indicate that there would be additional guidance coming. We do not have a specific time period for this at the moment. But it's one of the things that we are working on, I think for both of these issues, now that the guidance is released and we will get it to you as quickly as possible.

- Jessica Stephens: If you have any specific questions or thoughts or things that you are anticipating doing or are considering though, it would be helpful if you could reach out to us because it would help us to solidify the guidance and make sure that we're answering whatever questions states have.
- Jackie Glaze: Thank you. So let's move to the phone lines at this point. Operator, can you begin opening up the phone lines so we can take questions.
- Operator: So if you'd like to register for a question, please press one four. We have a question from the line of Pat Curtis, please go ahead. Your line is open.
- Pat Curtis: Yes, this is Pat Curtis from Illinois. And I think you've addressed this before, but I'm asking for additional clarification. In looking at the chart that is initial letter, that's what I'm referring to, and we've seen that chart before. It addresses all the various ways in which states were given flexibility to address primarily eligibility criteria. So a person is eligible under COVID, that would not be eligible. We're not under the PHE.
- Pat Curtis: And the dates are sprinkled all over. In other words, they expire. One individual could have benefited from two or three flexibilities that our state chose to elect under the PHE, but the two or three flexibilities expire on different dates, are those the dates that we're supposed to rectify and deal with within the six months?
- Pat Curtis: Let me just give you an example. We disregarded assets under our CHIP, excuse me, our Title XIX Disaster SPA, but we increased our reasonable compatibility under our verification plan and we also suspended premiums, okay? So those are various dates. How do we rectify the fact that they lost a specific eligibility criteria on different dates? Is that resolution part of the six months job that states have to work on? Are you understanding my question?
- Jessica Stephens: I am Pat. There may be other folks who want to weigh in on this, but at least sort of with the examples that you provided, I think those are some of the things that I think we're encouraging states to start thinking and planning for to the extent that there are flexibilities that are permitted to be extended beyond the end of the Public Health Emergency, and that might be beneficial to states to continue.
- Jessica Stephens: So for example, the specific verification related change that you discussed, which has an implication on assets I think is what you were just describing is something that could be continued for longer. And so we would want to work with you to ensure that your verification plan is updated to indicate that you'd like to continue such a flexibility.
- Pat Curtis: Okay. Can I ask a quick question about the verification plan? I see in here, it indicated that it says a state can request the end date for the verification plan. I think I saw somewhere on the chart maybe. Yeah. I think it says state can determine that. Under the template verification plan, it says we have within 90 days of the end date. So the state selection would be within the 90 days of the end date of the PHE, is that correct?

Jessica Stephens: I think I need to go back and look at that, Pat.

Pat Curtis: That's fine. That's fine. Thank you.

Jessica Stephens: That was not the intent, but we'll take a look.

Pat Curtis: I appreciate that. Yes. And maybe at a different date, you could spend some time on what I call the date confusion, the expiration of the eligibility date is sprinkled throughout and just give some guidance as to how we might affect that or how to deal with it. If somebody is still eligible for one criteria, but not eligible for another one because it expired. I think we would appreciate some guidance on that. Thank you.

Jessica Stephens: Sure. And Pat, if you happen to have any other examples, like the one that you just presented, or if there are other states that do, kindly share them that way we can address your specific questions when we do that.

Pat Curtis: We can come up with some scenarios. I just have one other comment, if it's okay and you can talk about this at a later time too. I don't know what page it's on, but in the SHO letter, you addressed the reinstatement component that is an individual gets you information and within 90 days of the date in which they were canceled, and the state can reinstate them.

Pat Curtis: But I think in this SHO letter, you indicate that we would deal with that as an application that requires a signature. I believe this is a new wrinkle on that, that they have to have a signature and we treat it as an application rather than just as a reinstatement. In other words, we just reopen the case as it was and keep in mind. Could you address that and explain that either now or at a later date?

Jessica Stephens: Let's come back to that. I actually think you're referring to guidance that might be in the renewal guidance that we put out also right before the holidays. But let us take a look to make sure I'm referring to exactly what it is that you're talking about and we can try and address that in our next conversation.

Pat Curtis: Absolutely. I will find that and send that section to you. Thank you.

Jessica Stephens: Sure.

Jackie Glaze: We can take one more question.

Operator: We have a question from Shelly Fox. Please go ahead. Your line is open.

Shelly Fox: Thank you. Just to clarify if you wouldn't mind, we just wanted to double check in the SHO, when you give reference to states developing a plan for how they will develop, excuse me, for how we would address the backlog within the four and six months timelines, are those plan necessary for all states that wish to claim FMAP, or is it only if you had an Appendix K Waiver? The plan would need to be.

Jessica Stephens: Oh, go ahead.

Shelly Fox: Oh yeah, no, ma'am, I'm sorry.

Jessica Stephens: The Appendix K is completely separate from, I think the development of this plan, which is specifically related to eligibility and enrollment related actions. And that is the plan. It doesn't need to be submitted to CMS. However, we will be providing stress tools to states in the near future that will help you develop it and you'll see more clearly there the areas that it addresses.

Shelly Fox: Perfect. Thank you so much.

Jessica Stephens: Sure.

Jackie Glaze: Thank you everyone for your questions. I'll now turn to Anne Marie Costello for our closing.

Anne Marie Costello: Thanks, Jackie, so much. I want to thank all of our presenters for their excellent presentations and information. Looking forward, we'll meet with you again next Tuesday. We plan to discuss the most recent set of frequently asked questions, which were released yesterday. Often we refer to them as our batch six FAQs. They were finally released yesterday, as well as provide more detail on the medication-assisted treatment, state health official letter.

Anne Marie Costello: I would like to flag for you that while we were on this call just today, CMS released another state health official letter on opportunities in Medicaid and CHIP to address social determinants of health. So please check your inboxes for that state health official letter.

Anne Marie Costello: As always, as questions come up between calls, feel free to reach out to us, to your state leads, or bring your questions to our next call. Thanks again for joining us today and have a great rest of the day. Bye.

Operator: That concludes the call for today. We thank you for your participation. Please disconnect your line.