



OTPs: New Medicare Benefit Proposed Rule Listening Session

Moderated by: Nicole Cooney
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Operator: At this time, I would like to welcome everyone to today's Medicare Learning Network® event. All lines will remain in a listen-only mode until the feedback session. This call is being recorded and transcribed. If anyone has any objections, you may disconnect. I will now turn the call over to Nicole Cooney. Thank you. You may begin.

Announcements & Introduction

Nicole Cooney: Good afternoon. I'm Nicole Cooney from the Provider Communications Group here at CMS and I'll be your moderator today. I'd like to welcome you to this Medicare Learning Network Listening Session on OTPs: New Medicare Benefit Proposed Rule. During today's session, CMS experts will briefly cover Opioid Treatment Program or OTP provision from the proposed rule and address your clarifying questions to help you formulate your written comments for formal submission.

Before we get started, you received a link to the presentation in your confirmation email. The presentation is available at the following URL go.cms.gov/npc. Again, that URL is go.cms.gov/npc. Today's event is not intended for the press and the remarks are not considered on the record. If you are a member of the press, you may listen in but please refrain from asking questions during the question-and-answer session. If you have inquiries contact press@cms.hhs.gov.

There may be questions today that we cannot answer because CMS must protect the rulemaking process and comply with the Administrative Procedure Act. We appreciate your understanding. It is also important to note that verbal comments on today's call do not take the place of submitting formal comments on the rule as outlined on slide 5 of today's presentation.

With that, we'll get started. Our speakers today are Dr. Pierre Yong and Lindsey Baldwin from our Center for Medicare, Joe Schultz from our Center for Program Integrity, and Sharon Donovan from our Medicare Medicaid Coordination Office. Dr. Yong, would you like to start us off with slide 3 and the overview?

Presentation

Dr. Pierre Yong: Sure. Thanks, Nicole. Thank you and let me echo Nicole's welcome to everybody for joining us for today's OTP Listening Session. We are very excited to be able to expand upon and talk a little bit about the proposals we included in this year's notice of proposed rulemaking for the Physician Fee Schedule. On slide 3, you can see an overview of the agenda today which the team at CMS will go through.

On slide 4, Nicole already addressed some of the points but just as - to familiarize everybody with how rulemaking works. CMS has issued a proposed rule. The comments which we welcome are due this Friday, September 27th. The feedback during the presentation as Nicole mentioned and questions, we certainly welcome but don't replace formal submissions for comment. And we encourage those who do have comments or questions to submit those in writing using any of the ways outlined in the rule and summarized at the bottom of the slide.

Once the rule -- the comment period closes, CMS reviews each individual comment submitted and then issues a final rule on or about November 1st of this year which will then take effect January 1st, 2020. And that's when the benefits will begin taking effect.



On the next slide, we are moving to more of the policy area and as we are all likely familiar, the opioid epidemic in this country is a huge public health concern and is a huge concern to CMS in particular as we are one of the largest payers of health care services. We believe we have a vital role in addressing the opioid epidemic and we're focused in three key areas.

Prevention, treatment, and data. And one of the areas in which more specifically relating to treatments where there's been a gap in terms of benefits for Medicare has been coverage of Opioid Treatment Programs or OTPs. And that's why we're excited to describe our proposed policy in order to implement this new benefit.

On slide 6, you may be familiar with the SUPPORT Act which was passed last year which addressed multiple components of the federal government's ability to address the Opioid Use Disorder epidemic. In particular, Section 2005 of the SUPPORT Act creates this new Medicare Part B benefit for OUD treatment services furnished by OTPs beginning on or after January 1st, 2020.

In particular, the law states and allows for implementation through one or more bundles based on the type of medication provided, the frequency of services, the scope of services furnished, and characteristics of the individual's furnished such services or other factors as the Secretary determines appropriate.

On slide 7, folks are likely familiar that OTPs are certified by SAMHSA and that they're currently about 1700 OTPs nationwide. These OTPs are geographically distributed predominantly towards urban areas. They tend to be freestanding facilities, and OTPs, as you well know, provide MAT in addition to a range of other services. The current payor mix for OTPs include Medicaid in some states, private payers, TRICARE, as well as individual pay patients.

Medicare currently covers office-based opioid treatment with buprenorphine and naltrexone and, as I previously mentioned, has not historically covered OTPs, which are the only entities authorized to use methadone for the treatment of OUD. And therefore, coverage of OTPs through Medicare is a new benefit that we anticipate will help address the opioid epidemic and expand access to care.

And with slide 8, I'm going to turn this over to Lindsey Baldwin.

OTP Proposals In The Proposed Rule

Lindsey Baldwin: Great. Thanks, Pierre. So in the proposed rule, we propose that OTPs must be enrolled in Medicare, have an effective certification by SAMHSA, be accredited by a SAMHSA-approved accrediting body, and meet any additional conditions the Secretary may find necessary to ensure the health and safety of individuals receiving services as well as the effective and efficient furnishing of such services.

Moving on to slide 9, the statute specifies that OUD treatment services provided by OTPs will include the following: the FDA-approved opioid agonists and antagonist's treatment medications, the dispensing and administration of such medications as applicable, substance use disorder counseling, individual and group therapy, toxicology testing, and other items and services the Secretary determines are appropriate.

On slide 10, we are proposing to adopt a coding structure for OUD treatment services that varies by the medication administered. To operationalize this approach, we're proposing to establish G-codes for weekly



bundles describing treatment with, Methadone, oral buprenorphine, injectable buprenorphine, and buprenorphine implants, extended-release injectable naltrexone, a medication not otherwise specified, and a non-drug bundle.

Moving onto slide 11, to provide more accurate payment to OTPs. In cases where a beneficiary is not able to or chooses not to receive all items and services described in their treatment plan or in which the OTP is unable to furnish services. For example: In the case of a natural disaster, we're proposing to establish separate payment rates for partial episodes that correspond with each of the full weekly bundles. We're also proposing to adjust the bundled payment rate for the use of an add-on code in order to account for instances in which effective treatment requires additional counseling or group or individual therapy to be furnished to a particular patient that substantially exceeds the amount specified in the patient's individualized treatment plan.

We're proposing to allow OTPs to furnish the substance use counseling, individual therapy, and group therapy included in the bundles via two-way interactive audio-video communication technology, as clinically appropriate, in order to increase access to care for beneficiaries.

Moving on to slide 12 under payments, the proposed code describing OTP treatment services are assigned flat dollar payment amounts. The services are not assigned RVUs. Each bundled payment is composed of a drug component and a non-drug component. For the drug component, we're proposing to use the typical or average maintenance dose to determine the drug cost for each of the proposed bundle. We're proposing to use the payment methodology in Section 1847A of the Act which is based on Average Sales Price to set the payment rates for the "incident to" drugs and ASP-based payment to set the payment rates for the oral product categories when we receive manufacturers' voluntarily submitted ASP data for these drugs.

The non-drug component includes payment for counseling, therapy, and toxicology testing and drug dispensing and administration as applicable. The non-drug component was priced based on a crosswalk to the non-drug portion of TRICARE's weekly bundled rate for methadone. For a full listing of the proposed payment rates, please see table 15 in the CY2020 Physician Fee Schedule proposed rule.

Moving onto slide 13, under Beneficiary Copayment. We're proposing to set the copayment at zero for a time-limited duration. For example, for the duration of the national opioid crisis as we believe this would minimize barriers to patient access to OUD treatment services. Setting the copayment at zero also ensures Medicare-enrolled OTP providers receive the full Medicare payment amount for Medicare beneficiaries if secondary payers are not available or do not pay the copayment, especially for those duly eligible for Medicare and Medicaid.

We intend to continue to monitor the opioid crisis in order to determine at what point in the future a copayment may be imposed. At such time deemed appropriate, we would institute cost sharing through future notice and comment rulemaking. We'd also note that the Part B deductible would apply for OUD treatment services as mandated for all Part B services by statute.

Moving on to slide 14, under Locality Adjustments. For the drug component because our proposed approaches for pricing the MAT drugs included in the bundles all reflect national pricing, and because there is no geographic adjustment factor applied to the payment of Part B drugs under the ASP methodology, we do not



believe that it is necessary to adjust the drug component of the bundled payment rates for OTP services based upon geographic locality.

For the non-drug component, unlike the national pricing of drugs, the cost for the services included in the non-drug component are not constant across all geographic localities. In order to account for the differential costs of OUD treatment services across the country, we are proposing to adjust the non-drug component of the bundled payment rates using an approach similar to the established methodology used to geographically adjust payments under the PFS based upon the location where the service is furnished. In order to apply a single adjustment, we're proposing to use the Geographic Adjustment Factor or GAF to adjust the payment for the non-drug component to reflect the costs of furnishing these services in each of the PFS localities.

Moving on to slide 15, under Annual Update to fulfill the statutory requirement to provide an update each year to the OTP bundled payment rates, we are proposing to apply a blended annual update, comprised of distinct updates for the drug and non-drug components, to account for the differing rate of growth in the prices of drugs relative to other services. We're proposing to update the payment for the non-drug component based on the changes in drug costs reported under the pricing mechanism used to establish the prices of the drug component – of the drug component at the applicable bundled rate. We're proposing to update the non-drug component based upon the Medicare Economic Index or MEI.

And with that to go over OTP enrollment, I will pass it off to Joe Schultz in the Center for Program Integrity.

OTP Enrollment

Joe Schultz: Thank you, Lindsey. As previously mentioned, in order for an OTP to be eligible for Medicare enrollment, they must be certified by SAMHSA and accredited by a SAMHSA-approved accrediting body. For more information, please visit SAMHSA's website.

The next slide includes additional OTP enrollment proposals. We propose to enroll using the CMS Form-855B, pay the application fee which is \$586 in calendar year 2019, have owners, 5% or greater owners including partners submit fingerprints, have the OTP undergo an observational site visit at the OTP practice location, and have the OTP report all ordering/prescribing and dispensing practitioners on the supplemental attachment specific to OTP. With that, I will turn it to Sharon.

Sharon Donovan: Thank you, Joe. We understand that the states currently covering OTP services under Medicaid transitioning to a Medicare-covered benefit can create unique challenges for those OTP providers serving dually eligible individuals. That is, individuals who are dually enrolled with the Medicare and Medicaid at the same time. We welcome feedback related to any unique circumstances or challenges related to this. For example, OTP providers will now need to enroll in Medicare to receive Medicare payment for these services. Other ways we can support you in serving dually eligible individuals to ensure a smooth transition to this new Medicare benefits. With that, I'll hand it back to Nicole.

Feedback Session

Nicole Cooney: Thank you. Before we get started on our Q&A session for today, I'd like to set a few ground rules. In an effort to get to as many participants as possible today, we'll spend a maximum of three minutes on each question and answer.

We're looking to take clarifying questions to help you submit your formal comments on the rule. Today's call is not the forum for specific questions about your medical practice or place of business. There may be questions today that we cannot answer because CMS must protect the rulemaking process and comply with the Administrative Procedure Act. We appreciate your understanding, and it's also important to note that verbal comments on today's call do not take the place of submitting formal comments on the rule as outlined on slide 4 of today's presentation. As a reminder, today's session is being recorded and transcribed. Dorothy, we're ready for our first caller.

Operator: To provide feedback, press star followed by the number one on your touchtone phone. To remove yourself from the queue, press the pound key. Remember to pick up your handset to assure clarity. Once your line is open, state your name and organization. Please note, your line will remain open during the time you are providing your feedback. So, anything you say, or any background noise, will be heard in the conference. Please hold while we compile the roster. Please hold while we compile the roster. Your first question comes from the line of Elizabeth Collier.

Elizabeth Collier: Good morning, everybody. My question is in regards to the accreditation request. Most OTPs are unable to be accredited until they've been open a year. So how will you guys address that if they are unable to become accredited for after being open for a year without being able to receive payment from Medicare?

Joe Schultz: Hi, this is Joe. So, in order for the OTP to be eligible for enrollment, they must have full certification status with SAMHSA. The question is to whether SAMHSA will certify you is not a question that I can answer. I think it's more of a question for SAMHSA.

Elizabeth Collier: Correct. SAMHSA will certify without the accreditation. You guy have stated that your requirements for SAMHSA certification and accreditation. Those are two different things.

Joe Schultz: Okay. So, I think it'd be best if we address in a comment. Thank you.

Operator: As a reminder, to provide feedback, press star followed by the number one on your touchtone phone. To remove yourself from the queue, press the pound key. Your next question comes from the line of Elizabeth Rodriguez.

Elizabeth Rodriguez: Hello. This is Elizabeth.

Nicole Cooney: Hello. Did you have a question for us?



Elizabeth Rodriguez: Oh! I do. I'm sorry. I didn't know someone was there. My question is -- I'm the billing supervisor for our company. I'm trying to find out, are we going to or is someone going to inform us or maybe send us information on the billing process, what the rates are going to be?

Lindsey Baldwin: Hi, Elizabeth. Thanks for your question. Yes, we are planning to put out instructions to OTPs for how they should bill for the services furnished to Medicare beneficiaries. You can look out for an update to the Medicare claims processing manual to include that and other materials as well. So, we're definitely considering that and the payment rate -- the proposed payment rates are in the proposed rule and the finalized rates will be in the final rule.

Elizabeth Rodriguez: Okay. Thank you.

Dr. Pierre Yong: Nicole, I'm sorry. Just to expand on Lindsey's response. Elizabeth, you may also want to potentially sign up for the listserv that Nicole and her colleagues manage as those will be one way to get more further information. We also have a website specifically at CMS for OTPs, and so you can also keep an eye out on that, and we'll be posting further information about some of the questions that you ask on that webpage as well and if you could.

Elizabeth Rodriguez: Okay. Thank you.

Operator: Your next question comes from the line of Nancy Turner

Nicole Cooney: Hello. Did you have question?

Operator: Your line is...

Nancy Turner: Sorry, I was muted. The Form-855B, when will there be an OTP option to choose on that application, because presently there is not one?

Joe Schultz: Yes, that is correct. The Form will be updated in a couple of years, so you won't see that selection for a couple of years. Until the form is updated, you can write in the other -- check the other box and write in the Opioid Treatment Program or OTP would be acceptable.

Nancy Turner: Okay, so, don't use clinic; use other and OTP?

Joe Schultz: That's correct. That's correct.

Nancy Turner: All right. Thank you.

Operator: Your next question comes from the line of Michelle Kornegay.

Michelle Kornegay: Hi. Good afternoon. My question is will you guys -- Medicare recognize the credential of an LCAS. I know currently you all recognize social work license, but I don't believe you all recognize LPC or LCAS.



Lindsey Baldwin: Thank you for your question. We did address some of that in the proposed rule. So I would encourage you to look at that, and otherwise we would definitely appreciate if you can put those comments into a public comment letter, and if you can put that in writing that will help us make sure we can be responsive to it in the final rule and just a reminder, those public comments are due by this Friday, September 27th.

Michelle Kornegay: Great. Thank you so much. I will get a whole bunch of us to send you letters.

Lindsey Baldwin: Okay.

Operator: As a reminder, to provide feedback, press star followed by the number one on your touchtone phone. To remove yourself from the queue, press the pound key. Your next question comes from the line of Kristin Gawlik.

Kristin Gawlik: Hi there. My question is, is there going to be a minimum dose requirement in order to bill the weekly bundled rate?

Lindsey Baldwin: No, there would be no minimum dose requirement. We propose the one bundled rate and you can see the typical doses that were used for the purposes of valuation but those are not requirements, rather, just typical cases.

Kristin Gawlik: Right. So, if the patient's doses are 1 day or 7 days, you can still bill the same weekly bundled rate?

Lindsey Baldwin: Correct, and again any clarifying questions you have, do put them into comments so that we can make sure to be responsive with clarifying that in the final rule.

Kristin Gawlik: Okay. Thank you.

Lindsey Baldwin: Thanks.

Operator: Your next question comes from the line of Marty Trosclair.

Marty Trosclair: Hi. My question is, will there be locality adjustment charts so that we'll know if those bundled rates have been decreased for our locality?

Lindsey Baldwin: I think what you could do in the meantime is, our proposal is to use the locality adjustments under the Physician Fee Schedule and those are available on the CMS website. So, if you're looking to get a sense of what the locality adjustment is under our proposal, you could certainly look at that to get a sense of it. Once our rates are finalized then the MACs will be posting the payment rates for each locality as well.

Marty Trosclair: Okay. May I ask a second question?

Lindsey Baldwin: Sure.



Marty Trosclair: This piggybacked off the last question about the bundled rates. So if we have a patient who received 2 weeks' worth of take-out medications, how do we bill for that, if they're going to come 1 week and they're going to get 2 weeks' worth of medication and the counseling is all done on the week that they come to get the medication? Will we be able to bill for 2 weeks?

Lindsey Baldwin: That's a great question. Thank you so much for raising that. That is something we've been contemplating and if you can put that specifically into a comment letter, we would appreciate that so that we can be sure to address it in the final rule.

Marty Trosclair: Thank you.

Operator: Your next question comes from the line of Teri Krantz. Teri, your line is open.

Teri Krantz: Hi. Hi. My office is currently enrolled in Medicare and has certification by SAMHSA. Do we need to re-enroll for this or just we're good to go?

Joe Schultz: Hi, Teri. Yes, you will have to re-enroll as an OTP provider.

Teri Krantz: And you said just mark handwrite on there as OTP?

Joe Schultz: That is correct.

Teri Krantz: Okay. Thank you.

Joe Schultz: Teri, I would encourage you as well too, and this goes for everybody on the call, to submit your enrollment applications as soon as possible after the rule goes final. It does take the Medicare Administrative Contractors sometime to process applications. So, in order to be prepared to start receiving reimbursement come January 1st, we want to make sure you guys are getting your applications in as soon as possible.

Teri Krantz: So, we can send them in immediately right now, right?

Joe Schultz: No, not right now. You would have to wait for the rule to finalize before sending in the applications.

Teri Krantz: Okay.

Operator: Your next question comes from the line of Steven Ghiglione.

Steven Ghiglione: Hey. A couple of questions. To operationalize the bundled payment, Medicare's proposing establishing a G-code, the State of Washington Medicaid currently uses 80020, do not all states use the H-code for reimbursement?

Lindsey Baldwin: Hi. Thanks for your question. I know that I can't speak for all of the State Medicaid programs. We are definitely familiar with those H-codes that are used; however, under Medicare, we do not use H-codes. The G-codes are the codes that we can create and use it for billing under Medicare.



Steven Ghiglione: So, will there be a clarification then when we have a dually eligible client and we have to submit the G-code first, and for whatever reason it needs to adjudicate down to the COB-2, how that crossover requirement is going to work?

Sharon Donovan: Hi. Yes, we can put out some clarifications around that, although as others, I encourage you to submit that comment. I'll just note as articulated that it's been proposed that there would be a deductible, but not an ongoing for service co-insurance, but obviously, at the beginning of each year that's when that would come into play.

Steven Ghiglione: Okay. Thank you.

Operator: Your next question comes from the line of Krispa Aeschbach Jachmann.

Krispa Aeschbach Jachmann: Yes. Hi. I'm looking at what's included in the non-medication section and first, I'm not clear what is the difference between counseling and therapy individual therapy would be considered, and second, it doesn't -- the proposal doesn't seem to be very clear about what counseling/therapy is required. It says here a typical case might include one substance abuse counseling session, one individual therapy session, and one group session per week. That's a very high level of care that I don't think any OTP is meeting on a regular basis for methadone patients and I was just wondering if you guys could clarify that please.

Lindsey Baldwin: Hi. Thanks for your questions. Yes. If you look at the language in Section 2005 of the SUPPORT Act, it had separate items on the list. One was substance use counseling by a professional to the extent authorized under state law to furnish such services, and then there's a separate item for individual and group therapy with a physician or psychologist or other mental health professional to the extent authorized under state law. So, our proposal was just consistent with the language in Section 2005 of the SUPPORT Act. As to the typical number of services furnished in a week to methadone patients, if you are able to put what you think is more typical into a public comment letter and submit that at [regulations.gov](https://www.regulations.gov), we would really appreciate that information.

Krispa Aeschbach Jachmann: Can I have a follow-up question too?

Lindsey Baldwin: Sure.

Krispa Aeschbach Jachmann: So, my OTP is set up to have -- we have mainly RN case managers who use a medical model, somewhat like hospice, and other medication-based treatments, and we have state and SAMHSA approval to do so. It doesn't look like our nurse medication counseling or medication case management work would be covered under this. Am I correct in that?

Lindsey Baldwin: I'll go ahead and encourage you to put that into a public comment letter, so that we can consider that for the final rule.

Krispa Aeschbach Jachmann: Okay. Thank you very much.

Operator: Your next question comes from the line of Charms Guillory.



Charms: Hi, this is Charms from Baymaur. Hey, actually answered my question or asked my question earlier about the certain category, so my question actually has been answered. We're going to break that apart.

Nicole Cooney: Okay. Thank you.

Operator: Your next question comes from the line of Latorie Jones.

Latorie Jones: Hi. This is Latorie Jones with SAMHSA in for Nicole. I wasn't able to get into the queue a little bit earlier to speak to the certification and accreditation, but they are correct. What the slide shows is that you'll need a full SAMHSA accreditation, excuse me, a full SAMHSA certification as well as an accreditation from one of the SAMHSA-approved accrediting bodies. So, if you have a provisional certification that wouldn't satisfy having a full accreditation. Thank you.

Nicole Cooney: Thank you for that clarification.

Operator: As a reminder, to provide feedback, press star followed by the number one on your touchtone phone. To remove yourself from the queue, press the pound key. You have a follow-up question from the line of Nancy Turner.

Nancy Turner: Yes, do we have a date that the rule will be finalized yet?

Lindsey Baldwin: Yes, the Physician Fee Schedule final rule typically publishes on or around November 1st.

Nancy Turner: So, do not submit applications until after November 1st.

Lindsey Baldwin: Yes.

Nancy Turner: All right, thank you.

Operator: Your next question comes from the line of Chris Henderson.

Chris Henderson: Hi. My question is in regards to the observational site visit requirement, two parts: one is which credentialing body would actually be conducting site visit? Second part of the question is, with approximately 1700 providers nationally, how will the site visits be conducted given the good number of sites that would need a visit?

Joe Schultz: Thank you for your question, Sir. So, the contractor that does the site visits is not affiliated with any accrediting body. They are a contractor used by CMS to perform the observational site visit. This is essentially what we refer to as a drive-by site visit. It's a verification that the brick and mortar exist and that the appropriate signage is in place and that the facility is open during normal business hours. The contractor that performs a site visit does a lot of site visits, so there's not a problem in terms of their ability to accomplish that.

Chris Henderson: Okay. Thank you.

Joe Schultz: Yes.



Operator: As a reminder, to provide feedback, press star followed by the number one on your touchtone phone. You have a follow-up question from the line of Krispa Aeschbach Jachmann. Krista, your line is open.

Krispa Aeschbach Jachmann: Yes. I'm sorry. You just mentioned proper signage is part of that contractor site visit. A lot of OTPs have minimal signage just because of confidentiality. Are there specifics about what proper signage needs to be there?

Joe Schultz: That is a very good question. I would encourage you to submit your comment and concern about that. Formally, what I will say is that they -- how they conduct the site visits today is that they just verify that your name is on the building and that you're open during the hours posted.

Krispa Aeschbach Jachmann: We -- we don't have our name on the building.

Joe Schultz: Okay -- please. Yes, that's a truth. Please submit that as a formal comment and we will address it. Thank you.

Krispa Aeschbach Jachmann: The other thing is just OTPs are already -- I mean we have the DEA; we have site visits from the accrediting bodies. We already get -- we have the state visits as well we're already highly, highly regulated. So, it is just -- it is a little bit redundant to have somebody else come in as well but thank you.

Operator: There are no further questions at this time. I will turn the call back over to you, Nicole.

Additional Information

Nicole Cooney: Okay. Thank you very much. One thing that I wanted to mention. Dr. Yong mentioned that you can subscribe to the MLN Connects newsletter. We will be using that vehicle for updates and information for OTPs and for this benefit. The subscribe language was included on the last few email distributions that SAMHSA sent out. You also had an opportunity to request that we sign you up when you registered for this call. In the event that you missed those opportunities, I will send out an email to all registrants with the subscribe language just so you can be sure that you sign up, if in fact you would like to. I wanted to direct you to slide 19 that lists the number of resources for obtaining more information on today's topic. An audio recording and transcript of today's session will be available in about two weeks at the same link where you obtain the presentation that's go.cms.gov/npc.

Again, my name's Nicole Cooney and I'd like to thank our presenters and also thank you for participating in today's Medicare Learning Network Listening Session on OTPs: New Medicare Benefit Proposed Rule. Have a great day, everyone.

Operator: Thank you for participating in today's conference call. You may now disconnect. Presenters, please hold.