Physician Fee Schedule Proposed Rule: Understanding 4 Key Topics Listening Session

Moderated by: Nicole Cooney
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Operator: At this time, I would like to welcome everybody 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 would now like to hand the conference over to Nicole Cooney. Thank you. You may begin.

Announcements & Introduction

Nicole Cooney: Hi, everyone. 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 4 Key Topics.

During today's session, CMS experts will briefly cover these four provisions from the proposed rule and address your clarifying questions to help you formulate your written comments for formal submission.

Today's topics include Telehealth and Other Virtual Services, Evaluation and Management, the Quality Payment Program, and Opioid Use Disorder and Substance Use Disorder Provisions.

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.

This call is open to everyone. If you are a member of the press, you are welcome to listen. But please refrain from asking questions during the feedback portions of the call. Your inquiries should be directed to press@cms.hhs.gov.

As I mentioned, the purpose of today's session is to address clarifying questions on these four topics to help you formulate your comments on the rule. After the presentation on each topic, we'll open the lines for clarifying questions on that specific topic.

With that, we'll start our first topic with Emily Yoder, Sarah Leipnik, and Christiane LaBonte from our Center of Medicare who are here to discuss provisions related to telehealth and other virtual services. Emily?

Extending Telehealth & Licensing Flexibilities

Emily Yoder: Yes, thank you, Nicole. Hi, everyone. I will be covering Medicare Telehealth Policies pertaining to communication technology-based services and remote patient monitoring as well as some changes to our direct supervision requirements.

So, 1834(m) of the Social Security Act specifies the circumstances on which Medicare – under which Medicare may pay for telehealth. Medicare telehealth services are services ordinarily furnished in person and are subject to geographic, site of service, practitioner, and technological restrictions.

During the public health emergency for COVID-19, CMS expanded access to telehealth through a combination of waivers through the statutory provisions and through emergency rulemaking. The following is a summary of the regulatory flexibilities we are proposing to adopt on either a temporary or a permanent basis.

For CY 2021, we are proposing to add a number of services permanently to the Medicare telehealth list. These include lower-level established patient home and/or domiciliary visits and assessment and care planning for patients with cognitive impairment, group psychotherapy, and two add-on codes associated with our previously finalized office outpatient E&M policies.

We are also proposing to create a third temporary category of criteria for adding services to the list of Medicare telehealth services. This new category, Category 3, describes services added to the Medicare telehealth list during the PHE that will remain on the list through the calendar year in which the PHE ends. This will give the community time to consider whether these services should be delivered permanently through telehealth outside of the PHE.

The services we are proposing to add to the telehealth list on a Category 3 basis include lower-level emergency department visits, higher-level established patient home or domiciliary visits, certain psychological testing services and nursing facility discharge day management.

We are also soliciting comment on services added to the Medicare telehealth list during the PHE that we are not proposing to add temporarily or permanently to the Medicare telehealth list.

For our communication technology-based services, we are clarifying that licensed clinical social workers, clinical psychologists, physical and occupational therapists, and speech language pathologists are examples of the types of practitioners that can furnish the brief online assessment and management, as well as virtual check-ins and remote evaluation services.

For the duration of the PHE, we established separate payment for audio-only, telephone evaluation and management services. While we are not proposing to continue to recognize these codes for payment under the PFS in the absence of the PHE, the need for audio-only interactions could remain as beneficiaries continue to try to avoid sources of potential infection. We are seeking comment on whether CMS should develop coding on payment for a service similar to the virtual check-in for a longer unit of time.

In recent years, CMS finalized payment for seven remote physiologic monitoring codes. In response to stakeholder questions about RPM, we are clarifying in this proposed rule our payment policies related to RPM services described by CPT codes 99453, 99454, 99091, 99457 and 99458. In addition, we are proposing a permanent policy to clarifications to RPM services that we finalized in response to the PHE for the COVID-19 pandemic.

So, we are proposing as permanent policy to allow auxiliary personnel to furnish certain remote monitoring services under a physician’s supervision. Auxiliary personnel can include contracted employees.

We are clarifying that the medical device supplied to a patient as part of the RPM service must be a medical device as defined by Section 201(h) of the Federal Food, Drug and Cosmetics Act and the device must be reliable and valid and that the data must be electronically, and that means automatically, collected and transmitted rather than self-reported by the patient.

So, that wraps up telehealth and virtual services. I'm now on slide 14 to discuss our changes to direct supervision. So, for the duration of the PHE, we adopted an interim final policy revising the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology.

We are proposing to continue this policy up through the year in which the PHE ends or December 31, 2021 whichever is the latter. We are seeking information from commenters whether there should be any guardrails in effect as we finalize this policy through December 31, 2021 or the end of the PHE, or whether we should consider adopting this policy on a permanent basis and what risks this policy might introduce to beneficiaries if they receive care from practitioners under remote supervision.

And now, I'm going to hand it off to Sarah.

Sarah Leipnik: Thank you, Emily. I'm now going to – I'm on slide 15 and I'm now going to discuss our proposal regarding professional scope of practice and related issues. So, the first one is supervision of diagnostic tests by certain non-physician practitioners.

And we are proposing to make permanent our policy for the duration of the COVID-19 PHE, Public Health Emergency, that allows non-physician practitioners, including nurse practitioners, clinical nurse specialists, physician assistants, and certified nurse-midwives to supervise diagnostic tests as allowed by state law and scope of practice. The non-physician practitioners would maintain any required statutory relationships with the supervising or collaborating physicians.

Moving on to slide 16, pharmacists providing services incident to physician's services. We are reiterating our clarification that pharmacists can be auxiliary personnel under our "incident to" regulations; as such, pharmacists may provide services incident to the services and under the appropriate level of supervision of the billing physician or non-physician practitioner if payment for the services is not made under the Medicare Part D benefit.

Moving on to slide 17, therapy assistants furnishing maintenance therapy. We are proposing to make permanent our policy that we adopted for the duration of the COVID-19 public health emergency that allows a physical therapist and occupational therapist the discretion to delegate the performance of maintenance therapy services as clinically appropriate to a therapy assistant, either a physical therapy assistant or an occupational therapy assistant.

Medical record documentation. We are broadly clarifying that therapy students and students of other disciplines working under a physician or practitioner who furnishes and bills directly for the professional services to the Medicare program may document in the medical record so long as it is reviewed and verified, signed and dated by the billing physician, practitioner, or a therapist.

I'm now going to turn it over to Christiane LaBonte.

Christiane LaBonte: Thanks, Sarah. Good afternoon and good morning. This is Christiane LaBonte and I'll spend a few minutes discussing the proposed rule provisions for teaching positions and residents.

And if you're following along on the slides, I'm on slide 18. For the duration of the COVID-19 public health emergency, we implemented several policies on an interim basis through the interim final rule to comment that we issued on March 31st and May 1st earlier this year. And we've summarized these policies in the following three bullets.

To start with the first, teaching physicians may use audio/video real-time communications technology to interact with residents through virtual means, which meets the legal requirement that teaching physician renders sufficient personal and identifiable physician services to the patient to exercise full personal control over the management of the portion of the case for which the physician fee schedule payment is sought.

The provision that permits the use of audio and video real-time communications technology also applies when a teaching physician involves a resident in furnishing services on the Medicare telehealth list that Emily was speaking about earlier.

Now, on to the second bullet, teaching physicians involving residents and providing care at primary care centers, commonly called the primary care exception, can provide the necessary direction, management, and review for the resident services using audio/video real-time communications technology.

Residents furnishing these services at primary care centers may furnish an expanded set of services to beneficiaries, including level four and five of an office visit for both new and established patients, care management services, and communication technology-based services.

We also allowed physician fee scheduled payment to the teaching physician for services furnished by residents via telehealth for the primary care exception services that are also on the list for Medicare telehealth.

Finally, the third bullet relates to moonlighting. For the duration of the public health emergency, Medicare considers the services of residents that are furnished outside the scope of their approved graduate medical education programs and furnished to inpatient of a hospital in which they have their training programs are separately billable physician services.

For these policies that I've discussed, we are considering whether they should be extended on a temporary basis or made permanent. And we are soliciting public comments on whether these policies should continue once the public health emergency – once the public health emergency ends.

That concludes the telehealth and licensing flexibility section of this presentation, so I'll turn it back to Nicole.

Feedback Session 1

Nicole Cooney: Thank you, Christiane. So, before we get started on our feedback session, I just wanted to set a few ground rules. In an effort to get to as many participants as possible today, we're asking folks to limit their

question, their feedback to just one item. And we will spend a maximum of about two minutes on each participant.

We are looking to take clarifying questions to help you submit your formal comments on the rule. 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'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 telehealth topic. There will be an opportunity to get into the queue after the other topics, so please limit your questions to the telehealth topic for this section. Blair, we are 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'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. Please hold while we compile the roster.

The first response comes from the line of Diane Patterson.

Diane Patterson: Yes. Hi. Diane Patterson. I'm calling from Maine Health, Maine Medical Partners. Question as far as teaching physician and residents telephone call. When a resident performs a telephone call, can that resident discuss that patient via telephone call rather than audio and video to fulfill the, you know, supervisory needs?

Christiane Labonte: Yes, that's a good question. So, under the public health emergency, we have revised the regs that a teaching physician may supervise the resident via a telephone call. [This response is clarified on page 19.]

Diane Patterson: Okay. Thank you.

Christiane Labonte: Sure.

Operator: The next response will come from the line of Shay Doggins.

Shay Doggins: Hi. Regarding the virtual visits, specifically what CPT codes are you referring to?

Emily Yoder: So, unfortunately, I do not have those codes in front of me. The audio-only phone E&Ms that we're not proposing to maintain are 99441 through 99443 and 98968 through 989 – excuse me, 98966 through 98968. The virtual check-in is G0 – is G2012 and the remote asynchronous service is G2010. But in terms of – we also have codes for e-visits, and I don't have those CPT codes in front of me.

Shay Doggins: Okay. You rattled those codes off pretty quickly. Can you just slow down a little bit? 99411?

Emily Yoder: It's 99441 through …

Shay Doggins: Okay.

Emily Yoder: …though 99443.

Shay Doggins: Okay.

Emily Yoder: 98966 through 98968. G2010 …

Shay Doggins: Okay, thank you.

Emily Yoder: … and G2012.

Shay Doggins: All right. Thank you so much. Those are ones that you're not proposing to go forward.

Emily Yoder: No. The codes that we are not proposing to maintain were only the first six that I gave you.

Shay Doggins: Okay.

Emily Yoder: The other two are codes that we have permanently. Thank you.

Shay Doggins: Okay. Thank you.

Operator: The next response will come from the line of Jim Collins.

Jim Collins: Hi, there. Yes. I'm trying to clarify just one specific about this remote physiologic monitoring. There's been just a complete void of guidance on it for Medicare until this proposed rule and in it, it specifically says that the service can be contracted to outside employees.

And my question is does the billing provider, the billing physician need to do anything at all in an average month in order to bill for remote patient monitoring if a contracted external entity is meeting all of the code definition components?

Emily Yoder: So, that is something that we would ask you to submit as a public comment to the proposed rule. I can't speak to it at this time. Thank you.

Jim Collins: Okay. Thanks.

Operator: The next response is from the line of Ann Gabowsky.

Ann Gabowsky: Hi. Can you hear me?

Nicole Cooney: Yes, we can.

Ann Gabowsky: Hi. I have a question regarding the review and verify documentation. So, in that part of the final rule, it mentions that residents, nurses, students, and other members of the medical team are some of those that their documentation can be reviewed and verified.

I was wondering what is the significance of including residents and medical students to that when there are other documentation rules that teaching physicians have to follow in order to consider their documentation?

Sarah Leipnik: Christiane, do you want to take that or do you want me to start?

Christiane LaBonte: Go ahead, Sarah.

Sarah Leipnik: Okay. So, are you looking at the proposed – at our proposed rule?

Ann Gabowsky: Well, it's – I'm referring back to the 2020 final rule that introduced this topic. But it would, I suppose, apply to your clarification. I mean, I think there's more clarification that needs to be done on this topic other than just therapy students are included, because there is a lot of questions surrounding that how does this affect other billing rules when a physician can review, verify, and sign and date somebody else's note and possibly use it for billing because that's how it's being interpreted.

Sarah Leipnik: Okay. Can you please submit your question as a comment?

Ann Gabowsky: Sure. Absolutely. Thank you.

Sarah Leipnik: Okay. Thank you.

Operator: The next response is from the line of Katie Jordan.

Katie Jordan: Hi. Katie Jordan, American Occupational Therapy Association. I can understand why you're considering not keeping the therapy codes as it's confusing since therapists cannot be providers. I'm just trying to figure out a solution for not removing access to beneficiaries who need our services to stay safely in their home and community. Any suggestions you have on how we can approach that?

Emily Yoder: Yes. So, that is the – one of the reasons why we are seeking a public comment on the services that we have not proposed to add either a category three or as permanent telehealth additions. We want to hear from you sort of those issues that you described, how the therapy services can be furnished remotely. And we will definitely consider comments like that as part of – as we are finalizing or to not finalize the policies.

Katie Jordan: Thank you.

Operator: The next response will come from the line of Claire Ernst.

Claire Ernst: Hi. I'm Claire Ernst. I'm with the Medical Group Management Association. I just want to say thanks for holding this call. We appreciate the opportunity to ask some questions.

My question is in regards to audio-only. It was our understanding that 1834N does not define telecommunication as needing to be audio/visual. I think it's defined at 42CFR41078 in the regs.

So, in the proposed PFS we saw that the reason why – while we saw that you guys said we were not able to waive the interactive two-way audio/visual communication technology and I'm just wondering why that is if it's not defined in 1834.

Emily Yoder: I would ask you to submit that as a public comment. Thank you.

Claire Ernst: Okay. All right. Thanks so much.

Operator: Our next question comes from the line of Grant Huang.

Grant Huang: Yes, hi. My name is Grant Huang with Doctors Management. I had a question about, in the proposed rule it says that, with regard to the telehealth flexibilities that do away with the geographic restrictions on originating and distant sites, you know, that would not be made permanent after the public health emergency. Yet it seems to be that is the single biggest and most important regulatory change when it comes to making telehealth services more widely available to Medicare beneficiaries. So, I was wondering if there is any possibility that might be reconsidered going forward.

Emily Yoder: Hi. This is Emily. I agree with you that those were really dramatic and impactful changes. Unfortunately, in terms of what have regulatory authority over, we don't actually have the authority to modify those requirements. Those are embedded in the statute and require an act of congress to change.

Grant Huang: So, it can only continue during the public health emergency you're saying?

Emily Yoder: Yes, that is correct. The waivers that allowed us to waive those portions of the statutes are tied to the duration of the PHE.

Grant Huang: Okay. Thank you.

Operator: The next response is from the line of Martina Flores.

Martina Flores: Hi. My name is Martina. I'm with Altese Health. We are a specialty group cardiology and pulmonary.

My feedback and my question is I see that initial nursing facility visits are being removed from the proposed waiver and I would like to see how could we then approach a new patient that are in such need of cardiologists and pulmonologists that are being admitted in the Skilled Nursing Facilities and assisted living, seeing how this community was affected by COVID and pandemic starting in March. It helped us a lot that we were actually finally able to see all the new patients as well, not only to continue with the established ones.

Emily Yoder: Yes. This is Emily again. And similar to the question a little bit ago about the physical therapy services, this is why we're taking comments on the services that we are not supposing to add even temporarily or permanently. We're very interested in how your experiences under the public health emergency with all of these additional flexibilities had impacted your clinical practice and we very much welcome comments to that end.

Martina Flores: Okay. Thank you so much.

Emily Yoder: Thank you.

Operator: And again, 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 entire time you're providing your feedback, so anything you say, or any background noise, will be heard in the conference.

Our next response will come from the line of Nicole Moscatelli.

Nicole Moscatelli: Yes. Hi. I just have a question about the platforms that are used for telehealth. Is that going to be evaluated in terms of what's currently available during the public health emergency versus what will be available at the close of the public health emergency?

Emily Yoder: Right. So, in terms of what we are evaluating for permanent policy, we're not making any adjustments to the requirements that work for the traditional Medicare telehealth outside of the public health emergency, that the technology must be two-way audio/video real-time communication technology.

During the public health emergency, we began paying for audio-only evaluation or if that's in a management services and that is a state like a discrete group of codes that we are not proposing to maintain permanently.

We are, however, seeking public comment on whether a sort of a longer virtual check-in, which the virtual check-in does not have any technological restrictions beyond the fact that it must be a synchronous interaction. We're seeking comment on whether a longer virtual check-in would be necessary to determine whether or not a patient needs to come into the office for an in-person visit.

Nicole Moscatelli: Okay. And can – thank you. And can you speak to, like, the use of different social media options like Zoom or Skype and things like that?

Emily Yoder: So, that is actually – that falls under HIPAA restrictions. So …

Nicole Moscatelli: Right.

Emily Yoder: …I cannot speak to that.

Nicole Moscatelli: Okay. Thank you.

Emily Yoder: Thank you.

Operator: The next response is from the line of Carrie Fletcher.

Carrie Fletcher: Thank you. Good morning. And thank you for having this session. So, my question is in regard to slide 16, scope of practice proposal for pharmacists.

So, my question is, currently – and you reiterated your clarification that pharmacists can be auxiliary personnel under the "incident to", but you just allowed for a COVID counseling reimbursement under the office visits and that is not a payment that's made under Part D. But if you're saying that it has to be paid as an "incident to" regulation, most pharmacists don't have that employee relationship with the physician.

So, at the time of testing, can they bill for that counseling themselves, or do they have to have an employment relationship with the physician to be able to submit that if they are the ones doing the counseling, or does it have to be an ancillary staff that is at that pharmacy site? Thank you.

Sarah Leipnik: Thank you. This is – sorry, go ahead, Ann.

Ann Marshall: No, if you had it, that's fine. Otherwise, I'm happy to jump in.

Sarah Leipnik: Okay. You can go ahead.

Ann Marshall: Okay. Yes. That's outside the scope of this presentation because it really kind of involves the policies that we passed specific to COVID testing for the PHE. But it is a kind of example that so, the counseling is billed to the regular E&M visit, and the only way that pharmacists can bill those for the COVID testing is through the use of the 99211 that the physician would be billing.

The "incident to" rule, you don't have to be an employee. You can be a contractor, which is one reason you keep continuing – you keep hearing us continuing to mention that for this duration and others as well. But they – even for the COVID testing, the payment for any counseling and the assessment on the front end is all through codes that the physician can bill and there has to be an "incident to" relationship in order for that to happen.

Carrie Fletcher: Okay. So, still some kind of a – whether employee or contracted situation, there has to be a monetary relationship. I appreciate the answer. Thank you.

Nicole Cooney: Blair, we can take one more for this session.

Operator: Thank you. And the next response will come from the line of Andrew Border.

Andrew Border: Hi. I have a question regarding the telehealth inclusion of the codes. And I didn't see anything around traditional office visits, so 99213, 214. Has that been designated whether that's permanent and here to stay or is that still a question?

Emily Yoder: Thank you for that question. This is Emily. So, those codes actually were already on the Medicare telehealth list. They were already – they were actually some of the first services that were added to the telehealth list. So, they will be on the telehealth list after the public health emergency ends. That said, all of the geographic and site of service restrictions of normal Medicare telehealth will apply to the services outside of public health emergency.

Andrew Border: Great. Thank you.

Payment for Office/Outpatient E/M Visits and Analogous Services

Nicole Cooney: Thank you. That's all the time that we have for our first feedback session on telehealth and other virtual services.

Up next, we have Ann Marshall and Christiane LaBonte from our Center for Medicare to discuss updating evaluation and management coding guidance. Ann?

Ann Marshall: Hi. Thanks. This is Ann Marshall in the Division of Practitioner Services. By way of background on this topic, as we finalized in last year's Physician Fee Schedule final rule, in 2021, we will be largely aligning our office outpatient E&M visit coding and payment policies with changes that were adopted and laid out by the AMA CPT editorial panel for the office outpatient E&M visits starting January 1st of 2021.

And these policies include redefining the codes to rely on either time of the billing practitioner or medical decision-making for selecting visit level with performance of history and exam as medically appropriate. It also includes deleting the level one new patient code which is 99201 right now. And there is going to be a new prolonged services code specific to office outpatient E&M visits. That's the 99XXX.

We also finalized that we'll be adopting the revised medical decision-making guidelines that the CPT editorial panel adopted for this code set. And you can find additional information about the changes that were made by CPT on the AMA website. And we have provided a link to that information here on the slide.

In the next slide, we'll talk about what we're proposing. It's really just some refinement. It's not as big of a proposal as we had last year because of the amount of stuff that was already finalized. But we are proposing a refinement to clarify the times for which the prolonged visit could be reported, and also proposing to slightly revise the times that are used for rate setting for this code set.

So, regarding prolonged services, that CPT code, 99XXX, that add on, will be reported when time is used to select the visit level and the maximum time for the level five visit is exceeded by at least 15 minutes of additional qualifying time.

I think there has been some back and forth on the language and the descriptor for what that floor time is when the prolonged time kicks in, and we are proposing that it would be at once the maximum time of the level five visit range is exceeded by the additional 15 minutes.

Also, we're proposing to use the sum of the component time as the total time rather than the rough recommended time. Last year, we proposed to adopt the rough recommended time, but we kind of used different math approaches and averaging in-depth, and we think that it is more consistent to use the sum of the component times. And so, we are proposing that, and it does slightly – would slightly reduce the time – the total times for a couple of the services, not all of them. And there's a table in the row that compares what the time differences would be.

We are also proposing to revalue several code sets that either include or rely upon or are analogous – closely analogous to the office outpatient E&M visits commensurate with the increases in the values that we finalized for the office outpatient visits for 2021.

So, these are situations where we feel that the service either includes explicitly an office outpatient visit or it's a bundle of services where we know, in contrast to some of the global service codes, that the visits are actually being furnished. And so, we feel that that relationship is close enough to sort of do a commensurate, a proportional bump up in these service codes commensurate with the increase that's coming for the office outpatient E&M visits.

So, for the ESRD monthly capitation payment services, those bundles were valued using a building block methodology and we do believe the visits that are in those bundles are largely being furnished. But we are seeking comment on whether there are instances where the number and level of visits being furnished in practice might not be consistent with the number and specified level that were built into the valuation of the bundles that may impact our final policy.

For transitional care management services, those were valued using a direct cross lock and they always include a level four or five office visit. So, we are proposing a commensurate increase to those codes.

And maternity service packages, similar to the ESRD codes, we believe the visits that are included in the valuation for those bundles are actually being furnished. And so, we propose to increase those bundles as well.

The cognitive impairment assessment and care planning code and the initial preventive physical exam and the annual wellness visits are kind of similar to transitional care management where the codes include an outpatient visit that is always furnished and is very similar to an office outpatient visit, and there were some cross-walking – direct cross-walking in the initial valuation of these services. And so, we're proposing to increase those.

For the emergency department visits, historically, these were valued in relation to the office outpatient visits, and there would be a rank order anomaly if we did not increase their valuation. We did note in the proposed rule that we are reviewing the use of Modifier 25 with the ED visit codes and other visits and thinking about

whether the rate of reporting that Modifier, depending on whether it's with another visit or a minor procedure on the same day, may indicate something of a distinction from the office visits that might not warrant an increase in the valuation of the ED visit or some other code sets that we discussed in the rule. So, I would just point you to that discussion and in – because we're seeking comment on that issue.

The last code set is therapy evaluations and the psychiatric diagnostic evaluations and psychotherapy services. These code sets involve work that is roughly equivalent to the office outpatient visits in that they are face-to-face assessment and managing – management or counseling in an office setting that is generally considered to be sort of the equivalent work for the practitioners who can't report E&M visit codes because of their benefit category under the law. And practitioners reporting these services generally use these codes instead. And so, we felt that those were similar enough to propose an increase – a commensurate increase to their valuation.

And finally, in the proposed rule, we're seeking public comment on how we might clarify the definition of an add-on G code, GPC1X. That's a Medicare-specific add-on code to the office outpatient visit that we've previously finalized for 2021 for office outpatient E&M visit complexity.

And we continue to get comments and questions about what we intended that add-on code to be reported, what situations, and what exactly the definition of that service entails, and accordingly whether our utilization assumptions for the code that we use for rate setting are – were appropriate or not.

So, we're seeking comment and we've provided some additional language and examples about what we intended this code to be used for and we're seeking comment on that, as well as appropriate rate setting utilization assumptions. And I think that wraps up our review for this section.

Feedback Session 2

Nicole Cooney: Thank you, Ann. We're now ready to take your clarifying questions on the evaluation and management topic. Please limit your questions to this topic. We'll spend a maximum of about two minutes on each question and answer. And, as a reminder, there may be questions today 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. All right, Blair, we're ready for our first caller.

Operator: And 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'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. Please hold while we compile the roster.

Your first comment is from the line of Judy Harris.

Judy Harris: Yes. Can you please confirm the times that are associated with these outpatient E&M codes because, in the proposed rule, they appear very different than what was in the November 2019 final rule?

Ann Marshall: Hi, Judy. This is Ann. Thanks for the question. I think that we've been working on getting you an email response back and I'm sorry for the delay.

I think in your question you were referring to the two different tables for what the different times would be based on either the rough recommended times or the new component times, and those are used for rate setting. So, those two tables are the times that are used in setting the price for the code essentially.

The times that you would use for reporting, for selecting visit level, which I think what you were asking about, would be the time ranges in these code descriptors. And you can see those in the 2021 CPT code book or on the AMA website, what those new ranges are going to be.

Judy Harris: Okay. And do you require that providers meet the total time or to bill the code requirement; if not, you would have to go back to the lower code?

Ann Marshall: You would need to be within the range that's in the code descriptor. So, first of all, it would just be a situation where you're using time rather than medical decision-making to select your visit level.

And then, you would look at the code descriptor which is now going to have ranges instead of a typical time. So, it will have, like, 40 minutes to 54 minutes, something like that, say. So, you do – the billing practitioner would have to personally spend between 40 minutes and 54 minutes on that day in order to report that code if that was the range.

Judy Harris: Okay. Thank you.

Operator: Your next comment is from the line of Michelle Wang.

Michelle Wang: Hi. My name is Michelle Wang. I'm calling from Oregon. And our office does home and domiciliary visits. And I see that the E&M proposal is only for office visits. Do you see a time where that's going to also be added to the home visits or domiciliary visits?

Ann Marshall: I don't have any new, you know, sort of information or intel for you at this point. I can say that – and this really is the culmination of sort of several years' worth of work and work with the CPT and AMA to decide which code sets we should take on first because we couldn't take them all on at one time and it was sort of recommended by stakeholders and we discussed in past rules that we would start that.

Emily Yoder: This is Emily. I can – I can wrap that up. So, as Ann was saying, when we sort of sought comment on which of the evaluation management visits would be most impactful for us and sort of collaboration with CPT to take on first, the – sort of the consensus was to see only outpatient E&Ms were sort of the right place to start. And as Ann said, we, unfortunately, don't have any additional information that we can provide at this time as to whether or when those – the other E&M code families will be looked at. Thank you.

Operator: The next comment will come from the line of Betsy Nicoletti.

Betsy Nicoletti: Hi. Thank you. I'm Betsy Nicoletti from Medical Practice Consulting and I have a question about the prolonged services code 99XXX and whether the time – since you're going to require that we reach the maximum time for 99205 and 99215 before adding on that 15 minutes, will your times and CPT times vary? Do you know that yet?

Ann Marshall: This is Ann. Thanks for the question. You would need to look on the AMA website to see if they have some tables of examples there. I think that this would probably, for the moment, produce a discrepancy. But you would need to confirm that with them by way of specific examples.

Because, right now, the CPT code descriptor just says something like the time above the total time. And the total time in a situation where level five has ranges really doesn't make sense. So, I think we were all kind of undertaking this work in a rush and this one has been a little difficult to get on the same page with. So, check in with them and look at the material on their website and feel free to also submit comments on our proposal.

Betsy Nicoletti: Thank you very much.

Operator: The next comment will come from the line of Grant Huang.

Grant Huang: Yes. Hi. Thank you. This is Grant Huang with Doctors Management. I just have two clarifying questions about the 2021 E&M guidelines. So, first of all, the language in the proposed rule and in previous final rules says that history and exam should be, quote, "medically appropriate", but won't count towards code selection.

So, does that mean that, if a provider decides that history or exam is not needed for an encounter and doesn't document it, that that would be acceptable if the – if they have the rest of the documentation.

And then, second, I was going to ask, in terms of time being used to select code level, does medical necessity still take precedence over time? So, even if they have a properly-documented time statement that needs a given code level, but it's not medically necessary to spend that amount of time, or so you could argue, but the medical necessity still take precedence.

Ann Marshall: Thanks for those questions. So, on the first one, I mean, we are not the audit arm of CMS and, as you may know, we have local contractors who also do some auditing and I – we definitely can't weigh in on how private insurers would look at it. But the code descriptor right now just says – the new ones just say history and exam as medically appropriate. So, that would be the bar that you would need to meet.

So, if you didn't include a history and an exam, I would think that an auditor would just be looking at the medical record. And if you could show – demonstrate from any of the material and the record that it was – that they were not medically necessary, then that would be okay. But I can't tell you how the – that individual decision would be made and it's probably on a case-by-case basis.

On your second question, that's a good one. I know that we had some discussion of this in last year's rule when we finalized it. You know, the Medicare law does have some general language saying that all of the

services that are paid for need to be medically reasonable and necessary. So, I think that is not something that we can just sort of dispense with in terms of judging whether time was needed or not.

And I think that we will also probably have further conversations as this goes – as this was implemented with the auditing folks on how they're going to look at time and think about. So, I think that, generally, anything that you bill for needs to meet medical necessity and have met that bar. But exactly how that's going to play into individual cases and documentation I think we haven't – we don't know yet. Thanks.

Grant Huang: Okay. There could be clarifying language in the final rule.

Ann Marshall: No, because we didn't really propose any change on that. The policy to – our policy to adopt the new CPT framework that uses time or medical decision-making to select code level was finalized last year. And generally, where we don't propose a change in policy, we don't discuss it in our final rule. But you can always submit the question in a comment.

Grant Huang: Okay. Thank you.

Operator: Our next comment will come from the line of Terry Fletcher.

Terry Fletcher: Thank you. My name is Terry Fletcher and I'm with Terry Fletcher Consulting. So, just kind of piggybacking a little bit on what Grant had said, as an auditor myself, one thing I'm going to be looking for are examples, vignettes.

And because there's no consistency right now, not only with Medicare, but also with CPT amongst specialty providers or internal medicine and primary care on what constitutes a medically-appropriate exam or what is medically necessary for that typical patient, will there be some kind of an audit tool, do you know or have you heard, for us to audit with or to self-police the providers or at least for compliance, because, right now, there's a lot of misinformation with a lot of providers feeling that what has been said was that a history and exam is not necessary since it doesn't factor into leveling a code and we're trying to explain that, again, you still have to have some kind of history and exam. But we're not getting the clear picture on what that really is based on their specialty.

So, if you could speak to that and what we're hopefully going to get to give more clarity there from an auditing perspective, that'll be great.

Ann Marshall: Thank you for the question…

Emily Yoder: This is Emily – go ahead Ann.

Ann Marshall: Sorry, I was on mute. Yes. It's a – it's – we understand I don't – CMS does not have any plans right now to issue any audit tools. We can certainly pass that thought and question along to our audit folks in – on our end.

I think that would be a good question to the American Medical Association though for – or the CPT editorial panel, because that language really didn't sort of arise with us. I think that everyone was looking for an

alternative to the clinically outdated method that we have now where there's sort of a specific number of body systems or a specific detail level of history that is really just, from what we were hearing, not clinically appropriate and very unwieldy and hard to document, so – and easy to kind of – easy to manipulate in electronic record documentation.

So, it's a – it's a good question. I don't have a definitive answer for you right now other than just the language that's in the code descriptor. But you would need to perform…

Ann Marshall: I would interpret that as you do need to perform a history and exam if medically appropriate because it's included in the code and you need to perform all of the pieces of the code in order to bill it. And it is still a piece of the code even though that piece is the same for each level.

Terry Fletcher: Okay. Would it be helpful if we submitted that as part of a question to the proposals just so we can get some feedback on it?

Ann Marshall: Again, it's always helpful for us to hear kind of what your thoughts and questions are, but we didn't make a new proposal on there. So, it wouldn't necessarily – probably wouldn't be something that we would discuss in the final rule. It would just be for our internal discussions.

Terry Fletcher: All right. Thank you.

Ann Marshall: And I heard that the AMA has also been doing some education or is going to be doing some education. And again, that – I feel like that would be a really good topic to get their – to get their feedback on as well.

Operator: And as a reminder, if your question has been answered, you may remove yourself from the queue by pressing the pound key.

The next comment will come from the line of Diane Patterson.

Diane Patterson: Hi, good afternoon. I have two quick questions – well, two questions, one relatively quick. The new medical decision-making table that CMS is going to adopt that AMA did, I'd like to confirm that that medical decision-making table is strictly for the outpatient office E&M codes of those 99202 to 99205 and not other E&M services such as hospital initial and subsequent daycare – or you don't accept consultations anyway, so let's eliminate that. But is it strictly for those few codes and not other E&Ms?

Ann Marshall: I believe that's right. But look at what's on the AMA website. And if it's not clear, then submit that question to them please.

Diane Patterson: Yes, that is not clear. My second question, prolonged services. It doesn't have to do with the 99XXX, but rather than 99358 which is the indirect prolonged service in which, today, you can use that for, like, review of – extensive review of records on a different date of service than your face to face.

It's my understanding in the previous final rule that the AMA may accept that in their – in their guidelines, but CMS said that that would no longer be a usable code on a different date of service. Can you confirm that?

Ann Marshall: That's correct. We finalized last year that that – the add-on 99359 would no longer be reported in association with office outpatient visits. And I'd just refer to that discussion of the – in last year's rule for what our reasoning behind that was.

Diane Patterson: Okay. Thank you.

Nicole Cooney: Thank you. That is all the time that we have right now for this topic. I do want to pass it back to Christiane who wanted to clarify something from earlier. Christiane?

Christiane LaBonte: Thanks so much, Nicole. I wanted to clarify a question from earlier which is about when a resident performs a phone call, if the teaching physician needs to supervise the resident through audio/video or is audio only okay.

So, I wanted to clarify the – under the primary care exception, when the resident is conferring with a teaching physician after the fact, the teaching physician is to direct the care and then to review the services furnished by each resident. That can happen during or immediately after each visit, so in the case of the phone call, maybe after the – after the resident has gotten off the phone with the patient.

So, the conferral with the teaching physician may be met using audio/video real-time communications technology and we've interpreted that as to mean both audio and video. And the reason for that is because the law does require the teaching physician to provide physician personal and identifiable physician services which you need – which you have interpreted to be both audio and video. Thank you for that, Nicole.

Quality Payment Program

Nicole Cooney: Sure. Next, we have Molly MacHarris from our Center for Clinical Standards and Quality, and Brittany LaCouture from our Center for Medicare and Medicaid Innovation, to discuss updates to the Quality Payment Program. Brittany, I think you're starting us off.

Brittany LaCouture: Hi. Thanks. So, for the Quality Payment Program, in 2021, we have a few proposals to update on. The first on the MIPS side of the house, the MIPS Value Pathways, or the MVPs, that were proposed in last year's rule are not going to be introduced for the 2021 performance period due to some of the confounding factors like the public health emergency. So, the earliest (Inaudible) would be in the calendar year 2022.

On the other hand, for folks who are (inaudible) and (inaudible) you are introducing the APM (inaudible) complementary reporting pathway that will have fixed measures that put you to the performance category. The quality category will have six measures that are preset for all MIPS APM participants. I want to flag that those in the Shared Savings Program will be required under the terms of the shared savings program to report quality measures via the APP.

The cost performance category will be released at zero percent because these participants are already averaged to the cost of either APM. The improvement activities performance category will still be weighted at 20 percent, but for calendar year 2021 APM participants will receive an unmet score of 100 percent based on the requirement of participation in their APM. And the inaudible category will be weighted at 30 percent and will be reported and scored at the individual group level as required by regular MIPS PR reporting rules.

Some other changes. The APM scoring standard is going to be sunset. But though we won't be scoring APM MIPS under the APM scoring standard, we will allow APM at least to report to any part of MIPS whether it's the APP or otherwise, and APM participants may report with their APM entity or they may report to MIPS as an individual or group however they choose to do so. So, those are a few quick updates. And let me turn this over to Molly to get more into the details of the individual performance categories.

Molly MacHarris: Thanks, Brittany. Okay. I'm going to go over some of the additional performance category updates. And if you're following along, I'm on slide 27.

So, the first update I wanted to give is that we've proposed to sunset the CMS web interface, which is the reporting option that Shared Savings Programs, ACOs, as well as registered groups, virtual groups, and other APM entities have historically used to report. We're proposing that that would end after this year, after 2020, so it would no longer be available in the 2021 year.

There would be other options for groups and virtual groups to select from outside of the CMS web interface. They would be able to select their own quality measures instead of reporting on this predetermined set of measures.

Also, when we look at the number of measures, they would be – they would have to report with the elimination of the web interface. We're reducing the number of measures, from typically 10 measures within the web interface to 6.

And I also want to touch along a lot because we've been getting questions related to this as well is that many of those measures that were previously available are still available as either a MIPS CQM or an ECQM. And the difference between a MIPS CQM and an ECQM is that an ECQM refers to our electronic clinical quality measures that are fully baked into your certified EHR technology.

MIPS CQMs are measures that are derived from a variety of data sources, some could include your EHR, but they also could include information that may come from your practice management system. And we have more information on the differences between those measure specification types on our website.

A few other quality updates I wanted to provide is we've also proposed to use the performance period, not historical benchmarks, to score quality measures for the upcoming 2021 year. We're concerned that we may not have a representative sample of historic data for calendar year 2019 because of the public health emergency.

And we have also proposed to make substantive changes to our quality measures, removed 14 measures, which would result in a total number of 206 quality measures that would be available for the 2021 year.

For cost, the really only main update I want to provide there is that we have included updates to our cost measures to include telehealth services. We do still have our 18-episode days cost measures and our two global cost measures, the total per capita cost measure and Medicare spending per beneficiary.

Moving on to the next slide, a few updates for improvement activities and promoting interoperability. For improvement activities, only a few updates there. We've made a couple of updates to the inventory to modify some of our existing improvement activities and we've also made some proposals regarding the method that new improvement activities can come to us, including establishing an exception to the nomination timeframe due to a public health emergency and also the ability for agency-nominated improvement activities to be included.

And then, for the promoting interoperability performance category, a couple minor updates and then one that I do want to talk about. The minor updates are that we've retained to – we've retained the Query of PDMP measures as an optional measure and propose to increase it from 5 to 10 bonus points.

We've also changed the name of *The Supporting Electronic Referral Loops by Receiving and Incorporating Health Information* by replacing *Incorporating* with *Reconciling*. And then, our more significant change that we've proposed for the promoting interoperability performance category for this year is we've proposed to add a Health Information Exchange bidirectional exchange measure, which would be worth 40 points, and it's an optional alternative to the two existing measures that deal with HIEs.

So, clinicians have the option to either report the new bidirectional HIE exchange measure, assuming it's finalized, or the two existing measures. And the two existing measures are *Support Electronic Referral Loops by Sending Health Information Measures* and then the other one I mentioned *Support Electronic Referral Loops by Receiving and Incorporating Reconciling Health Information* measure.

Just a few other updates I want to go over. Moving on to slide 29, we have also proposed to make some revisions to the MIPS performance category weight. Most notably, we've proposed to reduce quality down to 40 points and increase cost to 20 percent. This is separate and apart from the update of the performance category weights that Brittany went over for the new APP.

And then, moving on to the next slide, the additional updates that we've made for our proposals are that we've proposed to lower the previously finalized performance threshold for this upcoming year from 60 points down to 50 points.

And then, let me turn it back to Brittany – wait, sorry, one more slide for me. The – and then, moving on to the next slide on slide 31, a few other items I wanted to share regarding some of our COVID-19 flexibility. I know folks are tracking too that, per the 2020 year, we've already issued flexibilities where we have included a new COVID-19 improvement activity. And we've also released flexibility where clinicians can file an application to get their performance categories re-weighted.

We've also proposed to double the number of bonus points that would be available under our complex patient bonus, increasing that from 5 points to 10 points. And we also have made a proposal that would allow APM entities to submit a re-weighting application based off of extreme and uncontrollable circumstances for the 2020 year.

There are some nuances on how the proposal would work for APM entities in comparison to the rest of MIPS-eligible clinicians; most notably in that, if an APM entity files an application and it is approved, the act of submitting data would not override or void that application.

And then, additionally, for our third-party intermediaries, we have made proposals that would require our qualified clinical data registry, then qualified registry to support our new MVPs and APPs and also additional proposals that include strengthening data validation and action plan requirements based off of some of our past performance with third party intermediaries.

And now, from here, let me turn it back to Brittany to close out on the advanced Alternative Payment Models.

Brittany LaCouture: Thanks, Molly. So, on the APM, advanced APM side of CPP, the biggest change per CPP purposes is that we are changing the way that we would handle beneficiary attribution in the case where a beneficiary is considered attribution eligible for more than one APM entity or in one – more than one type of APM, where the attribution rules within those APMs are in conflict with one another.

The most obvious example would be a prospectively aligned ACO and a retrospectively aligned ACO that anyone can, in fact, or will be attributed to the prospectively aligned ACO in the past have been considered actually eligible for the retrospectively aligned ACO.

So, what we're going to – what we're proposing to do is to remove that beneficiary from the attribution-eligible population for that retrospectively-aligned ACO to have a better representation of who they actually have the ability to align and help them with them QP determination.

Outside of QPP, so this is not a MIPS or a QP status policy, the Medicare Shared Savings Program is proposing a change to their quality – and we have a quality redesign. And basically, they are – as you've heard, we're sunsetting the web interface and, instead what they're going to propose to do is require these ACOs to report on more measure sets that's being proposed for the APP to streamline reporting options and requirements for ACOs.

So, you would only have to worry about reporting that one measure set. It would only be six measures. And, if an ACO achieves a quality score – so, just the quality performance category, not the entire MIPS, but only the quality performance category above the 40th percentile, that would enable them to – or qualify them to share in savings and avoid owing money back for a lot of these programs.

So, let me turn it back over to Nicole.

Feedback Session 3

Nicole Cooney: Thanks, Brittany. So, we have a couple minutes now to take your clarifying questions on the Quality Payment Program. Please limit your questions to this topic and keep our time limitations in mind. We just have a few minutes for this topic. And, as a reminder, verbal comments on today's call do not take the place of submitting formal comments on the rules as outlined in slide 5. Blair, we're ready for our first question – or our 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. Please hold while we compile the roster.

The first comment will come from the line of Melissa Unger.

Melissa Unger: Hello. This is Melissa Unger with the Ohio State University Wexner Medical Center. Thank you for taking my call. I did want to ask just a couple of questions regarding the ACO for the MSSP participants in that, one, with the fixed quality measure core set that we have to report, did we have to report all six? Were we only required to report three of the six?

And then, the secondary part would be, for the 40th percentile, is it that, as the ACO would be above the 40th percentile for the MIPS quality category or do we have to be above the 40th percentile across all six measures or all three if we only have to report three?

Brittany LaCouture: Good question. So, in response to your – the first bit – yes and no. So, you will be scored on six measures. One is the CAP survey; two, our claims measures; and three, our CQMs that you will need to actively report. So, yes, you're reporting on six measures, but only three of them do you have to actually go in and score. The other three should be scored for you and more possibly.

For the shared savings under SSP, that is only for the quality performance category. So, say, your entire ACO gets QP status, and so, you're not – you don't have to report that performance category for MIPS, that's fine, like you don't have to go in and report that because that won't be part of your score. You only have to report on the quality performance category for purposes of SSP.

However, if you don't report everything for MIPS and you have anyone in your ACO who happens to not have QP status, so they missed a snapshot or whatever, they are going to need that reported for their MIPS score. But yes, for shared savings under SSP is just based on the quality performance category and those six measures.

Melissa Unger: So, then, if we – for the quality performance category, get 40 out of 50 points or do we have to be above the 40th percentile on all six of the measures because where track one continued next year because of the whole COVID pandemic, so we're going to be a MIPS APM through the APP.

Brittany LaCouture: Right. So, it's not 40 out of 50 points. It's just you have to earn a score that is higher than 40 percent of MIPS-eligible clinicians. So, you basically – as long as you're not in the bottom half of all of MIPS, you'll be fine.

Nicole Cooney: Thank you.

Brittany LaCouture: It's not – it's not a measure-by-measure question.

Melissa Unger: Okay. Thanks.

Nicole Cooney: Thank you. In the interest of time, Blair, I could just take one more – one more quick question, and then, we have to move on.

Operator: The next comment will come from the line of Jason Shropshire.

Jason Shropshire: Hi. This is Jason from UNC. So, I have a question regarding slide 27. So, I'm trying to make sure I understand this. Since there's no historical benchmarks for MIPS quality, the only way you can be assured of achieving a full 10 points is to work with measures that already have established benchmarks and just to try to use the 2019 guideline of where you think you'll fall within the decile mark. Is that fair to say or can you elaborate a little bit on that?

Molly MacHarris: Yes. Hi, Jason. This is Molly. So, this proposal is finalized, and I highly encourage you to submit a comment on this. It would result where we wouldn't have our historical benchmarks published ahead of time, where typically, you and other stakeholders can see these are the decile marks, this is for a given measure where performance would need to be for the various break points.

What would happen if this proposal is finalized is that we would use performance period data to calculate the benchmark, so, they would not be available prior to being submitted because we actually would be populating them based off of the data that's submitted.

So, for concerns on how would clinicians be able to identify and select their measures, again, if this proposal is finalized, they could use available resources such as our specialty sets and other guides to be able to determine which measures may be appropriate for understanding what their actual performance would need to be at.

Our recommendation is that they could look at prior performance to get an understanding of what it could look like. But you're correct. The concern with this proposal that we've commented on within – or that we've explained within the rule and we want people's feedback on is exactly the point you're touching on that people wouldn't necessarily know where exactly their performance would need to be at until after they submit a data. So, I hope that hopes clarify, and again, encourage you to submit a comment. Thank you.

Jason Shropshire: Thanks.

Opioid Use Disorder/Substance Use Disorder Provisions

Nicole Cooney: Thank you. In the interest of time, I do need to move on to our final topic which is for provisions related to opioid and substance use disorder. We have Lindsey Baldwin and Joella Roland from the Center for Medicare to discuss updates to the opioid treatment program benefit as well as the request for information on e-prescribing of controlled substances under Part D. Lindsey is going to get us started.

Lindsey Baldwin: Great. Thanks, Nicole. First, I'll go over the OTP benefits, starting on slide 36. So, Section 2005 of the SUPPORT Act established a new Medicare Part B benefit for opioid use disorder or OUD treatment services furnished by OTPs.

As finalized in CY 2020 Physician Fee Schedule Final Rule, CMS pays OTPs through bundled payments for OUD treatment services and episode of care provided to beneficiaries with Medicare Part D.

Under the benefit, Medicare covers the FDA-approved opioid agonist and antagonist medication-assisted treatment, or MAT medications, which includes methadone, buprenorphine or naltrexone, dispensing and administration of MAT medications as applicable, substance use counseling, individual and group therapy, toxicology testing, as well as intake activities, and periodic assessments.

Moving on to slide 37, for CY 2021, we are proposing to add naloxone to the definition of OUD treatment services and adjusting the bundled payment rate through the use of add-on codes to be used when OTPs provide beneficiaries with the supply of naloxone to take home with them.

In order to accomplish this, we're proposing to create two new add-on codes, one add-on code for nasal naloxone, another add-on code for auto injector naloxone. And we are also seeking comment on whether we should consider coding to describe a take-home supply of injectable naloxone.

We're also proposing to use Wholesale Acquisition Cost or WAC + 0 in the methodology for the drug component of the episode of care in instances where Average Sales Price or ASP is not available.

We're exploring enrollment and claims processing flexibilities to allow OTPs to submit claims using an institutional claim form. We're proposing to revise the regulation text in order to allow the periodic assessments to be furnished via two-way interactive audio and video communication technology, provided all other applicable requirements are met.

We're also proposing clarifications related to what activities qualify for billing the periodic assessment add-on code that was finalized for CY 2020, specifically that a face-to-face medical exam or biopsychosocial assessment needs to have been performed. We're also clarifying guidance on the date of service using claims for the weekly bundles and add-on codes.

Finally, we are seeking comment on whether we should consider stratifying the coding and payment to account for significant differences in resource cost among patients especially related to expected amounts of counseling.

Next, I'll go over policies related to bundled payments under the PFS for substance use disorders. This is on slide 38 now. In the CY 2020 PFS final rule, we finalized the creation of new coding and payment describing a bundled episode of care for office-based treatment of OUD. For CY 2021, we're proposing to expand these bundled payments to be inclusive of all substance use disorders.

And next, on slide 39, we're also proposing to create an add-on G-code for initiation of MAT to be billed with E&M visit codes that are used in the emergency department setting that includes payment for assessment, referral to ongoing care, follow-up treatment, follow-up after treatment begins, and arranging access to supportive services. And, with that, I will pass it off to Joella Roland to go over e-prescribing of controlled substances.

Joella Roland: Thanks, Lindsey. I'll be starting on slide 40. On slide 40, we define EPCS which stands for Electronic Prescribing of Controlled Substances. What this is, is the e-prescribing of drugs classified as controlled substances to reduce prescription drug diversion and reduce burden on prescribers. EPCS is allowed in all 50 states in the District of Columbia and more than half of the states have laws requiring it.

Section 2003 of the SUPPORT Act requires that Schedule II, III, IV, or V controlled substances under Part D be prescribed electronically beginning January 1, 2021. 98 percent of pharmacies support EPCS prescriptions.

We've decided to take a three-phased approach to implement EPCS. The first stage of this approach is to solicit comments on exceptions and penalties. We've done this via a request for information which went on display July 31 and has comments due October 5.

Second phase is to propose a standard for electronic prescribing. This standard will be effective January 1, 2022. This is the proposal in this physician fee schedule rule, which went on display August 4 and also has comments due October 5.

The third phase is to finalize the standard with the exceptions and penalties listed. This will be enacted in future rulemaking after we take into account all comments received on or before October 5.

The request for information where we solicited comments on the – on the exceptions and penalties was issued on July 31 and it specifically solicits feedback on the exceptions to the EPCS requirement, what circumstances and whether CMS should impose penalties for non-compliance with the EPCS mandate from the SUPPORT Act. And, with that, I'll turn it over to Nicole.

Feedback Session 4

Nicole Cooney: Thanks, Joella. At this time, we will take your clarifying questions on our opioid and substance use disorder provisions. Please limit your input to this topic and keep our time limitations 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. Blair, we'll take our 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. Please hold while we compile the roster.

The first comment will come from the line of Dr. Amy Davis.

Amy Davis: Hi. Thanks for taking call. I have two very quick clarifications. I just want to make sure that the changes referring to naloxone do not pertain to practices that are not OTPs. Is that correct?

Lindsey Baldwin: Hi, Dr. Davis. This is Lindsey, and yes, that is correct. The proposal …

Amy Davis: Okay.

Lindsey Baldwin: …pertains specifically to opioid treatment programs.

Amy Davis: And then, the other part, and again, probably very easy is it's my understanding from the rule and from what you just described then that the electronic – the requirements for electronic prescribing of higher – of restricted meds is going to be effective for 2022 so that you can get more feedback. Yes?

Joella Roland: Hi. This is Joella Roland. Just to clarify, our proposal would be to make it effective for January 1, 2022. But we are soliciting feedback on that and the – and the standard in both the RFI and in this proposed rule.

Amy Davis: Thank you for the correction. Yes, that's what I was intending. Thank you and thanks for taking the call.

Operator: The next comment will come from the line of Annie WehageZickwolf.

Annie WehageZickwolf: Yes. My name is Annie WehageZickwolf. I am from Bates County Memorial Hospital. And my question is regarding the emergency department MAT. Is that considered to be a bundle where all four elements need to be completed for the billing? Thank you for taking my question.

Lindsey Baldwin: Hi, Annie. That's a really great question. That is something that we would really encourage you to submit a public comment on that so that we can take it under consideration for the final rule. And all the information you need about how to submit a comment is on slide 5 of the presentation. Thank you.

Annie WehageZickwolf Wilson: Thank you.

Operator: The next comment will come from the line of Ashley Price.

Ashley Price: Hi. My name is Ashley. I am with Trixan Medical Technologies. I was just wondering if you could provide any insight on opioid use screenings becoming a requirement in the health risk assessment in AWV.

Lindsey Baldwin: Hi, Ashley. I don't know if we actually have the subject matter experts on the line today to speak to requirements for the AWV. I'll pause and just make sure no one is able to respond to that.

Okay, yes. Hearing none, if that is something that pertains to this proposed rule, you could certainly submit a public comment. Otherwise, Nicole, do we have a place that we could send Ashley to submit her question?

Nicole Cooney: Yes. Let me – let me pause for a minute to find that – you know what, you can actually just send it directly to me, nicole.cooney – C-O-O-N-E-Y – @cms.hhs.gov.

Ashley Price: Okay. Great. Thank you, Nicole.

Operator: And we are showing no further comments…

Operator: No, we're showing no further comments at this time.

Additional Information

Nicole Cooney: Okay. Thank you. Great. Slide 44 lists a number of resources for obtaining more information on to today's topics. An audio recording and transcript of today's session will available in about two weeks at go.cms.gov/npc.

Again, my name is Nicole Cooney. I'd like to thank our presenters and to 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 for participating in today's conference call. You may now disconnect. Presenters, please hold.