



## Stream Box

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TRANSCRIPT:

>> **JONATHAN BLANAR**: For joining us this afternoon. My name is, my name is Jonathan Blanar, and I'm the Deputy Director in the Partner Relations Group in the Office of Communications at CMS. I'll be moderating today's call again. Thank you so much for joining us today for our pharmacy enrollment office hours related to the expected transition of coverage from Medicare, Part D to Medicare part B for pre-exposure, prophylaxis, prophylaxis for HIV, also known as PrEP. The goal of our call today is to answer your questions about enrolling in Medicare Part B as a pharmacy, if you plan to bill for PrEP for HIV. For today's office hours, we will begin with remarks from Dr. Dora Hughes, CMS Acting Chief Medical Officer and Acting Director for the Center for Clinical Standards and Quality or CCSQ.

Following Dr. Hughes' opening remarks, I will moderate a question and answer session. We will answer as many questions as time allows. If we can't answer a question today, we ask that you email CAG inquiries, which is [CAGInquiries@cms.hhs.gov](mailto:CAGInquiries@cms.hhs.gov), and we'll drop that into the chat.

We have several CMS subject matter experts here today to help answer questions. They include Joseph Schultz from the Provider Enrollment and Oversight Group in the Center for Program Integrity,

who will answer questions regarding Medicare Part B pharmacy, enrollment, Joanna Baldwin and Rachel Katonak from the Coverage and Analysis Group in the Center for Clinical Standards and Quality, and Jason Bennett from the Technology Coding and Pricing Group in the Center for Medicare.

Before I turn it over to Dr. Hughes, I do have a few housekeeping items to go over. This call is being recorded today. The recording and transcript will be posted to CMS.gov, following this event. Closed captioning is available via the link shared in the chat by the Zoom moderator. All participants today will be muted unless called upon to ask question. If you want to ask a question, please use the raise hand feature, and I will call on you and ask our Zoom moderator to unmute your line. I ask that you tell us your name and the organization you're with before asking your question. And with that I'd like to turn it over to Dr. Dora Hughes to get us started. Dr. Hughes.

**>>DR.DORA HUGHES:** Thank you and good afternoon, I am Dr. Dora Hughes, Acting CMS Chief Medical Officer and Acting Director for the Center for Clinical Standards and Quality or CCSQ. CMS is continually looking for opportunities to better meet the unique health care needs of the Medicare community, as part of an overarching effort to improve the quality and safety of health care for everyone. And this certainly includes people who are at risk for HIV. HIV/AIDS has become much like many other chronic conditions which can be managed with medication and has an expectation for a normal, or near normal, life. Fortunately for us at CMS, this means we are seeing more people with HIV/AIDS reach age 65 making them eligible for Medicare coverage.

The number of traditional Medicare beneficiaries with HIV has more than doubled since the mid-1990s, rising from 42,500 in 1997 to 103,400 in 2020 (a 143% increase). Additionally, a substantially larger share of Medicare beneficiaries with HIV are dually enrolled in both Medicare and Medicaid compared to Medicare beneficiaries overall. While this is a true success story, new challenges have been raised by patient advocates related to coverage for long-term care, medications and the related services, as well as the need for continuity in one's providers.

CMS is working to address some of these challenges by looking to expand access to medications used to prevent HIV in individuals at high risk of HIV acquisition, as determined by a physician or healthcare practitioner who has assessed the individual's history.

Medications to prevent HIV have been shown to reduce the risk of getting HIV when they are used as prescribed. As many of you know, CMS has proposed to cover preexposure prophylaxis PrEP for HIV under Medicare Part B as part of the national coverage determination or NCD. This means that qualifying people with Medicare would not pay anything out of pocket for this medication (i.e., no deductibles or co-pays).

Currently HIV PrEP is covered under the Medicare Part D as in dog, and is typically subject to a deductible and coinsurance or co-pay. And in addition to the PrEP drugs, the proposal includes coverage of counseling, hepatitis B and HIV screenings and at no cost to people with Medicare. The changes are slated for release in late September 2024. Once finalized, this expanded coverage of HIV PrEP, counseling, screenings will help reduce rates of HIV. We are hosting today's office hours in direct response to the outreach and feedback that we have received from a number of HIV aids patient advocacy organizations. We thank you and we appreciate hearing concerns about transitioning these preventive drugs for Medicare Part D to Medicare Part B.

CMS has provided several resources in advance of the final NCD to hopefully minimize any potential disruption in access for those beneficiaries currently taking HIV PrEP.

Today's office hours are to answer questions from pharmacies, who may be new to Medicare and/or have questions about Medicare enrollment. CMS remains steadfast in its commitment to the HIV-AIDS community. We will continue to champion policies and initiatives that improve access to care, promote health equity and enhance the well-being of all individuals living with HIV/AIDS. Together we believe we can make meaningful differences in the lives of those at risk or affected by HIV/AIDS and move closer to achieving an AIDS free generation. So thank you

again for joining us and we look forward to answering your questions. Now I will turn this back over to you Jonathan.

>> **JONATHAN BLANAR:** Great, thank you Dr. Dora Hughes. Now we will jump into the question and answer portion of today's office hours. Just as a reminder, if you want to ask a question please use the raise hand feature at the bottom, it should be at the bottom of your screen and I will call on you and the zoom moderator will unmute your line. Please as a reminder, please introduce yourself and the organization you are with. And if we can't answer the question, we will ask that you e-mail one of the resources we have dropped into the chat.

So with that I welcome people to raise their hands and we'll get this started. So I see Katie Childs has her hand raised. Katie?

>> **KATIE CHILDS:** Hi yes thank you for the opportunity to ask a question, I am from UW health in Madison Wisconsin. I just have a question about what was just mentioned that this coverage will move, deductibles will not be applied, and that it will move from part D to part B. And you specifically mentioned counseling and hepatitis B testing. I was curious if other STI testing as well as both a HIV antibody antigen test and a HIV viral load test would also be covered I know in addition, we hear from many of our patients that the pharmacy costs are one thing but the lab cost can really be the greater burden. So I am curious if that change encompasses all of those recommended tests for PrEP?

>> **JONATHAN BLANAR:** Great, thank you Katie and I see Joanna came off mute so do you want to take that question?

>> **JOANNA:** Hello everyone I'm Joanna Baldwin from the Coverage and Analysis Group in the Center for Clinical Standards and Quality here at CMS. So thank you for that question. Is it possible, can we put the, and maybe we already have a link to the website in the chat? Perhaps it is already there. The answer to your questions we do have on our preventive services PrEP website that we were able to get up not too long ago but it contains a lot of that information. So what you will find on that website is

information related to the decision that we have proposed. And you will see, thank you Kai, it just went into the chat.

And you will see that what CMS has proposed to cover is that in addition to the PrEP for HIV drugs themselves are other services related. The administration of the injectable drug for example that's practitioner service and the counseling services as well as some additional testing for these patients.

So you will be able to find that on that website.

>> **JONATHAN BLANAR:** Great, thank you Joanna. Our next question is from Jason Bilyj, and if you can unmute Jason that will be great. Go ahead Jason.

Jason if you are speaking we can't hear you. Okay we will come back to Jason. So let's move on with the next person. Charley has a question. Kai.

>> **CHARLEY:** Hello this Charley, can you hear me? Hi I'm with Walgreens on our public policy side. Thank you for all this information that the CCSQ team has been sharing. It's really helped to keep us updated. I have one follow-on question to what was just asked. Maybe just a clarification and then I have a new question. On the new FAQs, under the billing codes that appear different than some of the previous guidances that were released. But it does show the counseling codes there that are listed and appears to be eligible to be billed by pharmacies. So if you can just I guess, maybe just confirm that pharmacies/pharmacists are eligible with in addition to all the drug codes that are listed here, also eligible to bill for the counseling code where they are licensed to do so? The other, and then I guess, I don't see under that list of codes, specific code for the other screenings and testing. Can you confirm that or clarify how pharmacies would bill for those services?

>> **JONATHAN BLANAR:** Joanna, or Jason, either of you want to answer?

>> **JOANNA:** Yes why don't I go ahead and start and then Jason can absolutely come behind me to fill in where I have missed or left off. Hi Charley, thank you for your question. So I guess let me start from the bigger picture I'm

not sure I can get down to the level of some of the detail that you asked and so kind of taking a bigger step back pharmacists are not currently recognized providers under the Medicare program. And we have other preventive services where in those decision memorandums that we have published, we have been able to respond to those comments that we have received which are very similar to the question you have now, to explain that since they are not recognized providers, they cannot bill Medicare directly for services furnished and that would also apply to PrEP for HIV.

So for as far as your additional follow-on questions. Some of the services that you, the procedure codes that you see listed. So pharmacy enrollment, these office hours for today, trying to help make sure that we are able to bring pharmacies in so that they can bill Medicare part B for the drug and for the supplying and dispensing fees for those drugs. And then Charley, I'm sorry do you have a follow-on question for that? I am afraid I am not tracking all the things that you asked.

>> CHARLEY: Yes, no, that was it on the codes. So I appreciate the clarification. A separate question I had is under the question where it lists the diagnosis code that subscribers would submit it puts it out as it includes the diagnosis. Is there a consideration to have sort of a definitive list of diagnosis codes that should be used? Asking for the instance that if it is not one of these, pharmacists might be left to like guess is this one that would be used for PrEP versus something else. Just curious of your reactions there?

>> JOANNA: I can take a try at that answer, what we have provided are the diagnosis codes that we would expect, that we believe we would expect and be appropriate for claims for PrEP for HIV. If there are additional codes, you know, certainly we will take a look at those and feel free to send them to us. But those are the ones that we have identified.

>> CHARLEY: Okay yes, okay I am not adjusting having additional codes. I think with previous guidances they would be listed as "appropriate codes include these" which implies that there may be other ones that are appropriate. And in that case that is when the pharmacist

is left to guess. So if prescribers are being guided that these are the codes you should be using and sort of only these, then that would be very helpful.

>> **JONATHAN BLANAR:** Great, thank you for the questions and feedback as well, Charley. I will try to go back to Jason again. If you are there and want to come off of mute? Are you there Jason?

>> **JASON:** --

>> **JONATHAN BLANAR:** We still can't hear you. You might be, maybe double muted somehow. We will come back. Kai, I will go to Ross next, Ross Dodge has his hand raised.

>> **ROSS:** Yes thank you very much for the opportunity, my name is Ross Dodge I'm calling with general healthcare. My question is kind of a two-part and is related to enrollments, looking at the who can bill section of the website. My question is, that we are, we operate in 47 different states and as such, we qualify for centralized flu biller and all of our claims go through one singular MAC which is in the state of Texas. I understand that roster billing is not appropriate for PrEP billing. However roster billing and part B pharmacy supplier both are a CMS 855 B PTAN type. My question is, is it possible for us to continue billing to the Texas MAC for that centralized flu biller roster billing process under our appropriate flu biller PTAN? And then also for example the same site be able to bill their local MAC for PrEP under a pharmacy provider type, 855B PTAN?

>> **JONATHAN BLANAR:** Thank you Ross for the question, Joseph I will kick this question to you.

>> **JOSEPH SCHULTZ:** Hello everybody, provider enrollment, thank you Ross for the question. I think the question is can you keep your PTAN as a mass immunizer flu biller and get an additional PTAN as a part B pharmacy. And the answer is yes, and submit a separate set of 855 B enrollment applications to enroll as Part B pharmacy in order to bill for PrEP for HIV.

>> **ROSS:** Great and my actual follow-on for that is we do

have many of our sites set up with an 855 B pharmacy provider type PTAN. I'm looking at a link to check to see if you are enrolled that goes to a data set where we can look it up by NPI. However, I was looking in that data set and far fewer of our pharmacy sites are represented in that data set than we expected based on our PECOS enrollment log. So my question is: Is that data set a source of truth or if we can confirm on PECOS that we have an active 855B pharmacy supplier type PTAN, even if it isn't represented on that data set are we good to go for enrollment and billing?

>> **JOSEPH SCHULTZ:** Another good question Ross. So I would be interested in looking at why there are discrepancies. Ultimately, the primary source for enrollment information is PECOS. So if you do have a part B pharmacy enrollment in PECOS, you've confirmed that, you are good to go. But if we can add to the chat please, there is a provider enrollment e-mail address that I would like for you to e-mail Ross, with some examples, provider enrollment @CMS.HHS.gov. I would be happy to look into that for you and see what's going on. But PECOS is the primary source.

>> **JONATHAN BLANAR:** Okay great, thank you Joseph for providing the response. And we will go to next, Talemah Jones. If you can unmute.

>> **TALEMAH:** Hello can you hear me? Calling from -- Parkland in Dallas. I'm calling to find out will you be expediting enrollments because we have done, we are a part B biller for immunizations but we are also a DME biller. I want to make sure if we have to get one of our sites up and running, will you all be able to expedite the enrollment process?

>> **JONATHAN BLANAR:** Okay, thank you, Joseph?

>> **JOSEPH SCHULTZ:** Happy to answer that. Yes, we are able to expedite the applications for enrollment applications. So our contractors will have the guidance to do so. If you are having issues, particularly with an application you are working on, use the e-mail box in the chat and I would be glad to get involved with our contractors to see if we can move it along.

>> **TALEMAH:** Thank you.



>> **JOSEPH SCHULTZ:** On that point just as a public service announcement I guess, as it pertains to submitting applications, the best way to ensure that your application is handled quickly and processed as quickly as possible is to ensure that you are submitting a complete application and so take your time if you are not familiar with the enrollment process or don't do it a lot be sure to take your time and use the educational resources available on our web sites to make sure you are filling out the applications accurately and that will be very helpful in terms of being able to process your applications quickly.

>> **JONATHAN BLANAR:** Thank you for that Joseph, can you repeat that website they can go to and Kai can drop that in the chat as well?

>> **JOSEPH SCHULTZ:** I believe it is in the chat already it is provider [enrollment@cms.hhs.gov](mailto:enrollment@cms.hhs.gov).

>> **JONATHAN BLANAR:** Okay so the next question comes from Kayla McFeely. If you can unmute.

>> **KAYLA:** Hello, can you hear me?

>> **JONATHAN BLANAR:** Yes.

>> **KAYLA:** Perfect, a few different questions here, first I will start on the diagnosis code piece. Can you clarify what is required regarding diagnoses codes with this change? I think the memo that was sent to plans stated that the codes are not required on prescriptions, but they are required on claims so it's up to pharmacies to make sure those codes get on the claims before they are submitted. Is that correct and if not can you clarify?

>> **JONATHAN BLANAR:** Thank you Kayla, Joanna or Jason?

>> **JOANNA:** Yes, so the Medicare part B claim that is submitted, claims that go to Medicare part B, they do require the presence of a diagnosis code as well as the presence of the procedure code and in this case for pharmacies the, drug code. So that is a departure from what we understand is the case in Medicare part D today. So we just wanted to be very explicit that for pharmacies to

submit a claim under Medicare part B it does need to contain a valid diagnosis code. And we have provided the list among appropriate diagnosis codes. And we put that out there so pharmacies will be aware of how we are setting up the system to process claims. So that is why the diagnosis code list is out there but yes, we offer that information because for those that are not familiar with billing Medicare part B, it is a departure from what they are used for Part D. So that information, the diagnosis code information, is necessary to process the claim.

>> **KAYLA:** And because the diagnosis codes will not be required for some of the same products when you bill part D, can you offer any guidance or clarification there?

>> **JOANNA:** Yes, no, I do understand your question, thank you. So we've offered some information on the website. Under our FAQs and under our fact sheet. And part of us having the call today and putting this much information out in advance of the final national coverage determination as possible is to help prepare pharmacies for this type of transition. It might be a departure from what you already are used to. But we are very much trying to encourage pharmacies and pharmacists to be aware that prescriptions for PrEP for HIV do have, the pharmacy will need to have a different set of information than they would if they were billing Medicare part D. So we would look to either more communication that can take place between the pharmacist and the ordering provider, or additional information could come in to the pharmacist, to the pharmacy and the pharmacist, when dispensing PrEP for HIV drugs. We are also working to spread this information to the providers, the practitioners who will be ordering PrEP for Medicare beneficiaries. To make sure that they have this information as well. And that they are also aware that when these drugs are ordered for PrEP that the pharmacy will be billing part B and additional information will be needed in order for that claim to be processed from the pharmacy.

>> **KAYLA:** Great, that communication is very much appreciated. I don't want to take up too much time, but the other question I have is: Do you know when the supplying fees will become available? When folks will know what

those look like?

>> JONATHAN BLANAR: Go ahead Jason.

>> JASON: Yes thank you for the question. So we have issued a notice of proposed rulemaking to discuss what type of methodology we would be undertaking as, from a national payment perspective. Beginning January 1, 2025. That is in our what is generally known as the Physician Fee Schedule proposed rule and that is open for public comment, and we would welcome public comment on that. So the national pricing will be available later this year for the beginning January 1st. In the interim between the date that the, that the NCD is published and becomes effective and at the end of December, our Medicare administrative contractors will be developing local payment or the jurisdictions with which they facilitate. And so the information will be available through them in terms of what the payment amounts will be for the drugs and the supply fees, and any other services that are priced by the MACs, by the Medicare administrative contractors locally in the interim period.

>> KAYLA: Thank you Jason, I was most interested in the interim period so thank you all.

>> JONATHAN BLANAR: Okay next we have Kathy who has a question. Kathy you are on mute, Kai, can you help unmute her?

Kathy, if you are speaking we cannot hear you but you are off of mute on our side. Okay Kathy we will come back to you.

Next Carrie has a question.

>> CARRIE: Hello can you hear me?

>> JONATHAN BLANAR: Yes.

>> CARRIE: Okay thank you, I am from optum and I was hoping to get some clarification on a few things. We do a lot of Medicare part B DME billing to the DME MACs, are there any required modifiers that you know of that would have to go to the DME MAC or the local carriers for part B?

>> **JONATHAN BLANAR:** Thank you for the question, Jason?

>> **JASON:** There are no required modifiers for submitting claims for these drugs and services.

>> **CARRIE:** Thank you that is very helpful. And then I guess I wanted some clarification on the question, the previous person asked regarding the pricing. So at this time the MAC pricing, I guess what I'm trying to say is will it be available how we normally have for the DME MACs, the quarter four, like the fourth quarter ASP pricing? Is there going to be any pricing available for these set of drugs?

>> **JASON:** We will not be providing a national level ASP pricing which is often used by those MACs when working with part B drugs that are part of the DME post benefit. But we are working with the MACs so that they will be ready to provide information about how they're pricing at the time the NCD is effective.

So I would recommend is continue to monitor the MAC web sites. And engage with them directly for the interim period.

>> **CARRIE:** Thank you for that clarification, those are the question as I have for now, thank you so much.

>> **JONATHAN BLANAR:** Thank you. And a reminder to folks, if you do want to ask a question please use the raise hand function at the bottom of the screen. We plan to take questions until about 4:25 PM, I see that we have more in the queue, I will try to go back to Kathy again. Kathy, are you there?

>> **KATHY:** Hello. It seems like there is a mix up. But a question, this is Peter from CVS specialty. A question for the ICD 10 codes. Will CMS be publishing more ICD 10 codes that will be covered for HIV PrEP? Seems to be an incomplete list for this one that was published.

>> **JONATHAN BLANAR:** Jason or Joanna, can you answer that question?

>> **JOANNA:** I will go ahead and try to address that question. Yes, we put out that initial list of diagnosis codes,

the list that we determined to be most appropriate for PrEP for HIV. And we will look to issuing, we will look to update information on the fact sheet and the FAQ as we get closer, should we need to update any information on there we will certainly do that. So please continue to use that as a resource to get information about this upcoming national coverage determination.

>> KATHY: Okay thank you.

>> JONATHAN BLANAR: Okay thank you Peter and Joanna. So next we have Lori Lewicki.

>> LORI: Can you hear me now?

>> JONATHAN BLANAR: Yes.

>> LORI: Hello I am from -- center an FQHC in Massachusetts. We currently do Medicare billing, and for our DME supplies we have physician order forms. And I'm wondering if that is something we should be utilizing for this billing so that we can have the provider, like a test, that the labs etc. had been done and we can put the code that, Z29.81, as the diagnosis code? And if so how long are those physician order forms good for because for diabetes they are good for six months and respiratory is good for one year?

>> JONATHAN BLANAR: Great, thank you for the question, Lori. Jason would that be?

>> JASON: I don't think I have any specific guidance in terms of documentation that would be appropriate in terms of what you are saying there. It is something that we have shared with our colleagues who are more closely involved with documentation on related efforts and if there is any specific guidance, we can offer, we will update our material online. And also, would recommend reaching out to your Medicare Administrative Contractors if there's any specific questions about any documentation now that you think they may request it at some point to see if they have any guidance for you.

>> JONATHAN BLANAR: Okay great, thank you Jason. Thank

you Lori.

Next we will go to Michael Murphy. Kai, if you can unmute Michael.

>> **MICHAEL:** Hello this is Michael Murphy can you hear me? Great, thank you so much Michael Murphy from the American Pharmacist Association. Really appreciate the previous comments related to the selection of diagnosis codes. And just wanted to ask to confirm that if a prescription is written for PrEP without a diagnosis code included as stated in the fact sheet, can a pharmacist select the diagnosis code that is then submitted on the CMS claim form?

>> **JONATHAN BLANAR:** Umm, Jason or anyone from CMS?

>> **JASON:** Yes, thank you for the question, I think this is similar to the question from the previous individual. We've share those questions with our colleagues involved -- medical documentation. And we don't have any particular guidance that differs at this time from what is available on our website. But should we have any additional information or guidance we can share we will update it on that website.

>> **JONATHAN BLANAR:** Great thank you Jason. Thank you Michael. Next up is Monica Brooks, Kai, if you can unmute Monica's line?

>> **MONICA:** Hello can you hear me? I appreciate you guys taking my question and providing the forum for all of us to ask our questions. Monica Brooks I'm with -- National Pharmacy Services. And my question is carrying this back to documentation here. With the DME MACs, we would be required to document the level of supplies on hand for a patient prior to a refill. And I haven't seen anything from the FAQs or fact sheet regarding this particular documentation requirement. So I was wondering if you guys had any direction other than we have no direction to give you, please refer to your local MAC?

>> **JONATHAN BLANAR:** Joanna or Jason?

>> **JASON:** And Monica is your question specific to, in a situation where the product would be refilled.

>> **MONICA:** Yes sir, that is the exact situation.

>> **JASON:** I don't have anything on that particular question, I don't believe we have an FAQ on that, we will engage with our colleagues that work in that area and see if there is additional guidance we can offer.

>> **MONICA:** Thank you, appreciate it.

>> **JONATHAN BLANAR:** Okay thank you. And we do appreciate the questions and the feedback and you know these questions you know if we don't have an answer, it does help inform future guidance and future policy so we certainly appreciate the feedback and the questions. Next Phil Doherty, is if you can unmute.

>> **PHIL:** Hello this is Phil Doherty, UDUB medicine in Washington. Just a quick follow up question related to enrollment. We are enrolled as a DME supplier at our locations but not as an 855B supplier. Will be need to enroll for that B side of the business?

>> **JOSEPH SCHULTZ:** So no, you do not. Enrolled DME suppliers as well as Part B pharmacies are able to bill for PrEP for HIV.

>> **PHIL:** Thank you very much.

>> **JONATHAN:** Next we have Logan, if you can unmute Logan.

>> **LOGAN:** Good afternoon I am Logan Yoho director of pharmacy services at FQHC 340B compliance. In response to the inflation reduction act, prescriptions going to the Medicare part B, that are 340 B require the use of a Tb modifier. We've heard instances where the MACs are not able to accept that modifier. Do you know if that's going to be capable? Because it's going to create huge access issues in the FQHC space if 340 B drugs cannot be used for these patients.

>> **JONATHAN BLANAR:** Logan, thank you for the question. Jason or Joe?

>> **JASON:** We will need to go back and research that one. I think, I understand your question because you are framing this as a part B drug. Where I think the distinction for us is this is a part B preventative service or what is considered a part B -- preventive service that happens to also be a drug. And so there is a little bit of distinction for us on how that applies. And so I think I need to run that specific question past a couple of colleagues but at this time no modifiers are required.

>> **JONATHAN BLANAR:** Great, thank you Jason and thank you Logan. Our next question is from Melissa Rosenberg. Kai, if you can unmute Melissa please.

>> **MELISSA:** Hello this is Melissa Rosenberg from OPTUM. My question is related to DME billing. Will accreditation apply to this? And if so which category would it be under?

>> **JONATHAN BLANAR:** Thank you Melissa. Jason or Joe?

>> **JOSEPH SCHULTZ:** So Melissa to maybe rephrase your question, are you asking that, do you need to have an accreditation specifically for PrEP in order to bill for PrEP? The answer to that is no, you don't have to have a specific accreditation. If you are already enrolled as a DME supplier, you are going to be able to bill for PrEP. Without specific accreditation.

>> **MELISSA:** Wonderful. Thank you.

>> **JONATHAN BLANAR:** Thank you Melissa and Joe. Next up is Steve Postal, Kai, is if you can unmute Steve.

>> **STEVE:** Yes I just have a quick question on my end, can CMS explore the feasibility in establishing a streamlined PrEP only enrollment process for entities that are not already enrolled in the part B?

>> **JONATHAN BLANAR:** Joe?

>> **JOSEPH SCHULTZ:** Thank you for the question Steve. Our hands are really tied in that manner. In allowing the enrollment, or allowing access to bill for PrEP to extend to the part B pharmacy we have kind of gone as far as



possible in terms of opening doors to alleviate burden in the enrollment process. My suggestion to you would be to use the online enrollment tool. So using PECOS online. There is a link to a video link in the chat that will take you step-by-step through enrolling as a part B pharmacy online.

>> **STEVE:** Okay thank you.

>> **JONATHAN BLANAR:** Thank you Steve and thank you Joe. We have one more question, but if folks have questions please raise your hand and we will keep going. I think Carrie is back, do you have another question?

>> **CARRIE:** I apologize as I heard other questions from people on the call. I had a few other things. I am looking through what has been published so far. Am I correct that we don't have any published limitations or any like with Medicare part B DME, we are used to seeing sometimes the medically unlikely edit, the MUE edit, would we have anything like any type of limitations available at this time to go by?

>> **JONATHAN BLANAR:** Thank you, Jason or Joanna? Do we have an answer for Carrie?

>> **JASON:** Hi, Carrie, I'm not aware of any that have been publicly announced at this particular time as part of the MUE --

>> **JONATHAN BLANAR:** Thank you Jason. Carrie, I don't know if you had more questions but you are welcome to ask them and you don't need to apologize for asking more. All right. Let's move on. Anne Mock, has a question. Kai, if you can unmute Anne.

>> **ANNE:** Thank you so much My name is Anne Mark and I met-- health in Seattle Washington. Part B, prescriptions are limited to a 30-day supply got will that be the case for PrEP also? Concern for a lot of PrEP teaching to state a 90-day supply in time for compliance. This wondering if there is going to be any change in the supply restrictions?

>> **JONATHAN BLANAR:** Thank you for the question. Jason or Joanna?

>> **JOANNA:** I will go ahead and take that one. So when you go to the website, you will see that we have put forward the codes that will be billable upon the final national coverage determination. So what you will see there and this is, Jason may certainly have more to add. They are a series of codes for the supplying dispensing fees. And the way those are set up they are in different periods. You will see that there is not a 30-day limitation on one fill. We have, I think and I don't want to misspeak so please check the website for these code descriptors. But I think what is in there is a 30, 60 and a 90.

>> **JONATHAN BLANAR:** Great, thank you Joanna. And thank you Anne, you for the question. Next we have Clint Hopkins.

>> **CLINT:** Hello good afternoon Clint Hopkins, PharmD, -- pharmacy in Sacramento and -- pharmacy in Los Angeles. My question is regarding pharmacist issued prescriptions for PrEP, I would like to ensure that pharmacist issued prescription in states where laws have been passed to allow pharmacist prescribing will be recognized by this program and additionally injectable PrEP, will injectable PrEP be covered by this program --?

>> **JONATHAN BLANAR:** Joanna or Jason?

>> **JOANNA:** I will go ahead and give a try first, and Clint I apologize if I was the only one that had trouble hearing you. I think I may have heard just part of your question. So I will address perhaps maybe part of it and then please, please ask again.  
So your question about injectable PrEP I will start there. The way that the proposed national coverage determination is written, it provides Medicare part B coverage with no cost sharing for additional forms of PrEP, so the way that it is proposed and the current PrEP on the market are both oral and injectable. The way that the proposed NCD is written and we have said expected to be finalized, it would include both types of the medication.

>> **JONATHAN BLANAR:** Great, thank you Joanna, and I was going to ask Clint if you could repeat the first part of your statement or question?

>> **CLINT:** I want to ensure that pharmacist issued prescriptions for PrEP will be recognized by this program in states where laws have been passed to allow pharmacists to test and prescribe?

>> **JOANNA:** Yes Clint thank you for the comment. As I mentioned earlier, pharmacists are not recognized under the Medicare program at this time. So when a claim comes in for PrEP for HIV to Medicare part B as a Medicare part B claim, there is a part of the claim for the referring and the ordering. And so the referring and ordering NPI would need to be a practitioner that is recognized to refer and to order for services under the Medicare program. Which currently does not include pharmacists.

>> **JONATHAN BLANAR:** Thank you Joanna. Okay I see that Clint's question was the last one. I will give it 30 seconds to see if anyone else has any questions. Yes we have one more, Ross Dodge.

>> **ROSS:** I want to go back to a question that was asked and answered earlier just to make sure and clarify. I'm used to looking up drug rates for Medicare under Medicare's ASP. I think I heard somebody say earlier that pricing for these oral and injectable PrEP medications will not be published under the ASP but rather under the physician fee schedule. I want to make sure to confirm if I have that right? And also, I guess an additional add-on to the question after that is answered.

>> **JONATHAN BLANAR:** Okay.

>> **JASON:** Yes, Ross I appreciate the question and the opportunity to clarify that. What we have proposed under the physician fee schedule proposed rule is a discussion that, beginning in January, we would look to ASP pricing as our proposal for these and at that time, should that policy be finalized, we would list those prices on the ASP file following the final methodology that we would adopt. We are in the process of taking public comments at this time. And we will deliberate on those public comments before making a final decision, which usually comes right around the beginning of November.

In the interim between the period when this NCD is finalized and the end of December, the Medicare administrative contractors would be locally pricing these products. And that is not dissimilar from sometimes what happens when new drugs enter the market and we do not yet have them through a national pricing approach.

>> **ROSS:** Great, thank you. And I guess the next part of my question: I think you had stated earlier that rather than thinking about this as reimbursing as a drug you are looking at this from the standpoint of a preventative service that happens to be a drug. I was wondering if you could expand a little bit more on that and if there's any sort of substantive or practical difference in how we need to be billing or providing to Medicare part B patients that would differ between those two approaches?

>> **JASON:** Thank you for the question. I think from the standpoint of the patient, it should be seamless and should not feel necessarily like a different service. They are engaging with the pharmacy or engaging with their practitioner and receiving a service provided by Medicare. I might point you to that proposed rule because it goes into more depth in there, in particular about how we are thinking about this from the payment standpoint, and helps draw some of those distinctions as to what we think of as a part B drug that has co-pays and other types of processes assigned to it versus how we are thinking about this is an additional preventative service. And that is some of the differences that you're hearing in both the questions and some of our responses in terms of the longer period of a fill being not necessarily the typical 30 days or being able to enroll as a part B pharmacy, rather than exclusively as a DMEPOS supplier. And some of the other nuances that we are talking about here today because we are looking at this as a slightly different benefit than what we would normally do for a Medicare part B drug that has the more traditional co-pays and coinsurance and so forth. Joanna, do you want to expand further?

>> **ROSS:** No, that is helpful, thank you very much.

>> **JONATHAN BLANAR:** Thank you. We have a couple minutes left. We have a couple questions here. I will go to

Adriann Deguzman, if you can unmute.

>> **ADRIANN:** Hello, Adriann here from UC San Diego in California. I understand that some patients with Part D currently do not have Part B. How is this going to impact that subset of patients from getting their medication?

>> **JONATHAN BLANAR:** Thank you for the question. Joanna or Jason, do either of you want to field that? Ok, Adriann If you can submit that question to the CAG e-mail address, so we will get back to you if you want to e-mail that question in to the CAG e-mail address.

>> **ADRIANN:** CAG Inquiries?

>> **JONATHAN BLANAR:** Yes. Okay we will take two more questions, the first is from Kayla McFeely.

>> **KAYLA:** Thank you so much I was just curious if there is an actual effective date for this change yet and if not, do you think one will be available in the next two weeks or any ballpark for getting that information on when this change will occur specifically?

>> **JOANNA:** Yes, thank you Kayla. What we have put and posted up on the website and in our FAQs, is that the end of September is what we are targeting.  
Jonathan, you are muted.

>> **JONATHAN BLANAR:** Thank you Joanna. [Laughter] so last question I will go to Carrie Addis. Carrie?

>> **CARRIE:** Does anyone know if the 2% sequestration is going to be applied to these claims?

>> **JONATHAN BLANAR:** Good question. Jason?

>> **JASON:** I think sequestration applies to all Medicare claims and there is not an exception to that. I believe it applies at the, it is basically a calculation that is performed at the end of the claim.

>> **CARRIE:** That helps a lot, thank you so much.

>> **JONATHAN BLANAR:** Thank you Jason, and I have 1 more here that I will take. It is Sima Shah.

>> **SIMA:** Thank you for taking my question. It is really quick, I was wondering, will this video be available and the questions that were asked in this video, will they be available as an FAQ as well?

>> **JONATHAN BLANAR:** So we are, I think the plan is to post the video and transcript. But I do not think it will be turned into an FAQ document. But I mean, if there's questions that we think would be helpful for FAQs, we may add them to the website. But I will let Joanna address that more specifically. Are you good? Okay. Thank you for the question.

>> **SIMA:** Thank you.

>> **JONATHAN BLANAR:** That is all our questions and we are just about out of time. I certainly appreciate everyone joining us today for our office hours. We appreciate all the questions. Again, the feedback in the questions helps us put out future guidance in where folks need further clarification, so we thank you for that. I want to thank Dr. Dora Hughes who gave us opening remarks today, the CMS Chief Medical Officer, as well as all of our subject matter experts today from CPI, CCSQ, and CM. Thank you to everyone and thank you to our zoom moderators and closed captioner as well. So thank you everyone and have a good rest of your day and talk soon. Take care.

>> Recording stopped.

[Event Concluded]