Physician Fee Schedule Proposed Rule: Understanding 3 Key Topics 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: Thank you. 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 the Physician Fee Schedule Proposed Rule: Understanding 3 Key Topics.

During today's session, CMS experts will briefly cover 3 provisions from the rule and address your clarifying questions to help you formulate your written comments for formal submission. Today's topics include Evaluation and Management Payments, The Quality Payment Program Improvements, and The New Opioid Treatment Program Benefit.

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 feedback sessions. If you have inquiries, contact press@cms.hhs.gov.

At this time, it's my great pleasure to introduce our CMS Administrator Seema Verma, who will provide opening remarks. Administrator Verma.

Opening Remarks

Seema Verma: Thank you, and good afternoon and thank you for joining the call today. Two weeks ago, we announced the release of the 2020 Physician Fee Schedule and Quality Payment Program Proposed Rule. It was a busy week for us, and we also announced the Outpatient Prospective Payment System and the Ambulatory Surgical Center Proposed Rule.

With historic proposals on Price Transparency, Site-Neutral Payment, as well as the End Stage Renal Disease and Durable Medical Equipment Proposed Rule, that bill from President Trump's recent executive order to advance kidney health and advances our strategic initiatives to strengthen Medicare and unleash innovation. It was an exciting week full of important proposals.

Following the leadership of President Trump's cut the red tape effort, we created the Patients Over Paperwork initiative in 2017. It's a historic effort that began with the nationwide listening tour and resulted in over 1300 providers identifying outdated and unnecessary regulations that cause undue burden and lead to higher health care costs.

I'd like to focus on the proposals that impact clinicians. Delivering on President Trump's commitment to strengthen and protect Medicare and cut unnecessary regulations. And I want to thank you all for your feedback and work that has helped to inform these important proposals.

Physicians are some of the best and brightest, spending years on education and training to care for patients. But the last 10 years have created a new level of regulation, and clinicians on the front lines of healthcare are growing more and more frustrated. You've told us unnecessary paperwork makes it harder to spend time with patients. That there are too many measurement requirements, and that the government undervalues the work involved in taking care of complex patients.

With increasing rates of physician burnout or moral injury and 10,000 new beneficiaries every day, these issues raised serious concerns. Clinicians spoke and the Trump Administration listened and we're getting things done. Last year, the Trump Administration made major changes to the requirements for the Evaluation and Management, or E/M visits, for the first time in more than 20 years.

Our goal was simple, reduce the amount of time the clinicians spend documenting an E/M visit for the purposes of billing Medicare. So, they can spend more time with patients. Since we announced this policy, the CPT editorial panel has made updates to the E/M code sets. As you know, CPT codes are used by the entire health system, not just Medicare.

These changes, which will go into effect in 2021, reduce the number of codes from 5 to 4 levels and give clinicians the choice of documenting to bill Medicare based on medical decision making or time. We're proposing to adopt these changes made by the CPT, as they are consistent with our shared goal to reduce clinician burden.

Our work on E/M reform does not end there. As Medicare pays for more and more procedures and at higher rates under a system where the total amount of Medicare payments is fixed, the value placed on E/M has actually decreased as more procedures become available. Even though the complexity of patient care has increased.

Clinicians are now spending more time managing patients with complex conditions, proactively taking steps to prevent disease, evaluating genetic information, and addressing the social determinants of health. The evaluation of the E/M codes must be modernized to reflect the time the clinicians are spending caring for complex patients.

For the past year, the American Medical Association Relative Value Scale Update Committee or the AMA RUC, developed recommendations to revalue E/M code, based on a robust process, surveying over 50 specialties, and we are proposing to accept the AMA RUC recommended values on these codes starting in 2021. This would increase Medicare payments for these visits across the 4 code levels, rewarding the times that doctors spend with patients.

This is a historic change that will help address inequities in payment for performing procedures versus spending time with patients. Building on this work to encourage and reward doctors for time spent managing complex care; I would next like to discuss how we're strengthening Medicare to help patients who are chronically ill.

Nearly 1 in 5 Medicare beneficiaries have 6 or more chronic conditions and account for over 50% of Medicare Fee for Service spending. In 2013, and 2015, Medicare began paying clinicians for care management and care coordination. But we heard that the billing requirements were burdensome and the codes are undervalued, limiting access to these important services, and this is evident with only 9% of beneficiaries receiving these critical services. So, we have proposed changes to fix this.

First, we're proposing to increase payment and pay doctors for spending more time doing care management. Second, Medicare's proposing to start paying for management of a patient with a single high-risk condition like diabetes or high blood pressure. Whereas previously, we only paid for care management for patients with multiple chronic conditions or after a patient is discharged from the hospital. With proper care management like making sure a patient is taking care of their medication, patients are less likely to return to the hospital and more likely to have better health outcomes.

These proposals will increase patient access to these crucial services. And as part of our Patients over Paperwork initiative, we also continue to advance our Meaningful Measures Initiative. Doctors are eager to engage in value-based reforms, but improvements are needed to develop a program that isn't burdensome, and we continue to hear that the MIPS reporting requirements cause confusion, that there's much choice and complexity when it comes to selecting and reporting measures, but the measures aren't always relevant to a clinician specialty and that it's hard for patients to compare performance across clinicians.

Ultimately, MIPS is a great example of government policies that are well-intended to help clinicians move to value-based care but end up being burdensome and complex and doesn't help doctors or patients. So, our proposed rule would create a new participation framework beginning in 2021 to overhaul the MIPS program.

The new participation framework called MIPS Value Pathways or MVPs would have different paths, focused on specialty or disease and would include a smaller set of what I call super measures and activities that meet the 4 current performance categories. The pathways would also include common measures in all sets that are focused on population health and interoperability. So that patients can compare performance across clinicians.

The goal of the new framework is to streamline reporting requirements, reduce reporting burden, and ensure that the measures are meaningful to clinicians and patients. So, let's take surgery as an example. Right now, under MIPS, our surgeon reports on over 20 measures, under the 4 performance categories that a primary care doctor would also report on and aren't necessarily related to surgery.

Under a Surgical MIPS Value Pathway, a surgeon could take a measure set that would include fewer measures and activities across the 4 performance categories, such as surgical site infection as well as cost measures for knee arthroplasty, which are measures that are meaningful to them. Over time, we would also add more administrative claims-based measures to reduce reporting burden, and finally the MIPS Value Pathways will include measures and activities that better aligns with Advanced Alternative Payment Models to help clinicians' transition toward value-based care.

We're looking for the public's input on this new framework so that we can build a better program together. And finally, I would like to highlight our efforts to advance site-neutral payment. Right now, independent physicians are increasingly selling their practices to hospital systems and new physicians are more often beginning their careers as employees of larger health systems.

This consolidation stymies position-independent competition and patient choice in this part of our Hospital Outpatient Proposed Rule, released 2 weeks ago; we are continuing our change to pay comparably for clinic visits essentially a checkup with the doctor either in physician offices or in off-campus hospital outpatient departments that we would save them over two years. This policy will both reduce out-of-pocket costs for seniors, and level the playing field for independent practices.

The Trump Administration is listening and responding to the concerns of clinicians, who for far too long have been drowning in paperwork and regulations. Clinicians are the backbone of the healthcare system and our policy should support the reasons you chose to practice medicine in the first place and ensure you can spend your valuable energy treating patients, providing high quality care, and improving the health of our nation's seniors.

After 20 years, we are reforming the entire healthcare system by changing how doctors bill Medicare. We are paying more for E/M office visits for time spent with patients. And we are improving payment for chronic disease care management. These historic changes will strengthen Medicare and change the practice of medicine for current and future generations of clinicians. During this comment period, I look forward to hearing from you and reviewing your comments to make sure that we get this right.

And so, with that, I will turn it over to the team to go over the proposal in more details. Thank you.

Presentation

Nicole Cooney: Thank you Administrator Verma. As I mentioned, the purpose of today's session is to address clarifying questions on these 3 topics, to help you formulate your comments on the rule. After the presentation on each topic, we will open the lines for clarifying questions on that specific topic. 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 rules as outlined on Slide 5 of today's presentation.

With that, we'll start our first topic with Ann Marshall and Emily Yoder from our Center for Medicare, who are here to discuss increasing the value of Evaluation and Management payments. Ann.

E/M Payments

Ann Marshall: Thank you Nicole. So, in the interest of time, we will try to stay a little bit of a high level, but we'll let you know which slide we're on as we go along.

So, we're going to start out with a slide 8, which is just a general slide about medical record documentation, given that our goal in the E/M space is to reduce burden and update the payment and the supporting

documentation framework for changes in the practice of medicine and the Medicare population, and to allow that information is in the medical record to be restructured to better facilitate patient care.

So, in terms of where we are on Slide 9 with E/M payment overall. We began with the office outpatient subset of code and considering how to begin our reforms. These codes account for approximately 20% of all Physician's Fee Schedule dollars. And currently they have 5 levels in each of them are separately paid, and they're distinguished in their complexity according to how complex each of the 3 key components is of history, physical exam, and medical decision making. And currently time does not drive at this level unless the visit is predominantly care coordination or counseling.

Moving to Slide 10. Also, there are extensive sets of guidelines that were developed in the 1990s and these specify what kind of medical record information is necessary to support each of the visit levels, for each of those 3 key components. So, for example for history, the number of body systems that are reviewed.

As Administrator Verma has noted stakeholders really iterated to us in the beginning of this administration and prior that the E/M documentation guidelines were outdated and the code set itself needed to be updated both for clinical practice and also for complexity of care, and so that the medical record would more readily document the most important information for clinicians to access for patient care, rather than bloating it kind of unnecessarily with all these review of systems and other information that was really no longer very relevant to caring for Medicare patients.

And so, beginning last year what we finalized in last year's Physician Fee Schedule Rule, that would be implemented in 2021, was a consolidation of the level 2 through 4 visits. So, we finalized the single average payment rate for those visits, which would enable a minimum documentation standard, and we also finalized several G-codes that would be add-on for these levels 2 through 4 to offset resulting payment decreases for primary care and other non-procedural care as well as for extra time spent with those patients.

We also finalized that and medical decision making or time could be used to select visit level, or alternatively, practitioners could continue using the current framework of the 95/97 guidelines such as using history and exam to help determine what level was performed and billed. Current medical decision making guidelines would apply when using medical decision making.

I'm in so on Slide 13, following the finalization of these policies last year, the American Medical Association and other key stakeholders continue to speak with us, and the AMA CPT developed a similar alternative approach through a work group that was convened in recent months. And we are proposing, as Administrator Verma mentioned, to largely adopt that approach starting in 2021.

I'm on Slide 13. We have provided the website where a set of materials from the AMA is available to assist you in sort of getting into the guts of what this would entail, but by way of an overview, they have revised all of the office outpatient code definitions and provided new times. The level 1 new patient code is deleted, starting in 2021, and the history exam will be performed only as medically appropriate and following our approach medical decision making or time will be used to determine the visit level.

We're proposing to adopt new medical decision making guidelines that were developed by the AMA in this process. The AMA RUC also resurveyed the codes. We're proposing to adopt the new RUC recommended

values with separate payment for each of the codes and levels as revised and redefined by CPT. So, there would be separate payment for each level rather than the compression of level 2 through 4 that we finalize last year.

On Slide 14, again following our approach. We would – we are proposing that medical decision making or time could be used to select visit level, and we're proposing to adopt the new times. There would be only one prolonged service code for use once the level 5 time is reached, when time determines the visit level, and time would be irrelevant if medical decision making were used to select visit level.

We are seeking input on the intersection of these policies with CPT codes 993589, which are for non-face-to-face for long service code, and whether those codes can still be used in their current form to account for related non-face-to-face time that would be performed on other days, and we refer you to the role for a discussion of that issue.

As Administrator Verma mentioned, the AMA RUC did resurvey the codes-- this code set, and we are proposing to adopt the values, largely adopt the value. There is one refinement related to a PE item for a computer that we proposed a refinement for, but largely we're proposing to adopt what the RUC has recommended in terms of valuation for these codes, and it would increase payments for the code sets.

And so, on Slide 16, the slide shows a comparison of the rates that we previously finalized for 2021 under the compressed level 2 through 4 visits compared to what the rate would be for each of the base code under our proposal.

And on Slide 17, we are proposing to retain, but consolidate into one G-code, the add-on for primary care and other non-procedural care that we finalized last year. This code would provide additional payment at any level for visits comprised of ongoing primary care or ongoing medical care related to a single serious or complex chronic condition.

We're continuing to seek input on how we could improve clarity regarding the use of this code, and how we can most accurately reflect the resources associated with this kind of visit or patient care.

And I'm going to turn it back I think to Nicole for a Q&A session on E/M. Thank you.

Feedback Session 1

Nicole Cooney: Thank you. Thanks Ann. Before we get started on the Q&A, I just want to set a few ground rules for today's session, very similar to other proposed rule listening sessions that we've held recently, in an effort to get to as many participants as possible today. We will spend a maximum of three minutes on each question and answer.

We are 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, as I mentioned before, because CMS must protect the rulemaking process and comply with the Administrative Procedure Act.

We appreciate your understanding. 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 5 of today's presentation. And as a reminder, today's session is being recorded and transcribed.

We will now take your clarifying questions on the E/M topic. There will be an opportunity to get in the queue after the other topics. So, please limit your questions to the E/M topic for this session. All right Dorothy, we're ready to queue up.

Operator: To provide feedback, press star followed by the number one on your touch-tone 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 responder is Leonta Williams.

Leonta Williams: Good afternoon. Leonta Williams calling from Georgia Cancer Specialist. Thank you for allowing us to have the session today. My question is regarding E/M services that will be billed based on time, is the requirement that the stop -- the start and stop time be documented in the record.

Ann Marshall: Thank you for that question. So, we did not provide any specific – anything that specific typically, that level of requirement is determined through a sub-regulatory guidance or by our Center for Program Integrity. So, no we did not propose that.

Leonta Williams: Okay, thank you very much.

Operator: Your next feedback comes from the line of Suzan Hauptman. Suzan, your line is now open.

Suzan Hauptman: Hi, sorry about that. Thank you for taking my call. Just to further, that around time you briefly quickly mentioned that the time and the proposed prolonged time could include non-face-to-face time. Is there anything that you could elaborate on that, as to what would be included in the non-face-to-face time. How that would be recorded.

Ann Marshall: So, we have not outlaid a detailed set of proposals as far as what exactly would have to be recorded in the medical record, but we propose to adopt the new prefatory guidance in the CPT language, which includes all time spent by the billing practitioner themselves on the day of the visit in the base code.

So, but the codes were also surveyed for time within 3 and 7 days afterwards, so we did feel that there was still a question around whether time that is spent on other days particularly within that window would be counted or not, so we're seeking feedback on that piece, but as far as the proposal, we propose to adopt the CPT structure, which we interpreted as all face-to-face time spent by the billing practitioner -- all time spent by the billing practitioner themselves whether face-to-face or not on the day of the visit.

Suzan Hauptman: What- you said billing provider if this was an incident 2 situation, could it be both the APP as well as the billing provider or only one.

Ann Marshall: I'm not sure what you mean by APP?

Suzan Hauptman: PA Nurse Practitioner, NPPs and Mid-Level Providers.

Ann Marshall: So, this will be a good question to submit for comment because in the case where those practitioners were submitting their own bill, I think there would be kind of a clear path that it would be their own time, but I think when it's incident 2 or if it were split share situation and that would be a bit different. So, it would be helpful if you could put that question in a public comment and submit it.

Suzan Hauptman: Okay, thank you.

Operator: Your next feedback comes from the line of Hamilton Lempert.

Hamilton Lempert: Hello, this is Hamilton Lempert with TeamHealth. My question is regarding the documentation requirements for history and physical. Are you exclusively keeping the documentation of the history and physical for relevant information just to this code set or that being expanded to all Evaluation and Management codes?

Ann Marshall: So, our proposals as well as the changes made by the AMA and CPT are at this point only for the office outpatient codes set. So, the changes that we proposed for history and exam stem from changes that the CPT editorial panel has made in the code descriptors only for the office outpatient codes set.

Hamilton Lempert: Understood, thank you.

Operator: Your next feedback comes from the line of Teresa Bolden.

Teresa Bolden: Good afternoon. This is Teresa Bolden from Peck & Associates in Norman, Oklahoma, and I apologize for my voice, I hope you can understand me. In the proposed rule and the attachments or the references that you provided to on the link. From the AMA, there was the updated medical decision making table, which needs further clarification. My question to you is will this be something we need to submit as part of our feedback, or is that something we need to go to the AMA for.

Ann Marshall: Thank you for that question. I would say both. What we have proposed is to adopt the new medical decision making guidelines that were you know passed at the AMA and CPT, and if clinician or other stakeholders feel that those are not clear. You know as a matter of process, we, CMS, does not have the ability to change something that has been adopted by CPT, but certainly we are working with them on this issue and we are proposing to adopt what they have put forth on this point, so I would say both that feedback should come to us in a public comment as well as be directed to the AMA.

My understanding, or our understanding from them, is that they may also be doing some education and outreach as the months go on. On, you know, what passed in the materials on their website, so you may also hear some more from them about the best avenues to engage with them on further education and clarification that may be needed.

Teresa Bolden: Thank you very much.

Operator: Your next feedback comes from the line of Susan Griffin. Susan, your line is open, and she has withdrawn her question.

Your next feedback comes from the line of David Basel.

Dr. David Basel: Good afternoon. Dr. Basel with Avera Medical Group. I applaud the increase in recognition of the cognitive aspect of chronic disease management by increasing the work RBU's of the office visit. My clarification question is, does it still fall underneath overall budget neutrality. So, well, you have to decrease the multiplier overall so that procedural codes and other codes are actually paying less to pay for this increase in office visit charges.

Emily Yoder: Hi there. Thank you so much for that question. Yes, these services, like all services under the PFS, would be budget neutralized, and so within an increased to the RBU's associated with 20% of the fee schedule. There would be a subsequent decrease for other services to account for that.

Dr. David Basel: Thank you.

Operator: Your next feedback comes from the line of Amber Nicholson.

Amber Nicholson: Yes, this is Amber Nicholson I'm with Parkland Hospital and my question is related to documentation of supervision of residents or students. I know that there was some recent clarification about that they could use -- the attendings could use that documentation, but is there any going to be any change in the attestation language or any of that?

Ann Marshall: Hi, thank you. So, I think since we're not covering that topic in depth on this session we don't have the staff to answer at that level, and if you could submit that to us in writing in a public comment that would be the best approach.

Amber Nicholson: Thank you.

Operator: Your next feedback comes from a line of Margaret Reina.

Margaret Reina: I'm sorry but that question was just asked by the last caller. Thank you.

Operator: Your next feedback comes from the line of Darryl Drevna.

Darryl Drevna: Hi good afternoon. This is Darryl Drevna with AMGA. Just to follow up on the question that the budget neutrality, I was wondering when you would have that updated like impact table or when those changes

would be rolled out, whether it's in separate guidance or next year's rulemaking, and when you might have an updated impact table? I noticed there's a lot of language in the proposal saying it was uncertain. There's more work yet to be done on what these E/M changes would mean?

Emily Yoder: Hi. Thank you again for this question. So, what was in the rule right now is an impact table that shows how the specialty level impact is if as we were proposing these for 2020, which we are not. We are proposing that for 2021. In next year's rulemaking, we will sort of take these through standard rulemaking process, and at that point we would have an impact table and a projected conversion factor adjustment that would account for all of these changes.

Darryl Drevna: Great. Thank you. You answered my question, I appreciate it.

Operator: Your next feedback comes from the line of Laura Pope De Rendon.

Laura Pope De Rendon: Yes, good afternoon. My question is with regard to various diagnosis codes such as I11.9 diabetes mellitus and other diagnoses that entail a more complex management process for the patients especially those who are noncompliant that - would that be a reimbursement that would be higher than typical?

Emily Yoder: So, for this year, as my colleague Ann said, we are proposing to sort of consolidate the 2 add-on codes, one with for primary care visits and one with for certain nonprocedural specialty visits, but we believe that the intensity of those services are not fully accounted for in the revaluation of the E/M codes because those are based on a typical patient, we think that in these cases be more complex patients. So, what you're describing could be a scenario wherein one could fill that add-on code for additional time spent in primary care or overseeing complex chronic conditions.

Laura Pope De Rendon: Okay. Thank you very much.

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

Karen Jones: Hi. I was wondering about whether any additional documentation requirements to use that add-on G-code?

Emily Yoder: Thank you that's a great question and that is we sent some stuff in last year's rule surrounding we know what kind of information would be sort of suitable for the purposes of billing one of the other 2 add-on codes. We're still seeking information from the public as to additional, like what would be sufficient to document that this was a reasonable and necessary medical service. And as I said, we are going to be taking this through rulemaking again, and so, we will have time in next year's rule as well to sort of nail down exactly how this code should be documented.

Karen Jones: Thank you.

Operator: Your next feedback comes from a line of Ed Gaines.

Ed Gaines: Hi. Thanks for taking my call. I'm with Zotec Partners. My question is what you alluded to earlier about how you're going to guide us with respect to documentation guidelines. The 95 and 97 guidelines were issued as guidelines, are you expecting that the next generation of documentation guidelines will be as guidelines or are you expecting that you're going to go through the notice of proposed rulemaking and comment process? Thank you.

Ann Marshall: So, we have put forth what I think is a proposal to adopt new guidelines to the extent that they're housed within the new materials that the AMA and CPT has issued. So, for example on medical decision making, they have put forth new language, and I believe we have kind of squarely pegged to that if you will. So, it would not require us to, you know, issue separate guidelines or reference a separate document like we did with the 95 and 97 guidelines, but if you have questions or there're specific aspects of that you're not clear about, it would be a good topic to submit a public comment on, certainly.

Operator: Your next feedback comes from the line of Marilyn Andrews.

Marilyn Andrews: Yes. Hi, this is Marilyn Andrews with PHW, and I was just wondering, the current changes are only for office outpatient set, but do you see changes occurring in E/M for like emergency department providers?

Emily Yoder: So, as of right now, we have not stated anything about making additional changes to the E/Ms of other settings. I would point out, however, that the emergency department visits were actually revalued I believe as part of either last year or the year prior rulemaking.

Marilyn Andrews: Thank You.

Ann Marshall: There's also a discussion in last year's rule around ED visits where they specifically asked us not to adopt certain changes for that code set. They - we solicited comments on other settings that they were pointing out. For example, the time is really not relevant to them as a parameter in deciding complexity of visit, so that particular aspect that is really in play with the office outpatient set, it is not really relevant clinically or otherwise for them. There're lot of unique issues to take into consideration and there was some - has been some discussion about that in the past rule, as well as the recommendations from commenters that we kind of try to get it right for one set - subset of codes before kind of taking on the rest of the universe, but we are seeking comments, certainly an open to feedback in this area.

Marilyn Andrews: Thank you.

Nicole Cooney: Thank you Ann and Emily. In the interest of time, we are now going to move on to our next topic. Up next is Molly MacHarris from our Office of Clinical Standards and Quality and Ann Vrabel from the Center for Medicare and Medicaid Innovation to discuss improvements to the Quality Payment Program, Molly.

Quality Payment Program

Molly MacHarris: Thank you, Nicole and thank you everyone for being here with us today. For those that are following along in the slides. I'm going to start on slide 20 to start talking through some of the proposed changes to the MIPS track of the Quality Payment Program. So, just as a reminder, under MIPS we assess clinicians' performance under 4 performance categories. To start with the changes, we propose for the Quality performance category and we have continued to implement our Meaningful Measures framework within the MIPS program. And as part of that we need to take a step back and conduct a thorough review of our existing measures to identify those that don't meet the criteria of the framework.

As a result of this review, we're proposing the largest reduction in Quality Measures since transitioning from the legacy program PQRS, with a total of 55 Quality Measures proposed for removal. In addition to our measure removals we are proposing to add 4 new Quality Measures and 7 new specialty sets which are available for Speech Language Pathologists, Audiologists, Clinical Social Workers, Chiropractors, Pulmonologists, Nutrition Dietitians, and Endocrinologists, along with a few additional proposed substantive changes to existing measures.

As we have continued to implement a Meaningful Measures framework, these proposals will streamline and revamp the available measures to allow clinicians to focus on the highest priority measures that are most meaningful to improving health outcomes. We also have proposed to increase the data completeness threshold from 60% to 70% for the 2020 performance period. Again, as a reminder data completeness deals with the act of reporting on a quality measure.

We also have made proposals that we would establish flat percentage benchmarks in limited cases, where we re-determined that the measures' otherwise applicable benchmark could potentially incentivize treatment that could be inappropriate for particular patients. For the Cost performance category, we are proposing 10 new episodes-based measures and we also are proposing to revise attribution methodologies for the 2 global measures that exist within the Cost performance category which are the total Per Capita Costs and Medicare Spending per Beneficiary clinician measure.

For the Improvement Activities performance category, much like in the Quality performance category, we are furthering the implementation of the Meaningful Measures' framework; using the framework as a guide we are proposing changes to the inventory including proposing 2 new Improvement Activities, modifying 7 existing Activities and removing 15 Activities.

We also are proposing to revise the way that groups can earn credit for Improvement Activities. Currently, groups are able to receive credit for an Improvement Activity if just one clinician of part of a group complete the Improvement Activity. We are proposing to increase that to 50% of the clinicians must participate in an Improvement Activity within the group to receive credit.

And then lastly, for our Promoting Interoperability performance category not too many changes here, I spoke to recall, we did overhaul this performance category last year. Our proposals here are mainly to maintain alignment with the Promoting Interoperability hospital program, so we are proposing a few updates to the objectives and measures for the 2019 year. We're reallocating the point that provides patients access to their health information measure, if an exclusion is claimed for the support electronic referral list by sending health

information measure and updating the query of PDMP measure to require yes, no response. For the 2020 performance period, we are maintaining the query of PDMP measure as optional and we are removing the Verify Opioid Treatment Agreement measure.

We also are making few modifications to our hospital based special status for groups. Currently, hospital-based clinician,100% of the group must have that status for proposing to lower that threshold to 75% for the Promoting Interoperability performance category.

Moving on to slide 21 for the performance category weight, we have laid out our proposal for what Quality and Cost will be set out for years 4/5, and as folks recall as required by law, by years 6 Quality and Cost must both be set at 30 points. Those folks can see on slide 21, our current weight for Quality for 2019 is at 45 points and for Cost is at 15 points. We are making gradual and incremental changes to slowly decrease Quality over the next few years and slowly increase Cost.

Moving on to slide 22, similarly to the proposals we have made to gradually and incrementally modify the performance category weight, we are proposing to gradually and incrementally increase the performance threshold which is the minimum number of points required to avoid a negative payment adjustment. We're proposing to increase that threshold from 30 points for where it is today in 2019 to 45 points in 2020 and 60 points in 2021.

We also are proposing to increase the exceptional performance bonus to 80 points in 2020 and 85 points in 2021. As a reminder, the exceptional performance bonus allows for a separate bucket of money that we can distribute outside of the regular performance threshold adjustments, which must be distributed in a budget neutral manner.

Moving on to slide 23, just a few other MIPS proposals I wanted to touch on. We have made a number of proposals to really strengthen and improve our partnership with our Third-Party Intermediaries most notably are qualified registries and our qualified clinical data registries. We really envision that the Third-Party Intermediaries in the future will be a one-stop shop for clinicians and groups to participate under the Quality Payment Program. So, as a result of that vision, we have made proposals to require qualified registries in QCDRs to support the Quality, Improvement Activities, and Promoting Interoperability performance category as well as to provide enhanced performance feedback and deliver quality improvement services.

And just a few other changes to touch on. For the definition of hospital-based clinicians, already mentioned that when I talked through Promoting Interoperability changes, I won't cover that again. We also have introduced a policy to allow for reweighting of certain performance categories if clinicians or groups have data issues that result in significant data integrity concerns and we clarified our timeline for requesting targeted review.

Moving on to slide 24, I'm going to turn the presentation over to my colleague, Ann Vrabel, Ann.

Ann Vrabel: Thanks, Molly. The first proposal for the APMs deals with the APM scoring standard. In 2017 rulemaking, we created the standard to reduce burden by eliminating the need for eligible clinicians in APM to submit data for both MIPS and/or APM. Where this policy is working, we're keeping it as is. However, for some APMs, the APM reported quality data is not available in time to generate a MIPS quality score under the APM scoring standard.

For these APMs, we're proposing starting in 2020 to apply a revised scoring standard with two key parts. First, we would assign an APM reporting credit in the Quality performance category. This does provide these clinicians at least neutral to score under MIPS. Second, we would allow the clinicians to supplement the credit through regular reporting to MIPS to earn a higher score and potentially positive payment adjustment.

In our other proposals or next proposal is around partial QP status. Currently, we apply partial QP status at the NPI, so that individual level across all of the TIN/NPI combinations for that eligible clinician, and this is the same as we've done for QP status. However, because partial QPs receive only a MIPS exclusion, they don't always see a similar MIPS positive outcome across all of their TIN/NPI combinations that we see with QPs. The partial QPs receive only neither the APM incentive payment nor MIPS payment adjustment, so they only get that MIPS exclusion.

To account for this, we're now proposing to apply partial QP status only to that specific TIN/NPI combination through which the partial QP status was attained. This would allow these clinicians to benefit from reporting to MIPS if they choose and to receive a MIPS payment adjustment with respect to some of all of their other TIN/NPI combinations, which may be beneficial especially where they might anticipate receiving an upward MIPS payment adjustment.

And then we also know a proposal dealing with the financial risk component of the advanced APM criteria for other payers, specifically the marginal risk dimension. Previously, we had specified that in other payer payment arrangement, must have a marginal risk rate of at least 30% when losses exceed the expected amount of expenditures as determined by the model of financial methodology. This overall standard is not changing. What we're proposing is to broaden our definition of marginal risk in a manner that allows for some flexibility in calculating the rate, while preserving the standard for payment arrangements to have robust financial risk.

Specifically, when making the other payer advanced APM determination, if the payment arrangements' marginal risk rate varies, we will calculate an average marginal risk rate across all possible levels with actual expenditures and use that average for comparison with the 30% marginal risk requirement. Again, the actual rate of 30% is only losing. We also note the proposal would not affect our total risk standard, meaning other payer payment arrangements continue to need to include minimum amounts of downside risks to be considered advance APM.

Our other proposal and comments solicitations are more minor updates in various issue areas designed to enhance flexibility where feasible, while preserving our strengthening policy goals for these APMs to have robust financial risk and to provide high value care. I'll turn it back to Molly to go over 21 and beyond turning to slide 25.

Molly MacHarris: Thanks, Ann. And as Ann mentioned, we're on slide 25 and the last piece I want to touch on is what Administrator Verma touched on in her opening remarks which is our comment solicitation on our new approach for the MIPS program which includes our MIPS Value Pathway. We really, really want to have folks' feedback on this revised approach.

So, as Administrator Verma, mentioned, we are listening to stakeholders and we have heard a really loud and clear that the current structure of the MIPS program and the reporting requirements have created some confusion. Overall, we heard that there's too much choice and complexity when it comes to selecting and

reporting measures, that the measures aren't always relevant to a clinician specialty, and that it's hard for patients to compare performance across clinicians.

So, our new participation framework, called MIPS Value Pathways for MVPs, would have different paths, which are focused on a specialty or disease that would include a smaller set of measures and activities that meet the 4 performance categories. The pathways would also include common measures and all sets that are focused on population health and interoperability, so that patients can compare performance across clinicians.

So, overall goal of this new framework is to streamline reporting requirements, reduce reporting burden, and ensure that the measures are meaningful to clinicians and patients. So, let's go ahead and move on to slide 26. We have a couple of diagrams here that again, if folks have not yet had a chance to take a look at, I highly encourage you to do so.

We also have these available separately on our website at qpp.cms.gov. So, as folks can see from the diagram here looking at the most left-hand side with our current structure of MIPS, we have 4 distinct performance categories. And what we have really heard is that clinicians overall feel that we are still asking them to do 4 separate and distinct things that still feels very similar to the legacy program.

So overall, we're hearing that there's too much choices, that what we're asking folks to do within those 4 performance categories is not meaningfully aligned, and there's a higher reporting burden. So, our proposed MVP framework, looking at the middle column here, what we envisioned that this would account for is much more cohesive participation within the program. We also envision a lower reporting burden. Again, we are focusing clinicians' efforts on the measures and activities that are most meaningful to your specialty or to a given health condition.

We don't anticipate that they would need to be the same number of measures and activities that folks are currently required to do. Also, as you can see by looking at our kind of our diagram here with our foundation, you're starting to see some closer alignment cross Quality, Improvement Activities, and Cost while still having that foundation of Promoting Interoperability and Population Health metrics.

We do believe it is critically important to have that foundation of Promoting Interoperability and Population Health, so as you can see as we move into the future state of MIPS for the most right hand side of the diagram here, there's an even closer alignment for Quality, Improvement Activities, as well as Costs.

We still have that same foundation of Promoting Interoperability and Population Health measures, but also at higher focus on patient reported outcomes and enhance performance feedback that we at CMS would be able to provide. So, we're envisioning in the future, the problem would be much more simplified and would increase voice of a patient, and that when we move to the MVP framework, it would facilitate movement into APMs.

And let me just go ahead and move on to slide 27. On both slides 27 and 28 these are 2 examples. In the interest of time, I'm just going to briefly talk through slide 27. And as you can see in this example here this is what it could look like for a surgeon. Again, this is all open for comment. We really, really want folks' feedback on this as we are designing these MVPs.

So, if folks feel that we have hit the right mark let us know, but if folks feel that we need to make significant changes and improvements, please let us know that as well. But, as you can see, and I'll just focus on kind of a call out box which is on the diagram here where it lists measures Improvement Activities and Cost measures, as folks can see what we're envisioning for the future is a smaller more cohesive set of measures in activities that are meaningfully aligned to a given specialty or clinical condition.

So, at this point, let me go ahead and stop. I'll turn it back over to Nicole. Thank you.

Feedback Session 2

Nicole Cooney: Thank you Molly. We're now ready to take your clarifying questions on the Quality Payment Program topic. Please limit your questions to this topic. We'll spend a maximum of three minutes on each question and answer. As a reminder there may be questions that we cannot answer because CMS must protect the rulemaking process and comply with the Administrative Procedure Act. 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. Dorothy, we'll take the first caller.

Operator: To provide feedback, press star followed by the number one on your touch tone 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.

Your first feedback comes from a line of Jason Shropshire.

Jason Shropshire: Hi. This is Jason, can you hear me?

Nicole Cooney: Yes.

Jason Shropshire: Hi. I'm calling from the University of North Carolina and I have kind of a tiered question, and everything in regards to my question is relating to a large group for the MIPS Value Pathways. So, one thing I haven't been able to decipher from the proposed rule. I guess the first question is are the MIPS Value Pathways replacing the entire other parts of MIPS or is it just an option you could report, or you still could report the old ways in MIPS? And the second part of my question is how is MIPS Value Pathway is going to work for a large again group or tax ID who could have 26 specialties, because if you're talking about reducing administrative burden, right now those groups report 6 quality measures, but according to these value pathways, you're suddenly increasing them to maybe 40 different Quality Measures rates, if you combine them cumulatively across the specialties, how do you envision that working for a large group?

Molly MacHarris: Yeah. Hey, Jason those are great questions. For both of those, I would encourage you to give us your feedback on those topics through the public comment process, but just to touch on them briefly here, one, as a reminder the MVP is a new approach, our proposals are not for this most current upcoming year, not for the 2020, but for the 2021 performance period, because we do really want to work with as many stakeholders as possible as we build out the MVPs.

For the questions on how large groups could participate and how it could work for multi specialties, there are a number of questions we actually have outlined as part of the comment solicitation portion of the rule and we very much want your thoughts and feedback on really how we should be addressing that. So, I would encourage you to submit your comments and feedback there. Thank you.

Operator: Your next feedback comes from the line of Chi Truong.

Chi Truong: Hi. This is Chi Truong with Women's Medical Specialist. I want to say thank you very much for holding these sessions and have been proven very useful. I have two questions. The first one is I noticed significant number of changes to several measures, the one I'm specifically asking about is measure 112, breast cancer screening. Do you know if that will change the benchmark, if there will be a re-benchmarking, i.e., that measure will no longer have a benchmark for the 2020 year?

Molly MacHarris: If I - from what I recall the changes we proposed for measure 112 I believe, they would be construed as substantive in nature which means that, that measure would fall subject to our benchmarking processes, which means that we would attempt to calculate a performance period benchmark. If in circumstances would not allow us to create a performance period benchmark, the maximum number of points that we could distribute for that matter is 3 out of 10.

However, if I remember this measure correctly, this is a fairly common measure, so I don't necessarily anticipate that we would not be able to calculate a benchmark, but overall I would encourage you to submit any sort of comments or questions that you have on this particular measure through the comment process as well.

Chi Truong: And the other question I had was adult immunization status, I've seen it reference, but I cannot find a specification for it in the proposed rule. Is there a specification listed anywhere else?

Molly MacHarris: I apologize. We don't have those SMEs with us. Okay. So, what I can encourage you to do is for the Quality Payment Program, we do have a designated service center. A help desk that you could reach, you can contact them at qpp@cms.gov and they should be able to address your question.

Chi Truong: Okay. Thank you.

Operator: Your next feedback comes from a line of Sharon Tompkins.

Sharon Tompkins: Well, yes. Thank you for taking my call. My first question is regarding the percentage benchmarks that are going to be flat for the diabetes, hemoglobin, and the controlling high blood pressure measures. Can you give me a little more detail on how that's expected to work?

Nicole Cooney: Give us one second.

Molly MacHarris: Sure. So, just to give a little bit more background on the problem we're trying to solve for, is we have identified those two measures that you referenced. Measure one diabetes, hemoglobin poor control, and controlling high blood pressure where we do envision that in some very limited cases when we're asking clinicians to have 100% performance, it could lead to potential patient risk.

So, what we have proposed to do to address that is we would modify the benchmark for the top decile only in instances where the collection type associated with the measure is greater than 90%. So again, the 2 measures we have found that fall within this criteria are hemoglobin poor control, and controlling high blood pressure. The way it would work is that when we apply the flat percentage benchmark, the methodology any performance rate that is at or above 90% would be in the top decile and any performance rate between 80% to 89.99% would be in the second highest decile and so on. So, it really removes the incentive to achieve 100% performance which again could result in inappropriate care for these 2 measures. I hope that helps.

Sharon Tompkins: I guess what I'm hearing is between 90% and 100%, it would be in the 9th decile, but that's pretty much where it is now between 90 and 99 well no, okay never mind I just answered my question, I got it. Thank you for that explanation.

My other question is regarding the supporting of the Quality, Improvement Activities, and Promoting Interoperability through qualified registries and clinical quality data, QCDRs -- is it for the 2020 reporting year, is it expected that QCDRs in the qualified registries extract and aggregate data for the Promoting Interoperability category, or is it sufficient to be able to allow the providers to input their results taken from a vendor such as patient portal, and then the qualified registry or QCDR would then submit those results on their behalf?

Molly MacHarris: Yeah, sure. So, the proposal that would require QCDRs and registries to support the Promoting Interoperability performance category, that would be effective the earliest the 2021 years, so about 18 months or so from now. Right now, it's optional for registries and QCDRs to support and prevent activities in Promoting Interoperability. As I'm sure you saw within the rule we're seeing that overall the majority of registries and QCDRs are already providing the support to their clients. So again, that's why we feel, based off of our overall vision of really having the QCDRs and registries being treated as a one stop shop, that it should be possible for the majority of all QCDRs and registries to be able to support this in the 2021 year.

Sharon Tompkins: Okay, thank you for that and just one more question or comment. On slide 23, it actually says MIPS proposal for the 2020, have you seen that management typo?

Nicole Cooney: We have to move on to the next caller, I'm sorry. In the interest of time, we've exhausted our three minutes on this one. We'll take the next caller please.

Operator: Your next feedback comes from the line of Julie Lundberg.

Julie Lundberg: Hi, thanks for taking my call. This is about MIPS PI, I'm looking for some help on the re-weighting for the supporting electronic referral loop by sending health information, have we decided yet where we're redistributing those points if the exclusion is claimed?

Molly MacHarris: Apologies, we do not have the subject matter expert in the room to address that. So if you can submit that question via a comment, we can get it addressed there. Thank you.

Julie Lundberg: Okay. I did send it to the QPP, but as of July 3rd I think it was --- the statement was we still haven't decided. I think we're talking about this year, 2019. Okay, I'll send it again, thanks.

Nicole Cooney: Okay, thank you.

Operator: Your next feedback comes from the line of Jay Misrobian.

Jay Misrobian: Hi, Jay Misrobian, Medical College of Wisconsin, thank you. I just have a question conceptually about the Value Pathways looking to the far right. Will the foundation measures for topics also require their own individual measures and then the ones above for Cost and for Quality will be specialty specific, I'm not quite sure I understand the concept here in terms of how this is constructed and how that would then reduce the total number of measures required?

Molly MacHarris: Sure. So great question, so for the foundation what we think and what the way that we've been approaching this, but again this is why we really want your guys feedback on whether or not this is the right approach. We are envisioning a very close alignment to Quality, Improvement Activities, and Cost. So again, as you can see within the examples reflected on slide 27 and 28 for surgeons and the diabetes example, all of the measures, activities, and Cost measures that we are envisioning would be included within that MVPs are related to either a specialty or a specific condition.

For the foundation of Promoting Interoperability, one of the things that we feel is really important is to maintain as much alignment as possible with the hospital Promoting Interoperability program, as I'm sure you will recall. We did our overhaul last year to get that alignment back between the clinician space of Promoting Interoperability and the hospital space of Promoting Interoperability. We do envision that there could be a future where there are some modifications that could be made to that performance category.

Again, we are requesting a lot of feedback on the future of that category as well, but we do feel it's important to have that close alignment so that by we're building Promoting Interoperability in as a foundation. The same for our Population Health measures. We envision that the foundation are items that would be available and applicable to all clinicians and groups. I hope that helps clarify in a little bit more detail. Our vision for the MVPs, again we very, very much want your thoughts and feedback as well as all stakeholders as we look to build our proposals on the future of the MIPS program beginning for the 2021 year. Thank you.

Operator: Your next feedback comes from the line of Nancy Dearoff.

Nancy Dearoff: Hi, Nancy Dearoff, here from the National Healthcare Quality Institute, Qualified Registry. Referring back to slide 23, would you please clarify what is meant by enhanced performance feedback? And thank you.

Molly MacHarris: Sure. So what we have found based off of our experiences to date for registries and QCDRs, some registries and QCDRs are providing really great innovative feedback to their clinicians and groups throughout the performance year much more than the 4 times that is currently required, but we also have heard from clinicians that some QCDRs and registries are really providing the bare minimum amount of feedback only at the 4 times a year and only on the specific values that we require.

So, what we're trying to do is, the enhanced feedback is really trying to level the playing field on the feedback that clinicians receive from their registries and QCDRs for all clinicians. So, some of the enhancements include

the ability to provide peer comparisons on the given Quality Measures or QCDR measures that you may have available within your organization.

We understand that clinicians feel very strongly and we agree with this, that for them to make concrete action they need to receive timely feedback, and we believe that registries and QCDRs have that ability to do that based off of their relationships that they have with those clinicians and how they receive the data throughout the year. So that's about that proposals in relation to, I hope that helps. Thank you.

Opioid Treatment Program

Nicole Cooney: Okay. And with that, we're going to move on to our final topic. For the final topic, we have Lindsey Baldwin and Dr. Pierre Young from the Center for Medicare and Joe Schultz from the Center for Program Integrity to discuss the new Opioid Treatment Program benefits. Lindsey?

Lindsey Baldwin: Thanks, and I think Pierre, did you want to start us off?

Dr. Pierre Young: Sure. Thanks Lindsey and Nicole. I'm starting on slide 31. As folks are well aware, CMS has been very dedicated to addressing and making progress in combating the opioid epidemic in this country. And in order to do that, one of CMS' key areas of focus is really expanding access to treatment and that's what decided to include proposed policies in this year and in the counting year 2020, a Physician Fee Schedule to implement coverage of a new Medicare Part B benefits for Opioid Treatment Program, or OTPs.

On slide 32, this part new Medicare Part B benefit for OTPs providing Opioid Use Disorder treatment services began on or after January 1, 2020, and was created in section 2005 of the SUPPORT Act that was passed last year. The statute specifically allows for implementation of bundled payments that can vary via several characteristics including the medication provided, the frequency of services, scope of services furnished, characteristics of individuals furnishing the services, and other factors as the Secretary determines is appropriate.

Just some background about OTPs on slide 33, there are currently about 1,700 OTPs nationwide that are certified by the Substance Abuse Mental Health Services Administration or SAMHSA. These OTPs are located predominantly in urban areas and they tend to be free-standing facilities, and these OTPs provide Medication-Assisted Treatment or so MAT, in addition to a range of other services such as counseling and therapy services. SAMHSA has defined MAT as the use of medication in combination with behavioral health services to provide individualized approach to the treatment of substance use disorder including OUD or Opioid Use Disorder.

The current payer mix for OTPs includes Medicaid, private payors, and TriCare, as well as individual pay patients. Medicare currently covers office-based opioid treatment with Buprenorphine and Naltrexone, but has not historically covered OTPs, which are the only entities authorized to use methadone for the treatment of OUD. So therefore, coverage of OTPs is a new benefit that we anticipate will expand access to care for Medicare beneficiaries. With that, I'm going to pass this off to Lindsey to describe the proposals in more detail.

Lindsey Baldwin: Great. Thanks Pierre. So, starting at slide 34. In the proposed rule we proposed 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 that 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.

On slide 35, the statute specifies that OUD treatment services provided by OTPs will include the following: the FDA-approved opioid agonist and antagonist treatment medications, the dispensing and administration of such as medications if applicable, substance use disorder counseling, individual and group therapies, toxicology testing, and other items and services that the Secretary determines are appropriate.

On slide 36, we're 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, buprenorphine implants, extended release, injectable naltrexone, and medication not otherwise specified, and a non-drug bundle.

On slide 37, to provide more accurate payment 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 bundle payment rates through 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 for a particular patient that substantially exceeds the amount specified in the patient's individualized treatment plan.

We are proposing to allow OTPs to furnish the substance use counseling, individual 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.

On slide 38, under payment, the proposed codes describing OTP treatment services are assigned flat dollar payment amounts. Each bundle payment is composed of a drug 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 bundles. We're proposing to use the payment methodology under section 1847 AFP 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, 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 and the CY 2020 PFS proposed role.

Moving on to slide 39, we're proposing to set the co-payment 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 co-payment 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 co-payment, especially for those dually eligible Medicare for Medicare and Medicaid.

We intend to continue to monitor the opioid crisis in order to determine at what point in the future co-payment maybe imposed. At such a time, we would institute cost sharing through future notice and comment rulemaking. The Part B deductible would apply for OUD treatment services as mandated for all Part B services by statute.

Moving on to slide 40, 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's no Geographic Adjustment Factor applied to the payment for Part B drugs under the AFP methodology, we do not believe it is necessary to adjust the drug component of the bundle payment rates for OTP services based upon geographic locality.

For the non-drug component, unlike the national pricing of drugs, the cost for services included in the non-drug components are not constant across all geographic localities. In order to account for the differential cost of OUD treatment services across the country, we're 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 to adjust the payment for the non-drug component to reflect the cost of furnishing these services in each of the PFS localities.

Moving onto slide 41. To fulfill the statutory requirement, to provide an update each year to the OTP bundled payment rates, we're 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 and prices of drugs relative to other services. We're proposing to update the payment for the drug component based upon the changes and drug costs reported under the pricing mechanism used to establish the pricing of the drug component of the applicable bundled payment rates. We're proposing to update the non-drug component based on the Medicare Economic Index or MEI. And to go over OTP enrollment, I will pass it off to Joe Schultz in the Center for Program Integrity.

Joe Schultz: Yes. Thank you, Lindsey. Hi everybody. I'm on slide 42. In order for an OTP to be eligible for enrollment in Medicare, an OTP must be certified by SAMHSA and accredited by a SAMHSA group accrediting body.

To slide 43. Other enrollment requirements include submitting CMS form 855B, paying the application fee, submitting fingerprints for 5% or greater owners including partners, undergoing an observational site visit, and reporting all ordering, prescribing, and dispensing practitioners on a proposed supplemental attachment. That is all that I have.

Feedback Session 3

Nicole Cooney: Thanks Joe. Thank you. We're ready to take your clarifying questions on the OTP benefit. Please limit your input to this topic and keep our three minutes maximum in mind. As a reminder, 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. All right, Dorothy, we're ready for the first caller.

Operator: To provide feedback, press star followed by the number one on your touch-tone 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, please state your name and organization. Please note your line will remain open during the time you're providing your feedback so anything you say, or any background noise will be heard in the conference.

Please hold while we compile the roster.

Your first feedback comes from the line of Dr. Ron Short.

Dr. Ron Short: Yes, in your non-drug bundle that you mentioned, will that include payment for non-drug pain treatment options?

Lindsey Baldwin: So, these bundled payments are only used for the treatment of Opioid Use Disorder by Opioid Treatment Programs.

Dr. Ron Short: Okay. But would not part of getting the person off the opioids be finding the way to manage the pain without using the drugs?

Lindsey Baldwin: Oh. I see, so are you asking whether the bundle would include payment for other non-opioid pain treatment services?

Dr. Ron Short: Yes.

Lindsey Baldwin: That's a great question. We are seeking comment on other items and services, means we might consider including in the bundle, so we would love it if you could put that in a public comment and submit it through the formal process and definitely include if you have any specific ideas on what you would want to see included.

Dr. Ron Short: That's very great. Thank you.

Lindsey Baldwin: Sure.

Operator: Your next feedback comes from the line of Jason Kletter.

Jason Kletter: Hi, thanks so much for taking my call. This is Jason Kletter, BayMark Health Services, and my two quick questions. First question is I'm hoping you can explain or clarify how a provider might meet the 51% percent threshold for the full bundle as opposed to the partial bundle especially given that some treatment plan services are prescribed to be delivered monthly or less than weekly and the bundle is intended to be a weekly rate.

And my second question is with respect to the counselor credentialing requirements, I'm wondering if you can clarify specifically what you will require for counselors in terms of a credential given that where I am in California, the state has a counselor certification regime. So, counselors are not licensed per se but are certified by private entities by certifying organizations, but the rule seems to require that counselors be licensed to provide counseling services? So, those are my two questions.

Lindsey Baldwin: Hi Jason. Those are great questions. Thank you. So for your first question about how they would meet the requirement to furnish 51% or more of services in order to build a full weekly bundle, we definitely recognize that there's going to be great variation between different patients' treatment and also variation in treatment over time for any particular given patient. And we hope to account for that in this proposal, so this is based on the patient's individualized treatment plan which is required by SAMHSA. And so, we really are going to defer to the OTP and the clinicians there to determine what is appropriate for each patient and when more than half of services are furnished or not.

As you pointed out, we recognized that after a period of time, patients will have a decreasing frequency of services, and so a patient who has maybe just one service over the period of time, I think we said that, that would be sufficient for billing the partial episode. But we defer to the clinicians to determine whether more than half of the services were met or not. And then, Pierre, did you have anything to add to that?

Pierre Young: No, I didn't, thanks Lindsey.

Lindsey Baldwin: Okay. And so then, Jason, your other question about counselor credentialing is a great one. These are "incidents to" services and so --- I'm sorry I think that back. The counselors that are furnishing the services, I believe we did mention licensed professional counselors in the proposed rules, but any feedback you have on that topic we would love to see that from you in a public comment letter that would be really helpful.

Jason Kletter: Great. Thank you.

Operator: Your next feedback comes from the line of Sonya Smith.

Sonya Smith: Hi, yes, can you hear me?

Nicole Cooney: Yes, we can.

Sonya Smith: Okay. I just wanted to ask you, does the Medicare application and enrollment as an OTP, is that separate from if you're already enrolled with Medicare to provide Medicare services?

Joe Schultz: Hi, this is Joe Schultz. I can answer that question. Yes, so if you already have an enrollment, you will have to submit an additional form to enroll as an OTP, your current involvement does not count. You will have to enroll.

Sonya Smith: Okay. Thank you, that's what I needed to know.

Operator: Your next feedback comes from the line of Roger Smith.

Roger Smith: Hello. I'm Roger Smith with the American Association for Marriage and Family Therapy. We represent licensed marriage and family therapist providers licensed in all 50 states. I just had a follow-on question for the question two. Two questions go in the counseling requirements. In this --- I just want to clarify its proposed rules meant to include as providers for subsidy services in individual and group, individual and family therapy provider types that are currently not recognized specifically as Medicare Part B independent

practitioners. And the follow up question is if so, which I think it is, whether you might consider guidance to make it a little more specific in the rule that might give more certain to the Opioid Treatment Programs maybe we utilize those people.

Lindsey Baldwin: Great. Thanks Roger. I appreciate that question. Since this is a bundle of services billed by the one OTP entity, we recognize that there would be a treatment team furnishing the service and that team would consist of a variety of professionals. We welcome comments on that particularly about licensed professional counselors or licensed marriage and family therapists, what their role in these services could be. So, we'd love to see that from you and a public comment.

Roger Smith: Thank you very much.

Operator: Your next feedback comes from the line of Yehuda Moradian.

Yehuda Moradian: Hello. Can you hear me?

Nicole Cooney: Hello. Yes, we can.

Yehuda Moradian: This is Yehuda Moradian from Pikesville Health services. I had a question regarding the process of the application process slide for the CMS phase such as 855B, how does that work exactly, what are the credentials that we have to submit and are they going to be more trainings in submitting those applications?

Joe Schultz: Hi, this is Joe Schultz, I think that's-- [I can answer that] question. So, the 855B is the enrollment form. There will be additional resources that we will develop when the rule goes final to assist in the enrollment, policies, and procedures. So, expect to have some additional resources to help you once the rule does go final, and we can field questions through the general mailbox that we would be developing as well.

Additional Information

Nicole Cooney: Thank you. We are out of time for today's session. I'd like to point out that Slide 45 lists a number of resources for obtaining more information on today's topics. For anyone who may be interested, on Wednesday of this week we have a listening session on the Outpatient Prospective Payment System and Ambulatory Surgical Center proposed rule. The call is from 2:30 to 4:00 eastern time and you may register at go.cms.gov/mln-events, that's all lower case, go.cms.gov/mln-events. An audio recording and transcript will be available in about two weeks at go.cms.gov/npc where you obtained your slide presentation.

Again, my name is Nicole Cooney. I'd like to thank our presenters, and also thank you for participating in today's Medicare Learning Network Listening Session on the Physician Fee Schedule proposed rule. Have a great day everyone.

Operator: Thank you ladies and gentlemen, that does conclude today's conference call. You may now disconnect. Presenters, please hold.