Centers for Medicare & Medicaid Services Physicians, Nurses, and Allied Health Professionals Open Door Forum Thursday, July 11, 2024 2:00 – 3:00 p.m. ET

Webinar recording: <u>https://cms.zoomgov.com/rec/share/5a8SMLxqCo3nrHPASkAr9W6Sgm-ufwjAFFXk9vvRvNtlcuruWwkFPDWhIylsODLO.vZ6YBGByEU_fvigU</u>

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Jill Darling: Hi, everyone, and welcome. Thank you for your patience. We are just going to give it another moment to get more folks in the room. All right. Well, thank you, everyone, we'll begin. Good morning and good afternoon, everyone. My name is Jill Darling and I'm in the CMS Office of Communications. Welcome to today's Physicians, Nurses and Allied Health Professionals Open Door Forum (ODF). Before we begin our agenda, I have a few announcements. For those who need closed captioning, a link was provided in the chat function of the webinar, and I will provide it again for you. This webinar is being recorded. The recording and transcript will be available on the CMS Open Door Forum podcast and transcript webpage, and that link was on the agenda, and I will share it in the chat. If you are a member of the press, please refrain from asking questions during the webinar. If you do have any questions, please email press@cms.hhs.gov. All participants are muted upon entry. For today's webinar, you will see the agenda slide and then I will also provide a resource slide during the Q&A (question and answer) portion of the call.

We will be taking questions at the end of the agenda today. We note that we will be presenting and answering questions on the topics listed on the agenda. We ask that any live questions relate to the topics presented during today's call. If you have any questions unrelated to these agenda items, we may not have the appropriate person on the call to answer your question. As such, we ask that you send any of your unrelated questions to the appropriate policy component or you can send your email to the ODF resource mailbox that I will provide, and we will get—try to get your question to the appropriate component for a response. You may use the raise hand at the bottom of your screen, and we will call on you when it's time for Q&A. Please introduce yourself with your organization or business you're calling from. And when the moderator says your name, please unmute yourself on your end to ask your question and one follow-up question. We will do our best to get to all your questions. And now I'll turn the call over to Lindsey Baldwin.

Lindsey Baldwin: Great, thanks so much, Jill. Good afternoon, everyone. I am Lindsey Baldwin. I'm the Director of the Division of Practitioner Services in the Hospital and Ambulatory Policy Group in the Center for Medicare. I'm pleased to report that the calendar year 2025 Physician Fee Schedule (PFS) proposed rule was posted as of yesterday. This proposed rule aims to strengthen primary care, expand access to behavioral health, oral health, and caregiver training services, maintain telehealth flexibilities, and expand access to screening for colorectal cancer and vaccinations for hepatitis B. Before we dive in with an overview of several of the topics in the Physician Fee Schedule proposed rule, first, we just wanted to make everyone aware of a proposal in the ESRD (End-Stage Renal Disease) proposed rule. So for that, I will pass it to Abby Ryan and Nick Brock to talk about the ESRD-based geographic adjustment. Thanks.

Abigail Ryan: Thank you, Lindsey. Good afternoon, everyone. Good morning, for those of you who are on the West Coast. Nick Brock is here to answer questions. I'll give an overview. We also have Russell Bailey online with us today as a subject matter expert to give just a very highlevel overview of things that would be pertinent for the ESRD PPS (Prospective Payment System). On June 27, CMS issued a proposed rule to update payment rates and policies, and it also included Requests for Information (RFI) for the End-Stage Renal Disease Prospective Payment System for renal dialysis services that are furnished to Medicare beneficiaries on or after January 1, 2025. In this rule, and this is a particular note here, CMS is proposing a new ESRD PPS-specific wage index that would be used to adjust only the ESRD PPS payment for geographic differences in area wages. The proposed methodology would combine data from the Bureau of Labor Statistics Occupation Employment Wage and Statistics along with freestanding ESRD facility cost reports to produce an ESRD PPS-specific wage index for use instead of using the hospital wage index for each geographic area, which are derived from the hospital cost report data. The rule can be viewed at the Federal Register and along with any comments that come in. The comments are due by August the 26th, 2024, and we encourage everyone, including everyone on this call, to send in comments with whatever you may want to share with us about this new proposal. Any questions that you have, you can save to the end, but as I said, we will have our subject matter experts on the line. Thank you, and I'll pass this to Michael.

Michael Soracoe: Hello there, everyone. Good to have you here on the call. So I am here to discuss the conversion factor and PFS rate setting in general. So the conversion factor is something there's always a lot of interest in. It is the number by which we translate relative value units, or RVUs, into dollars on the Physician Fee Schedule. There's a number of things that go into how we calculate the Physician Fee Schedule's conversion factor. The first one is whether we have any statutory update factor that Congress has approved. For 2025, the statutory update factor is 0.0%, so that did not factor into this particular conversion factor. We also have a budget neutrality adjustment that's mandated by statute. For any year in which spending would exceed our \$20 million threshold, we have to apply budget neutrality, and that applies pretty much every single year. In this particular year, we have calculated that the budget neutrality adjustment is 0.05%, so one-twentieth of 1%, and that is a positive adjustment to the conversion factor.

Then in addition, we had one other statutory provision this year, which is that for the current year, 2024, there is a one-year 2.93% increase to the conversion factor that is scheduled to go away at the end of 2024. So we had to calculate the conversion factor with the 2.93% going away since it will not be in place for 2025. After we factored in the 0.05% budget neutrality adjustment and the negative 2.93% adjustment from that provision going away, we ended up with a conversion factor decrease. Currently projected to decrease from \$33.29, which is the current conversion factor, down to \$32.36. That is a decrease of \$0.93 or about \$2.80. In past years, Congress has oftentimes provided another one-year bump to the conversion factor. That's happened in the last two years. That is currently not in legislation. It is potentially—could potentially change before the end of the year, but as I said, for right now, we've calculated it with that 2.93% going away and not being replaced.

But one other thing that I've listed on here is a mention of the clinical labor pricing phase-in, so I will mention that this is our fourth and final year of our clinical labor pricing update. After this

year, we will be complete—we will be completed with the four-year transition that's been going on. We did not propose any changes to clinical labor pricing in the proposed rule, as this is the fourth and final year. Most of the changes that we are making are kind of already in place. That said, if there are interested parties that have information about clinical labor pricing, they are welcome to include that in their public comments, and we will take a look when the comment period closes. With that said, I will now turn it over to Lindsey Baldwin to cover behavioral health payment policy.

Lindsey Baldwin: Great, thanks so much, Michael. So under behavioral health in this proposed rule, we are proposing to establish separate coding and payment describing safety planning interventions for patients in crisis, including those with suicidal ideation or at risk of suicide or overdose. Additionally, we are proposing to create a monthly billing code that requires specific protocols and furnishing post-discharge follow-up contacts that are performed in conjunction with a discharge from the emergency department for a crisis encounter as a bundled service. Also, to further support access to psychotherapy, we are proposing payment for digital mental health treatment devices furnished incident to or integral to professional behavioral health services used in conjunction with ongoing behavioral health treatment under a plan of care.

We are proposing to create three new HCPCS (Healthcare Common Procedure Coding System) G-codes for these services, and we discuss in the rule that we intend to monitor how digital mental health treatment devices are used as part of overall behavioral healthcare in the ongoing and evolving landscape. We are also proposing to create six G-codes to be billed by practitioners and specialties whose covered services are limited by statute to the diagnosis and treatment of mental illness, including clinical psychologists, clinical social workers, marriage and family therapists, and mental health counselors to mirror current interprofessional consultation CPT (Current Procedural Terminology) codes that are used now by practitioners who are eligible to bill for evaluation and management visits. And with that, I will pass it off to Emily Yoder to cover telehealth.

Emily Yoder: Thanks so much, Lindsey. So we are proposing to add several services to the Medicare telehealth list on a provisional basis, including codes describing the demonstration prior to initiation of home INR (International Normalized Ratio) monitoring and codes describing caregiver training services. We are also proposing to continue the suspension of frequency limitations for E/M (Evaluation and Management) visits in certain settings. We are proposing that beginning January 1, 2025, the definition of "interactive telecommunication system" may include two-way, real-time, audio-only communication technology for any telehealth service furnished—furnished—to a beneficiary in their home if the distant site physician or practitioner is technically capable to use two-way audio/video communication technology, but the patient is not capable of or does not consent to use this video technology. We are proposing that we will continue to permit the distant site practitioner to use their currently enrolled practice location instead of their home address when providing telehealth services from their home. We are also proposing for a certain subset of services that are required to be furnished under the direct supervision of the physician or other supervising practitioner to permanently adopt a definition of "direct supervision" that allows the physician or supervising

practitioner to provide such supervision through real-time audio/video interactive telecommunication. For all other services furnished under the direct supervision of a physician or other practitioner, we are proposing to continue to define "immediate availability" to include real-time audio and video technology through December 31, 2025. We are also proposing to continue our current policy to allow teaching physicians to have a virtual presence for purposes of billing for services furnished, involving residents in all teaching settings. With that, I'll turn it over to Pam West for therapy.

Pam West: Thank you, Emily. The first therapy issue regards supervision policy for physical therapists (PT) and occupational therapists (OT) in private practice. For calendar year 2025, we are proposing regulatory changes to allow for general supervision of therapy assistance by the supervising PT or OT in private practice for all applicable physical and occupational therapy services. This proposed change will give PT and OT private practitioners more flexibility in meeting the needs of beneficiaries and safeguard patient access to medically necessary therapy services. The second therapy issue relates to the certification of therapy plans of treatment with an order from a physician or non-physician practitioner. As a point of reference, the non-physician practitioners that can order therapy services as well as certify or re-certify treatment plans include physician assistants, nurse practitioners, and clinical nurse specialists.

For calendar year 2025, CMS is proposing amendments to the certification regulations to lessen the administrative burden for therapists as well as physicians and non-physician practitioners. If finalized, these changes would provide an exception to the physician or non-physician practitioner's signature requirement on the therapist established treatment plan for purposes of the initial certification in cases where a written order or referral from the patient's physician or nonphysician practitioner is on file and the therapist has documented evidence that the treatment plan was transmitted to the physician or non-physician practitioner within 30 days of the—of the—initial evaluation.

CMS is also soliciting comments on two issues as suggested by interested parties as to the need for a regulation. First, by addressing the amount of time during which the physician or non-physician practitioner who has written an order for the therapy services could make changes to the therapist-established treatment plan by contacting the therapist directly after the receipt of the plan from the therapist. And second, to determine whether there should be a 90-day or other limit to the physician or non-physician practitioner order extending from the date of the order of the first—date of the order to the first date of treatment, including the evaluation by the therapist. That completes the therapy issues. And now, I'll hand off to my colleague, Zehra Hussain.

Zehra Hussain: Hi, good afternoon. My name is Zehra Hussain, and I'll give a brief overview of our proposals for dental and oral health services. We are proposing to amend our regulations to add to the list of clinical scenarios under which fee-for-service Medicare payment may be made for dental services inextricably linked to cover services to include: one, dental or oral examination in the inpatient or outpatient setting prior to Medicare covered dialysis services for beneficiaries with end-stage renal disease, and two, medically necessary diagnostic and treatment services to eliminate an oral or dental infection prior to or contemporaneously with Medicare covered dialysis services for beneficiaries with end-stage renal disease. CMS is also proposing

two policies related to billing of dental services inextricably linked to covered services including: one, proposing to require the submission of a KX modifier on claims for dental services that clinicians believe to be inextricably linked to covered medical services beginning in CY 2025, and two, proposing to require the submission of a diagnosis code on the 837D dental claims format beginning January 1, 2025. CMS is also soliciting comment on the potential connection between dental services and covered services used in the treatment of diabetes, and covered services for individuals with autoimmune diseases receiving immunosuppressive therapies as well as requesting any additional evidence regarding covered services for sickle cell disease and hemophilia. Lastly, CMS is including a Request for Information regarding services associated with furnishing oral appliances used for the treatment of obstructive sleep apnea. Thank you. And with that, I will hand it over to my colleague, Sarah.

Sarah Leipnik: Thanks, Zehra. Good afternoon, and good morning. My name is Sarah Leipnik, and I'm going to discuss the policies regarding strategies for improving global surgery payment and accuracy. For 2025, we are—for calendar year 2025, we are proposing to broaden the applicability of the transfer of care modifiers for global packages and require the use of the existing modifiers, modifiers 54, 55, and 56, for all 90-day global surgical packages in any case when a practitioner or another practitioner from the same group practice expects to furnish only the pre-operative portion, the procedure itself, or the post-operative portions of a global package, including but not limited to when there's a formal documented transfer of care as under current policy or an informal, non-documented but expected transfer of care.

We are proposing for practitioners to report the transfer of care modifiers in all transfer of care scenarios, which will provide CMS with more accurate information on the resources involved in furnishing components of global surgical packages. This proposal will inform CMS about how global package services are typically furnished and will help CMS to make more accurate Medicare payments. For calendar year 2025, we are also proposing a new add-on code, a G-code, GPOC1, for post-operative care services to more appropriately reflect the time and resources involved in these post-operative visits to compensate the additional resources involved by practitioners who are not involved in furnishing the surgical procedure. I'm now going to turn it over to Eric Carrera to discuss the inherent complexity add-on code. Eric?

Eric Carrera: Thank you, Sarah. Hello, everyone. We are proposing to allow payment of the office/outpatient evaluation and management visit complexity add-on code HCPCS G2211 when the office/outpatient E/M based code, which is CPT99202 through 99205 and 99211 through 99215, are reported by the same practitioner on the same day as an annual wellness visit, vaccine administration, or any Medicare Part B preventive service furnished in the office or outpatient E/M visit complexity add-on code G2211. We also finalized that the complexity add-on code would not be payable when it was reported with CPT modifier 25, denoting a significant separately identifiable office/outpatient E/M visit by the same physician or other qualified health care professional on the same day as a procedure or other visit. In response to concerns interested parties have communicated to us, we make this proposed refinement to our current policy beginning in calendar year 2025, and we welcome comments on this proposal through the

comment period. Thanks very much. Passing it on to Mikayla Murphy, who will discuss updates to caregiver training services. Thank you.

Mikayla Murphy: Thanks, Eric. Good afternoon, everyone. For calendar year 2025, we are proposing to establish new coding and payment for caregiver training for direct care services and support. The topics of trainings could include, but would not be limited to, techniques to prevent decubitus ulcer formation, wound dressing changes, infection control, special diet preparation, and medication administration. We are also proposing to establish new coding and payment for caregiver behavior management and modification training that could be furnished to the caregiver or caregivers of an individual patient. We are also proposing to allow caregiver training services to be furnished via telehealth. Thank you. And I'm turning over to my colleague, Sarah, to discuss APCM (Advanced Primary Care Management Services).

Sarah Irie: Thanks, Mikayla. Hi, my name Sarah Irie, and I'm with the Division of Practitioner Services. Today, I'll cover Medicare CY 2025 PFS proposed rule policies that aim to strengthen primary care while driving quality improvement and innovation. We recognize that a strong foundational primary care system is fundamental, and a person-centered approach to health care starts with a trusting relationship with the primary care team. Over the last decade, value-based primary care models tested by the CMS Innovation Center have demonstrated that comprehensive primary care can lead to reductions in ED (emergency department) and hospital visits while better meeting patients' needs. We are proposing to use these lessons to establish coding and make payments under the PFS for a newly defined set of advanced primary care delivery model.

As an important first step in a multi-year effort, we are proposing three new G-codes to recognize the resources involved with furnishing ongoing person-centered care management when provided by primary care teams under this advanced primary care delivery model. We are taking lessons from a series of Innovation Center advanced primary care models, such as CPC+ (Comprehensive Primary Care Plus) and PCF (Primary Care First) to inform proposed service elements of APCM, incorporating elements of several existing care management and communication technology-based services to really reflect those essential elements of the delivery of advanced primary care. These include Principal Care Management, Transitional Care Management, as well as complex and non-complex Chronic Care Management.

The proposed codes are intended to be reported monthly, simplifying the billing and documentation requirements that are currently associated with existing codes. We also are proposing to include adjustments for patient medical and social complexity to promote health equity. The proposed APCM codes are stratified by three levels based on the patient's number of chronic conditions and enrollment as a Qualified Medicare Beneficiary. Beginning January 1, 2025, physicians and non-physician practitioners who use an advanced primary care model could bill for APCM services when they are the continuing focal point for all needed of health care services, and they're responsible for the patient's primary care services. We are also proposing a performance measurement requirement which can be satisfied by reporting the Value in Primary Care MIPS (Merit-Based Incentive Payment System) Value Pathway (MVP). This MVP was

developed to include quality measures which reflect clinical actions that should be considered the foundation of primary care and holds practitioners accountable for the total cost and quality of the care they provide. In this way, APCM services would be tied to primary care quality measures to improve health outcomes for people with Medicare.

Finally, we are taking comments from interested parties through an advanced primary care hybrid payment RFI and potential payment policies to build upon the proposed APCM services by further recognizing and supporting the development of advanced primary care and the move towards paying for primary care services with hybrid payments to support longitudinal patient/provider relationships and drive accountable care. I'll turn it back over to my colleague, Mikayla.

Mikayla Murphy: Thanks, Sarah. The CMS Innovation Center tested the Million Hearts Models, which coupled payment for cardiovascular risk assessment with cardiovascular care management and was found to reduce the rate of death by lowering heart attacks and stroke amongst Medicare fee-for-service beneficiaries. In order to incorporate these lessons learned and increase access to these lifesaving interventions, beginning in CY 2025, we are proposing coding and payment for Atherosclerotic Cardiovascular Disease, or ASCVD, risk assessment and risk management services. The standardized, evidence-based risk assessment tool used would include demographic data, modifiable risk factors, possible risk enhancers and laboratory data. The output for this tool must include a 10-year estimate of the patient's ASCVD risk. We are proposing coding and payment for this annual ASCVD risk assessment service that may be performed in conjunction with an E/M visit when a practitioner identifies patients at risk for, but do not currently have a diagnosis of, cardiovascular disease. We are also proposing coding and payment for ASCVD risk management services that include service elements related to the ABCs of CVD risk reduction, which includes aspirin, blood pressure management, cholesterol management, and smoking cessation. And this would be for beneficiaries at medium or high risk for cardiovascular disease, which we are defining as greater than a 15% risk in the next 10 years.

In addition, for CY 2025, we are issuing a broad Request for Information on the newly implemented Community Health Integration (CHI) services, Principal Illness Navigation (PIN) services, Principal Illness Navigation peer support services, and the Social Determinants of Health (SDOH) Risk Assessment to engage interested parties on additional policy refinements for CMS to consider in future rulemaking. We are requesting information on other factors for us to consider such as other types of auxiliary personnel, including clinical social workers and other certification or training requirements that are not adequately captured in current coding and payments for these services. We are also seeking comments on how to improve utilization in rural areas and how these codes are being furnished in conjunction with community-based organizations. Thank you, and I'm turning it over to my colleague, Rachel.

Rachel Radzyner: Thank you very much, Mikayla. This is Rachel Radzyner, and I'm going to speak about the Medicare Part B payment for preventive services in this year's rule. For CY 2025, we are addressing two items related to Part B coverage and payment of hepatitis B vaccine and its administration. In this proposed rule, we proposed to expand coverage of hepatitis B vaccinations and more on that possibly at another time in this call. If the proposed coverage

expansion of hepatitis B vaccine under Part B is finalized, we clarify here that a physician's order would no longer be required for the administration of a hepatitis B vaccine in Part B, which would facilitate roster billing by mass immunizers for hepatitis B vaccine administration. We also propose that payment for hepatitis B vaccines and their administration be made at 100% of reasonable costs in RHCs (Rural Health Clinics) and FQHCs (Federally Qualified Health Centers) in order to streamline payment for all Part B vaccines in those settings.

In addition, in this year's rule, we are proposing a fee schedule for Drugs Covered as Additional Preventive Services, or DCAPS drugs for short. CMS has not yet covered or paid for any drugs under the benefit category of additional preventive services. And on July 12, 2023, CMS released a proposed NCD (national coverage determination) regarding coverage for HIV (Human Immunodeficiency Virus) PrEP (Pre-Exposure Prophylaxis) drugs under Part B as additional preventive services. We propose to determine a payment limit for DCAPS drugs according to the ASP (Average Sales Price) methodology set forth in section 1847A of the act when ASP data is available for those drugs. We propose alternative payment mechanisms for calculating payment limits for DCAPS drugs if ASP data is not available. We also propose payment limits for the supplying and administration of DCAPS drugs. Finally, we propose to use this same fee schedule for DCAPS drugs and any administration and supplying fee when those services are provided in RHCs and FQHCs. In RHCs and FQHCs, DCAPS drugs and any administration and supplying fee when those services are provided in RHCs and FQHCs. In RHCs and FQHCs, DCAPS drugs and any administration and supplying fee when those services are provided in RHCs and FQHCs. In RHCs and FQHCs, DCAPS drugs and any administration and supplying fee when those services are provided in RHCs and FQHCs. In RHCs and FQHCs, DCAPS drugs and any administration and supplying fee when those services are provided in RHCs and FQHCs. In RHCs and FQHCs, DCAPS drugs and any administration and supplying fee when those services are provided in RHCs and FQHCs. In RHCs and FQHCs, DCAPS drugs and any administration and supplying fee would be paid on a claim-by-claim basis. And now, I'm going to turn it to my colleague, Adam Brooks.

Adam Brooks: Thanks, Rachel. Starting with the topics for drugs separately payable under Part B, CMS is proposing an approach for calculating payment limits when manufacturers report negative or zero average sales price data to CMS. Being situations when either an NDC (National Drug Code) has a negative or \$0 value for the manufacturer's ASP or a positive dollar value for the manufacturer's ASP with a negative or zero number of units sold. Generally, we are proposing that negative and zero ASP data be considered not available under section 1847A of the act and that positive ASP data be considered available. We are proposing calculations for several possible scenarios. And now, on to my colleague Jae, who will cover discarded drug payment policy.

Jae Ryu: [no audio] ... for proposal in the 2024 rule, we finalized that DME (Durable Medical Equipment) suppliers who furnish but do not administer Part B drugs would use the JZ modifier for billing. The clarification we are proposing is to require the JW modifier for any discarded amount during drug preparation by DME suppliers prior to dispensing. We are reiterating that DME suppliers who are only dispensing and not administering are not responsible for monitoring discarded amounts that occurs after the drug is applied to the patient. Now, I'll hand over to Becky to discuss clotting factors and radiopharmaceuticals.

Rebecca Ray: Thanks, Jae. This provision under Part B drugs is for payment for radiopharmaceuticals in the physician office. In order to alleviate confusion from MACs (Medicare Administrative Contractors) and other interested parties about which exact methodologies are available to MACs for pricing of radiopharmaceuticals in the physician office

setting, CMS is proposing to clarify that for radiopharmaceuticals furnished in a setting other than a hospital outpatient department, MACs shall determine payment limits for radiopharmaceuticals based on any methodology used to determine payment limits for radiopharmaceuticals in place on or prior to November 2003. Such methodology may include, but is not limited to, the use of invoice-based pricing.

And the last provision under Part B drugs is for blood clotting factors. Clotting factor furnishing fees are paid when self-infused products are furnished to beneficiaries. In contrast, when clotting factors—clotting factors—are administered in health care settings, administration fees are paid reflecting the resources involved in administering the product. We want to ensure that double payment of administration fees does not occur, as we do not believe this is what Congress intended in directed—directing CMS to establish clotting factor furnishing fee. Accordingly, we proposed to update regular—regulatory text to clarify that existing CMS policy that blood clotting factors must be self-administered to be considered clotting factors for which the furnishing fee applies. And with that, I'll it over to Elizabeth November to discuss the Medicare Shared Savings Program (MSSP).

Elizabeth November: Thank you, Becky. The proposed changes to the Medicare Shared Savings Program are expected to drive growth and participation, particularly in rural and underserved areas, promote equity and advance alignment across accountable care initiatives and are central to achieving CMS' goal of having 100% of people with traditional Medicare and a relationship with accountability for quality and total cost of care by 2030. We are proposing to establish a new, prepaid shared savings option to encourage eligible Accountable Care Organizations, or ACOs, with a history of earning shared savings to invest in direct beneficiary services and staffing or health care infrastructure to improve care coordination and aid beneficiaries. We are also proposing modifications to the Shared Savings Program's financial methodology that would ensure that benchmarking methodology includes sufficient incentive for ACOs serving underserved communities to enter and remain in the program, to the application of a proposed health equity benchmark adjustment. Additionally, we proposed several policies to align Shared Savings Program quality measure reporting with the universal foundation of quality measures and promote digital quality measure reporting.

To improve the accuracy, fairness, and integrity of Shared Savings Program financial calculations, we are proposing a methodology to account for the impact of improper payments in recalculating performance year and benchmark expenditures used in financial reconciliation upon reopening a payment determination along with the methodology for excluding payment amounts for HCPCS and CPT codes exhibiting significant anomalous and highly suspect billing activity during calendar year 2024 or subsequent calendar years that warrant adjustments. These proposals complement proposals in a separately issued proposed rule that seeks to address significant anomalous and highly suspect billing activity associated with selected intermittent catheter supplies in calendar year 2023. We are also proposing changes to update the beneficiary assignment methodology to reflect new primary care codes, allow existing ACOs whose number of assigned beneficiaries falls below 5,000 during their agreement period more time to increase their numbers, ensure clarity of provisions on application procedures, refine advanced

investment payment requirements, and improve beneficiary notification requirements. Thank you. And with that, I'll pass it back to Jill.

Jill Darling: Great. Thank you, everyone. We will be going into our Q&A. If any of the links you see on the screen right now, please let us know. We can put them in the chat for you. We'll just wait a moment till we see some hands. Remember, please ask one question and one follow-up question. So we have room for more folks. So we'll just give it one moment.

Jackie (Moderator): OK. The first hand I see is Erin. Erin, you're able to unmute yourself.

Erin Solis: Hi, this is Erin Solis with the American Academy of Family Physicians. I was just wondering if you could clarify the impact of the audio-only proposal in the telehealth section, especially if the originating site is—reverts to—is back in place except for mental health treatment, diagnosis of mental health conditions.

Sarah Irie: Yeah, sure, I can take that one. So you're right. The way that we have sort of worded this provision is that the audio-only flexibility is tied to the beneficiary's home being an eligible originating site for purposes of Medicare telehealth. When we sort of implemented this policy for mental health services a couple years back, our rationale was that beneficiaries would be much more likely to have access to things like reliable broadband and staff that can assist them using two-way audio/video in a medical facility and that they were more likely to have issues with both of those things if they were in their own homes. And so it made sense at that time, given that Congress had made the home an eligible originating site for mental health services, that we allow audio-only to be the available technological modality in those cases. When we were thinking about it, we felt that the rationale was the same for all telehealth services when the beneficiaries in their home, right? That they might have the issues with broadband and not being able to use two-way audio/video. And so we thought that it would be appropriate that as long as the home is an eligible originating site, that the beneficiary would be able to also use audio-only communication technology. And so what that means is that if the home is no longer an originating site, then once again, if the telehealth service would need to be furnished to a twoway audio/video and that is set to sort of the statutory waivers that are allowing a home to be an originating site for non-mental behavioral health services. Currently, those are set to expire at the end of the year.

Erin Solis: OK. Thank you.

Jackie: All right, Valerie, your hand is raised. You're able to unmute yourself.

Valerie Rinkle: Thank you. I have a question. It is on page 139 of the proposed rule and there are a few new AMA (American Medical Association) CPT codes, Category I CPT codes proposed for CAR-T (Chimeric Antigen Receptor T-cell) therapy services and CMS specifically says they're seeking comment on getting direct practice expense values. And so, my question is if CMS gets analog information, so commenters supply analog codes that already have direct P/E values defined by CMS, would CMS consider or be able to adopt in the final rule those practice expense values and update those codes?

Gift Tee: Valerie, this is Gift Tee. I think we consider all the comments that were submitted on the topic and—and—move forward one way or the other.

Valerie Rinkle: OK. So a follow-up would be if you do value direct practice expense, for example, for the—the—cell collection code, which is currently 3X018, does that mean that CMS recognizes separate payment for those services that would be incurred in the non-facility setting, meaning like the doctor's office, for example?

Gift Tee: There are a lot of questions packed into your question. Why don't you go ahead and submit that one to our mailbox, and we'll think about it a little bit more carefully?

Valerie Rinkle: OK.

Gift Tee: Thank you.

Jackie: All right, Tricia, your hand is raised. You're able to unmute yourself.

Tricia Carroll: Yes, hi. I am asking on behalf of Dr. Piyush Sheth. He said that per the Federal Register, colonoscopies performed for positive stool-based CRC (colorectal cancer) tests are to be considered screening colonoscopies for payment purposes. The Federal Register further states that under current policy, a positive result from the CRC screening stool-based test would be a sign of illness or disease. This has created some confusion and this question is whether or not an evaluation and management visit for a positive stool-based colorectal cancer screening test, though the subsequent colonoscopy is to be considered a screening colonoscopy, can an E/M visit for a positive stool-based CRC screening test to be billed for medical necessity since it is considered sign of illness or disease?

Gift Tee: Thanks for that question. We received something similar, so we've been thinking about it behind the scenes with other colleagues and we'll follow up as soon as we have a more definitive answer.

Tricia Carroll: OK, thank you.

Jackie: All right. Karen, your hand is raised. You're able to unmute yourself. Karen, I think it's Pete? You're able to unmute yourself.

Karen Pettit: Can you hear me?

Jackie: Oh, there you are.

Karen Pettit: Hello. Sorry. Sorry about that. Yes, my name is Karen Pettit. I'm calling from Texas Health Resources. I have a question related to telehealth services. The allowance of the patient's home as an acceptable originating site for telehealth services is set to end on 12/31/2024, and I was just wondering what the plan is for after that for 2025. Will the exception

be made permanent, or will we be looking at another extension? And really just curious as to what the considerations after that.

Sarah Irie: Hi, Karen. I think that that is a fantastic question. It's one that, you know, we ourselves are asking because the flexibility around the originating site is something that is specified in statute and so that would need additional legislation from Congress in order to extend that flexibility or make it permanent. The past few years since the end of the pandemic, there have been year-long extensions in the various Consolidated Appropriations Acts (CAAs). However, the most recent CAA did not include an extension on the originating site waivers. And so without the intervention of Congress, that will, once again, beginning January 1, 2025, the beneficiary will need to be in a rural area and a medical facility in order to receive non-behavioral health telehealth services.

Karen Pettit: OK, thank you.

Jackie: All right. It looks like Meghann, your hand is raised. You're able to unmute

Meghann Dugan-Haas: Thank you so much. My name is Meghan Duggan-Haas. I'm with the American Psychological Association. I just wanted to first thank the agency for all of the positive behavioral health policies that are being proposed. But I did have a quick question about an issue that was raised in the 2024 rulemaking cycle. CMS had raised that practice expense adjustments and alternative methodologies for behavioral health services, and they were requesting comment on whether to consider further modifications. However, we didn't see any follow up in the 2025 proposed rule. So we were just wondering if the agency plans to revisit this issue during this rulemaking cycle.

Lindsey Baldwin: Hi, Meghann. Thanks. I can cover this one. So in the CY 2024 PFS final rule, we ended up finalizing an adjustment to the payment rates for behavioral health services based on the work RVUs. It was a 19.1% increase phased in over four years. And so that was all finalized for last year. So this year we are seeing the second portion of that four-year update to those rates. So the rates are being increased for standalone behavioral health services, psychotherapy, and a few other codes as well. But we ended up going the route of the increase via the work RVUs, but always interested to hear more if folks have other thoughts on how we might continue to consider paying more accurately for these services.

Meghann Dugan-Haas: Great. Thank you.

Jackie: All right. Amanda, you are able to unmute yourself.

Amanda George: Hi, thank you so much. I have a question around the 90-day global surgery. So currently, modifier 54 we're using for the pre-op and intra-op portion and then 55 for the post-op. It looks like with the proposed rule, we're introducing 56 for pre-op only. I'm just wondering if we will see some guidelines where you could potentially still have the 54/55 split but also times with the 54, 55, 56 or if it's going to be only one, like, always just the three moving forward.

Sarah Leipnik: Hi, thanks for your question. So I think we are expecting that any—whichever modifier is appropriate would be appended to the claim. So I'm not sure what you mean by, like, every three going forward.

Amanda George: Oh, sorry. Like a pre-op, intra-op, post-op split, where right now 54 would really take care of the pre-op and intra-op.

Sarah Leipnik: Right. Do you mind sending your question to our mailbox? I can give it to you.

Amanda George: Yeah. Thank you so much.

Sarah Leipnik: It's medicarephysicianfeeschedule@cms.hhs.gov.

Amanda George: OK, thank you.

Sarah Leipnik: Thank you so much.

Jackie: All right, the next hand I see is Suzanne. Suzanne, you're able to unmute.

Suzanne Joy: Hi, can you all hear me OK?

Jackie: Yes.

Suzanne Joy: OK, perfect. Thank you. My name is Suzanne Joy. I'm with the American Medical Association. I appreciate you all hosting the call. I just wanted to clarify because it's kind of hard to prove a negative. Last year, there were some proposals related to the Medicare Shared Savings Program and Advanced APMs (Alternative Payment Models) more generally. The first being requiring all MSSP ACOs to report promoting interoperability data from the MIPS program, and then also related on the Advanced APM side, so including ACOs but also beyond them to other APMs that you were raising the threshold from 75% of all participants to 100%. And I was just wondering, I didn't see anything so far. I mean, it's a long rule but I hadn't seen any details on that, and we've been—I know, corresponding with the MSSP team since the final rule last year. So I just wanted to see if there were any updates on that since we are still awaiting some details on some of the APM-specific criteria, for example, and some exclusion criteria. So just was kind of wanting to check in on that.

Tim Jackson: Hi, Suzanne. This is Tim Jackson from the Shared Savings Program. We don't have the APM folks on the call with us, but we'll take your notes and circle back with them and—and—get a response to you. Thanks for—thanks for—your—your question and your comment.

Suzanne Joy: OK. Thank you.

Jackie: All right. And it looks like Kimberly Johnson, you're able to unmute yourself.

Kimberly Johnson: Hi, thank you very much. I have a question concerning G2211. Our MAC had told us that CMS will be publishing a Q&A to go along with that code. Do you know what that will happen?

Gift Tee: Yeah, hi. We are actively—I know you all have heard me say this a number of times, but there truly is no rest for the weary. So now that the rule is out, we are going to turn our attention to a lot of things that we put down and will actively prioritize putting those FAQs (Frequently Asked Questions) out. We have been in conversation with a number of MACs just trying to understand some of their perspective on how to implement the policy and we've been taking that into account in addition to a lot of feedback we've heard from interested parties, practitioners, and others. So thank you for the question and we are working—we are working—on those FAQs.

Kimberly Johnson: Thank you.

Jackie: All right, Barbara, you are able to unmute yourself.

Barbara Sorenson: So I'm calling with University of Iowa Hospitals and Clinics, and I needed some clarification. I heard it mentioned that there was a proposal about using a different address than the home address. Was that in regards to the telehealth providers that we currently have to enroll at their home address as a location?

Sarah Irie: Yes. This is just continuing the pandemic era flexibility that allowed practitioners who are practicing from their homes to, rather than using their—reporting their—enrolling their home address, they could use the address of the, you know, clinic or, you know, wherever where they would be practicing if they were providing services in person. So that's what that is.

Barbara Sorenson: And does that also apply if the provider is working at home in a different state? We've been told that when we have teleradiologists in different states, that we have to currently enroll our group in that state and then enroll the provider in that state under their home address.

Sarah Irie: Gotcha. Can you send that to the mailbox, please?

Barbara Sorenson: Sure.

Sarah Irie: That might take a little bit of additional work. Thank you so much.

Barbara Sorenson: Thank you.

Jackie: All right. Ronald, you are able to unmute yourself.

Ronald Hirsch: Hi there. First of all, hello, Jill. In regards to G2211, the last comment, I would urge you not to ask the MACs what they're doing, but instead tell them what they should be

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doing. As some people may have heard recently, Meridian put out a notice about the use of the observation hospital services codes. Those codes were eliminated over a year and a half ago, but they're now putting out notices about it. So none of us really trust the MACs to understand the rules properly, but we would hope that you would tell them what they should do. Thank you.

Gift Tee Dr. Hirsch, I appreciate the comments and understood. We are working through implementation with our partners, so we will—we will—we will—work to do better.

Ronald Hirsch: Thank you.

Jackie: All right. Carol, it looks like your hand is raised. You're able to unmute.

Carol Yarbrough: Yeah. Thank you. Carol Yarbrough. Pleased to follow Dr. Hirsch on this question and answer session. I did notice the lack of PTOTSLP (Physical Therapy, Occupational Therapy, Speech Language Pathology) references for facility billing in order to see patients still, even in a, like, say the pre-PHE (Public Health Emergency) waivers are all gone, Congress doesn't act, patients are in rural areas and non-urban, dah, dah dah, would it be possible still then for the facility providers to see patients in those areas, even if home is not an originating site, or is that a moot point since they're not specifically telehealth providers?

Sarah Irie: Hi, Carol.

Carol Yarbrough: Hi.

Sarah Irie: It's great to hear from you. So I would point you to some discussion in the CY 2025 hospital Outpatient Prospective Payment System where we outline our sort of general approach to aligning the policies for hospital employed practitioners with the policies—with the policies—that sort of govern and regulate those practitioners when they're furnishing services in private practice. Put another way, we say that we sort of were proposing that to the extent to which changes are made to the Medicare telehealth statute that govern, as I said, these practitioners in private practice, that that would sort of—that our intention is to align the policies as well when those same practitioners are employed by the hospital and the hospital is billing for their services.

Carol Yarborough: Understood. All right, thank you.

Sarah Irie: Thank you.

Jill Darling: All right everyone, that will conclude today's call. We appreciate all your questions. If you were unable to get a question in, then please email the <u>medicarephysicianfeeschedule@cms.hhs.gov</u> mailbox, and I'll pass it over to Gift Tee for closing remarks.

Gift Tee: Thanks, Jill. I'll just echo what she just said. Thank you for your questions, everyone, and thank you to our experts that covered a lot of the content in the Physician Fee Schedule rule.

There's a lot packed in there, so encourage everyone to read. We certainly encourage you to provide comments during the 60-day comment period, which then is September 9, I'll put in a personal plug, please get your comments in to us sooner rather than later. The team certainly appreciates it and well, there you go. There's your summer reading and there are other rules that are out there as well, too, so I'm sure you're reading them. But thank you for your attention today, and take care.