Centers for Medicare & Medicaid Services

Open Door Forum: Physicians, Nurses and Allied Health Professionals

Moderator: Jill Darling

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2:00 pm ET

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode until the question and answer session of today's conference. At that time you may press star 1 on your phone to ask a question.

I would like to inform all parties that today's conference is being recorded. If you have any objections, you may disconnect. I will now turn today's call over to Jill Darling. Thank you. You may begin.

Jill Darling: Great. Thank you, Denise. Good morning and good afternoon, everyone. Welcome to today's Physicians, Nurses and Allied Health Professionals Open Door Forum. We have a pretty lengthy agenda today, so I will be really quick with my announcement and then we'll get started and pass it to our chairs.

This Open Door Forum is open to everyone. But if you are a member of the press, you may listen in, but please refrain from asking questions during the Q&A portion of the call. If you do have any inquiries, please contact CMS, at press@cms.hhs.gov. And I'll hand the call off to Gene Freund.

Gene Freund: Hi. This is Gene Freund and on behalf of my chair, Mr. Gift Tee, I want to welcome you to this Physicians, Nurses and Allied Health Open Door Forum.

The other thing I get to do since I'm not the person who put the blood, sweat and tears into getting all of these rules together is offer kudos to Mr. Gift Tee and his team for the amazing amount of work that went into getting this through - I guess it's more a gate than the finish line because it's a proposed rule.

And I just want to thank him on behalf of the beneficiaries and providers for all the work that he and his team have done getting this proposed rule out.

And I want to emphasize to everybody that public comments are critical. And so, you know, if you have comments and think there are changes, think there are things that are great, we really need to see those and you can follow the instructions in the rule to make those comments.

So that's my only other announcement, and I'll turn it over to Mr. Gift Tee without further ado.

Gift Tee: Thanks, Dr. Freund. Way too kind. I mostly just try to stay out of people's way and others really get the work done across the agency. So thank you for that.

Good morning. Good afternoon, everyone. Thank you for joining this open door forum and I hope you've had a moment to absorb some of what we included in the CY 2023 proposed rule that we released last Thursday.

As you all know, this proposal updates payment policies, payment rates and other provisions for services furnished under the Medicare physician fee

schedule and other Part B services for dates on or after January 1, 2023. As Dr. Freund pointed out, comments are very important to this process, this rulemaking process. So please submit your comments as soon as possible. We certainly look forward to hearing from you and reading the information that you include in your comments.

As a reminder, the comment period for this rule closes September 6, 2022 so please, please, please pay attention to that date. And with that, I'll turn the call over to my colleagues who will cover our proposals on several topics discussed in the rule. And Michael Soracoe, I believe you're up first.

Michael Soracoe: All right. Thank you, Gift. And thanks all you for joining us on the call today. So I'm going to start by talking about PFS rate setting and conversion factor. And then I have a few words to say as well about the second year of the clinical labor pricing update before I turn it over to my colleagues.

Starting with PFS rate setting. So in this proposed rule, we're proposing a series of standard technical proposals involving practice expense, including the implementation of the second year of the clinical labor pricing update, which I'll have more to say on in a minute, along with (inaudible) to develop a more consistent approach to bring more expected results, reduce burden or results in efficiencies of time, expense or maintenance to update the PFS practice expense data in the hopes of promoting transparency and more predictability in payments.

First, statutory requirements, we're also updating the data that we use to develop the geographic practice cost indices, or GPCIs, and also the malpractice RVUs.

All right. Now with regard to the conversion factor, I'm sure that there is much interest on those listing in about the PFS conversion factor that we're proposing for 2023. As a quick reminder, this is the way that we convert RVUs, the relative value units used on the physician fee schedule into dollars.

So there are a couple things that always go into the conversion factor. We have statutory provisions that are associated with this. One thing that we always have to include is a budget neutrality adjustment. Again, this is required by statute.

In other words if there are more total RVUs in the upcoming year as opposed to the current year, then we have to have a negative adjustment to the conversion factor to balance that budget neutrality adjustment. If there are fewer RVUs, then we will have a positive budget neutrality adjustment.

For 2023 we have a rather sizeable increase in the number of RVUs. This is largely due to the re-valuation of some of the other E/M services, which is one of the main things that we discussed in the rule. So we have a larger than normal budget neutrally adjustment.

We have a budget (unintelligible) which is one of the things that's causing the number on the proposed conversion factor to decrease.

The other big thing that's affecting the conversion factor is there is a statutory provision that's affecting the conversion factor. Currently for calendar year 2022, the year we're in right now, there was a one year increase to the conversion factor of 3%, which was passed into law last year in December. That is currently slated to end at the end of 2022.

So we calculate the budget - we calculate the conversion factor with that 3% going away because it is slated to expire at the end of this year. So after factoring in that budget neutrality adjustment and the fact that that 3% increase is going away at the end of 2022, we end up with a proposed conversion factor of $33.08, which is a decrease of $1.53 cents from the current 2022 conversion factor of $34.61.

So it is a rather sizable decrease, but this is again due to the budget neutrality adjustment, which is required by law, and also the expiration of that 3%, which is also a statutory provision, which is required.

All right. Shifting topics here, the other thing that I have to discuss briefly is the clinical labor rate update for year two. So we are in the second year of our clinical labor pricing update. This was a policy that we proposed and then finalized in last year's 2022 PFS final rule.

We finalized the policy that we would transition to updated clinical labor pricing over four years. So last year was the first year and then 2023 will be the second year. So we are in the second year of that four year transition.

For 2023 in year two of the pricing update, we're proposing modest updates to the price of a couple clinical labor types due to data that was submitted by some interested parties. And there are details about that in the rule.

We also want to note that this is an open comment period on the clinical labor pricing update. So we are interested in any additional information that might be helpful to us as we are updating clinical labor pricing.

So if there are people listening in on this call who think that what our proposals have may not be entirely accurate or that there might be better data out there, we would be happy you to take a look at that and consider it as part of our open comment period. So there's more information in the rule.

If you have clinical labor wage data to suggest that there is more information that we could consider, we would be happy to take a look at that as part of this ongoing four year clinical labor pricing update. All right. With that said, I will now turn it over to colleague Morgan Kitzmiller with the next portion of the presentation.

Morgan Kitzmiller: Hi, everyone. I'm going to be talking about the Medicare Economic Index and a little more about the geographic practice cost indices or the GPCIs, which Michael mentioned earlier.

So first the MEI, the Medicare Economic Index, for CY '23, we are proposing to re-base and revise MEI, which includes updating the base year for the index from 2006 to 2017.

These proposals allow for the scope of the sample to be more reflective of current market conditions, particularly physician-owned practices rather than only reflecting costs for self-employed physicians.

These changes will be used to implement annual updates to the payment rates for telehealth originating site, facility fees, preventative vaccine administration fees and other applicable rates.

And historically we've used MEI cost year weights to set RVU weights and to calculate the GPCIs. But for CY '23, we are proposing to postpone the application of these proposals to the MEI until the public can comment on every base and revised MEI. So we welcome comment on that.

And I'm going to move on to GPCI. CY '23 is a statutorily required tri-annual geographic practice cost indices, or GPCIs, update year. For CY '23 we are proposing new work practice expense and malpractice GPCIs for each Medicare locality.

The updated GPCIs reflect the first year of the statutorily required two year phase-in and there is a 1.0 floor on the work GPCI, which was extended through calendar year '23.

So as you mentioned the CY '23 GPCIs reflect that floor, but since it's only extended through CY '23 under current law, that floor would not apply for the CY '24 GPCIs. And with that, I'm going to turn it over to Anne Blackfield to discuss E/M.

Anne Blackfield: Thanks, Morgan. My name is Anne Blackfield. I'll be covering the proposals for other evaluation and management visits and splitter shared visits.

For CY 2023 CMS is proposing changes to a collection of E/M code families referred to as other E/M visits. Other E/M visits include hospital inpatient, hospital observation, emergency department, nursing facilities and home and residence services and cognitive impairment assessments.

The American Medical Association CPT editorial panel approved revisions for other E/M visits effective January 1, 2023. So in the CY 2023 PFS, we are proposing to adopt many of the CPT changes for other E/M visits.

Our proposal includes, first, revisions to the other E/M code descriptors, including new descriptor times where relevant, revised interpretive guidelines for levels of medical decision-making, choice of medical decision-making or time to select code level, except for a few families like emergency department visits and cognitive impairment assessments, which are not timed services.

And finally the elimination of the use of history and exams to determine code level. Instead, there would be a requirement for a medically appropriate history and exam. These proposed revisions are generally similar to the revised framework to be finalized for office and outpatient E/M visits since CY 2021.

Our second proposal, we are proposing to adopt CPTs for consolidation of several E/M families, including a consolidation of the hospital, inpatient and observation codes and the consolidation of the home and resident visit codes.

And then third, we are proposing a re-valuation of the other E/M visit codes. The AMA RUC has revalued the other E/M visits. And we are generally proposing to adopt the RUC recommended re-valuations. In many instances, this would increase payment for these services.

I will note two areas where CMS' proposals differ from the CPT changes. First, CMS is not proposing to adopt the 2023 CPT coding framework for prolonged other E/M visits. Prolonged service codes provide additional payments for extended visits.

CMS is proposing to create Medicare specific codes for payments of other E/M prolonged services. The purpose of these Medicare specific codes is to help provide oversight and to reduce instances of duplicative billing. This is similar again to what CMS adopted in CY 2021 for payment of office outpatient prolonged services.

Second, CMS is not proposing to adopt any revised CPT billing guidelines that run contrary to our current billing policies. There are some instances in the 2023 CPT guidance that suggest that practitioners could bill more than one E/M visit in a single day. However we are proposing to retain our longstanding policy that in most cases a single practitioner may report only one visit per patient per day.

Now moving to split or shared visits. In the CY 2022 PFS, last year's rule, we finalized policy for split or shared visits. Under the split or shared billing policy, physicians may bill for a visit where the visit was performed by both

the physician and a non-physician practitioner, but the physician personally performed a substantive portion of the visit.

Last year we finalized the definition of substantive portion as being determined based on time, specifically more than half of the visit's total time. In the CY 2023 PFS, we are proposing to delay implementation of this time-based definition of substantive portion for one year.

Under this proposal services that would have transitioned to using the total time to determine the substantive portion would continue to have a choice of history, exam, medical decision-making or time to determine the substantive portion of the visit.

Additionally we are issuing a technical correction for critical care services performed as split or shared visits. We are clarifying this year that consistent with our overall billing policy for critical care practitioners' billing, split or shared critical care can bill CPT Code 99292 only after reaching at least 104 minutes.

And now I'm going to pass the baton to Lindsey Baldwin. Thank you.

Lindsey Baldwin: Great. Thanks, Anne. So there are several proposals in this proposed rule that are aimed at expanding access to behavioral health treatment for Medicare beneficiaries.

First, regarding supervision of behavioral health professionals. We note that in the 2022 CMS behavioral health strategy, CMS included a goal to improve

access to and quality of mental health care services and included an objective to increase detection, effective management and/or recovery of mental health conditions through coordination and integration between primary and specialty care providers.

In light of the current needs among Medicare beneficiaries for improved access to behavioral health services, we've considered regulatory revisions that may help to reduce existing barriers and make greater use of the services of behavioral health professionals, such as licensed professional counselors and licensed marriage and life and family therapists.

Therefore we are proposing to make an exception to the direct supervision requirement under our incident two regulation to allow behavioral health services to be provided under the general supervision of a physician or non-physician practitioner rather than under direct supervision when these services or supplies are provided by auxiliary personnel incident to the services of a physician or nonphysician practitioner.

Additionally, regarding behavioral health integration and past year's PFS rulemaking, we received comments stating that CMS should consider allowing professionals who are not eligible to report the approved initiating visit codes, such as clinical psychologists and clinical social workers to serve as a primary hub for billing behavioral health integration services.

Considering the increased needs for mental health services and the feedback we've received, we are proposing to create a new general BHI service that is personally performed by clinical psychologists or clinical social workers to

account for a monthly care integration where the mental health services furnished by these professionals are serving as the focal point of care integration.

We're also proposing to allow a psychiatric diagnostic evaluation to serve as the initiating visit for the new general BHI service. And with that, I will pass it to my colleague, Erick Carrera, to discuss the request for information on community health workers. Thank you.

Erick Carrera: Hello. Thank you, Lindsey. I will discuss several topics. First, our comment solicitation related to community health workers. Second, our proposals for chronic pain management and treatment services. Third, later in the hour, our proposals and comments solicitation regarding dental and oral health services.

I'll begin with community health workers and I'll begin with our governing statutes. Section 1862(a)(1)(A) of the Act generally excludes from coverage services that are not reasonable and necessary to the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

We believe there are significant benefits that services involving community health workers can potentially offer to the health of Medicare beneficiaries, including a reduction in health disparities.

And so we are soliciting comments. We are interested in learning more about how services involving community health workers are furnished in association with specific Medicare benefits established by statute.

We're also interested in learning whether and how community health workers as auxiliary personnel of physicians and hospitals may provide reasonable and necessary services to Medicare beneficiaries under the appropriate supervision of health care professionals.

We're looking to understand whether and how services involving community health workers are accounted for under the existing care management or behavioral health integration services, including whether common employment and supervision arrangements ordinarily adopted within the industry would meet the requirements that allow for billing by supervising professionals or providers, including rural health clinics and federally qualified health centers.

I'll now proceed on to the next topic, which is our specific proposals for chronic pain management and treatment services effective January 1, 2023.

We made the effective treatment of pain a key goal in our CMS behavioral health strategy. We understand that treatment of pain in older adults and people with disabilities, including those enrolled in Medicare, is most successful when a focused multimodal approach to care is utilized.

For more than a decade, HHS has been involved in making improvements in the lives of people living with chronic pain, including through our work on the national pain strategy and through the Federal Advisory Committee process by the HHS Pain Management Best Practices Interagency Task Force.

We are now proposing new HCPCS codes and valuations that we believe if finalized will facilitate payment for medically necessary services, would prompt more practitioners to welcome Medicare beneficiaries with chronic pain into their practices and would encourage practitioners already treating Medicare beneficiaries who have pain to spend the necessary time to help them manage their condition within a trusting, supportive and ongoing care partnership.

The proposed codes include a bundle of services furnished during the month that we believe to be the starting point for holistic chronic pain care. We are proposing to include the following service elements in the chronic pain management codes, diagnosis, assessment and monitoring, administration of a validated pain rating skill or tool, the development, implementation, revision and maintenance of a person-centered care plan that includes strengths, goals, clinical needs and desired outcomes, overall treatment management, facilitation and coordination of any necessary behavioral health treatment, medication management, pain and health literacy counseling, any necessary chronic pain-related crisis care and ongoing communication and coordination between relevant practitioners furnishing care, such as physical and occupational therapy and community-based care as appropriate.

We welcome comments from the public, clinicians, other providers, advocacy and professional groups, people with chronic pain, their caregivers as to whether these are the appropriate elements and if there are any gaps in what we are proposing.

Proceeding to our next topic I will turn it over to (Patrick).

(Patrick): Thank you. I will be discussing telehealth and other services involving communications technology. So for 2023 we are proposing a number of policies, including a proposal that many of the services that are temporarily available as telehealth services for the duration of the PHE, we are proposing that those continue to be available through 2023 on a Category 3 basis and this will allow us more time for collection of data that could support the eventual inclusion of these services as permanent additions to the Medicare telehealth services list.

Additionally we are proposing to extend the duration of time that services are temporarily included on the telehealth services list here on the PHE but are not included already on a Category 1, 2 or 3 one, two or three basis.

We are proposing that this period be extended for an additional 151 days following the end of the PHE to align with other telehealth related flexibilities, which are granted by the Consolidated Appropriations Act of 2022.

We're proposing to implement these CAA mandated policies, including that, for a period of 151 days. Following the end of the PHE, we will allow telehealth services to be furnished in any geographic area and in any originating site setting, including the beneficiary's home.

In addition, we would allow certain services to be furnished via audio only telecommunications systems, allowing physical therapists, occupational

therapists, speech, language pathologists and audiologists to furnish telehealth services.

And in addition, delaying the in-person visit requirements for mental health services furnished to be a telehealth until 152 days after the end of the public health emergency.

Also, we are proposing that telehealth claims will require the appropriate place of service indicator to be included on the claim rather than the 95 modifier after a period of 151 days following the end of the PHE and also that modifier 93 will be available to indicate that a Medicare telehealth service was furnished via audio only technology where appropriate.

And finally, we are seeking comment on whether the flexibility that defines direct supervision to allow the supervising professional to be immediately available through virtual presence using real-time audio-video technology should be made permanent or alternatively if it should be made permanent for a specific subset of services.

And with that, I will hand it over to Pam West.

Pam West: Thank you, (Patrick). This is Pam West, and I'll be talking about the audiologist services. Currently, audiologists are recognized under Medicare Part B to provide certain diagnostic hearing and balance assessment services at Section 1861,(ll)(3) of the Social Security Act.

And by regulation all these diagnostic services require an order from a physician or non-physician practitioner who is managing a patient's condition.

However for Calendar Year 2023, CMS is proposing as part of the physician fee schedule proposed rule to allow audiologists to furnish certain diagnostic tests without an order from the beneficiary's treating physician or non-physician practitioner.

To accomplish this and to distinguish these directly accessed services from those services provided with an order from a physician or non-physician practitioner, we are proposing to create a HCPCS code with placeholder GAUDX. That's spelled G-A-U-D-X.

In defining the HCPCS Code GUADX, we believe that it may be more appropriate for the safety of the patient to seek treatment from a physician or non-physician practitioner first before receiving treatment from an audiologist.

For this reason, we are limiting the physician order exception to certain audiology services furnished personally by an audiologist to those beneficiaries with non-acute hearing conditions.

This would not include hearing conditions with an acute onset or the balance assessment services that are used for patients with dis-equilibrium. These patients would need to see their physician or non-physician practitioner to treat and manage their conditions.

Therefore the services encompassed by the HCPCS Code GUADX would be personally furnished by the audiologist and would allow beneficiaries to receive care for non-acute hearing assessments that are unrelated to dis-equilibrium or hearing aids or their examinations when used for the purpose of prescribing and interchanging hearing aids.

We are proposing to permit this direct access to audiologists by beneficiaries once every 12 months.

Now I'd like to turn the mic over to my colleague, Erick Carrera, for a discussion of dental and oral health services.

Erick Carrera: Thank you, Pam. I am back quicker than I thought. I am now going to discuss our specific proposals regarding dental and oral health services.

We are proposing to clarify and codify certain aspects of our current Medicare fee for service payment policies for dental services.

Currently, Medicare pays for dental services in a limited number of circumstances, such as when that dental service is an integral part of specific treatment of a beneficiary's primary medical condition.

Some examples include one, jaw reconstruction following accidental injury, two, tooth extractions in preparation for radiation treatment for jaw cancer or three, oral exams preceding kidney transplantation.

For Calendar Year 2023, we are proposing and seeking comment on payment for dental services, such as dental exams and necessary treatments prior to organ transplants, cardiac valve replacements and alveoloplasty procedures that we believe are inextricably linked to and substantially related and integral to the clinical success of an otherwise covered medical service.

We're also requesting comments on, and may consider finalizing based on a review of public comments, other types of clinical scenarios where dental services may be inextricably linked to and substantially related and integral to, the clinical success of other covered medical services.

Additionally we are also seeking comment about the potential establishment of a process to review public submissions of recommendations for considering additional clinical scenarios for future updates.

Finally we are also seeking comment on potential future payment models for dental and oral health care services and other impacted policies. We proceed to our next topic presented by Zehra Hussain.

Zehra Hussain: Thank you, Erick. Good afternoon. My name is Zehra Hussain and I will be discussing our proposals for skin substitutes.

We are proposing several changes to our policies for skin substitute products to streamline the coding, billing and payment rules and to establish consistency in how we code and pay for these products across various settings.

Specifically CMS is proposing to change the terminology of skin substitutes to wound care management products in order to accurately reflect how clinicians use these products to provide a more consistent and transparent approach to coding for these products and to treat and pay for these products as Incident 2 supplies under the PFS beginning January 1, 2024.

Additionally we are soliciting feedback on our key objectives related to skin substitute policies, which include first ensuring a consistent coding and payment approach for skin substitute products across the physician office in hospital outpatient department setting.

Second, ensuring that all skin substitute products are assigned an appropriate HCPCS Level 2 code, including proposal regarding what documentation is necessary to provide CMS for currently marketed and future products.

Third, utilizing a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of material so we can incorporate payment methodologies that are more consistent. And lastly, maintaining clarity for interested parties on CMS skin substitute policies and procedures.

And with that, I will hand it over to my colleague, Dan Feller.

Dan Feller: Thank you. We are proposing to expand coverage for colorectal cancer screening in two different ways. First we are proposing to decrease the minimum age requirement for certain covered colorectal cancer screening tests from 50 to 45 years of age.

And second, we are proposing to expand the regulatory definition of colorectal cancer screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool based screening test returns a positive result, the functional outcome being that in this unique scenario beneficiary cost-sharing would not be applicable to the follow-on colonoscopy.

And both proposals were made with consideration of updated U.S. Preventive Services Task Force recommendations as well as recommendations from professional and specialty societies, including the American Cancer Society. And with that, I'll hand it over to my colleague (Rachel) to discuss vaccine administration.

(Rachel Radzyner): Thank you, Dan. Section 3713 of the CARES Act amended Section 1861(s) (10) of the Social Security Act to add a COVID-19 vaccine in its administration to the Medicare Part B vaccine benefit, which previously covered the influenza, pneumococcal and HBV vaccines and their administration.

In this proposed rule we are proposing refinement to the payment amount for Medicare Part B preventative vaccine administration.

Last year in the CY '22 PFS final rule we announced a uniform payment rate of $30 for the administration of an influenza, pneumococcal or HBV vaccine and $40 for the administration of the COVID-19 vaccine.

We are now proposing to annually update those payment amounts based upon the increase in the Medicare economic index, or MEI, and to use the geographic adjustment factor, or GAF, to adjust for geographic locality based upon the fee schedule area where the preventive vaccine is administered.

We are also proposing to continue the additional payment of $35.50 for the administration of at home COVID-19 vaccinations for CY 2023.

Additionally, in light of the timing distinction between a public health emergency declared under Section 319 of the PHS Act and an EUA Emergency Use Authorization Declaration under Section 564 of the FD&C Act, we propose to clarify our policies finalized last year in the CY 22 PFS final rule regarding the administration of COVID-19 vaccine and monoclonal antibody products to reflect that certain policies will terminate when the FDA ends its EUA declaration for drugs and biologics with respect to COVID-19.

This includes the $40 payment for the administration of the COVID-19 vaccine. This will be paid at a rate of $30 ounce the EUA declaration ends. I will now turn it over to my colleague, Laura Kennedy.

Laura Kennedy: Hi. My name is Laura Kennedy. I'll be discussing discarded amounts of certain single dose drugs payable under Part B.

Section 90004 of the Infrastructure and Jobs Act establishes a requirement that certain manufacturers provide refunds to CMS for certain discarded amounts from refundable, single dose container or single use package drugs.

The definition of refundable, single dose container or single use package drugs excludes radio pharmaceutical or imaging agents, drugs that require filtration during the drug preparation process and drugs approved on or after the date of enactment of the Infrastructure Act for which payment under Part B has been made for fewer than 18 months.

The refund amount is the amount discarded that exceeds an applicable percentage, which is required to be at least 10% of the total charges for the drug in a given calendar quarter.

We are proposing implementation of Section 90004 of the Infrastructure Act, including how discarded amounts of drugs are determined, a definition of which drugs are subject to refunds and the exclusions, when and how often CMS will notify manufacturers of refunds, when and how often payment of refunds from manufacturers to CMS is required, refund calculation methodology including applicable percentages, a dispute resolution process and enforcement provisions.

With that, I'll pass it along for a discussion of the Medicare Shared Savings Program.

Elizabeth November: Hi. Thank you. This is Elizabeth November, and I'll briefly review some of the major proposed changes to the Medicare Shared Savings Program.

The proposals for the Medicare Shared Savings Program are designed to advance the overall value-based care strategy of growth, alignment and equity.

We are proposing to allow new, low revenue ACOs that are joining the BASIC track to apply for advance investment payments beginning with ACOs that start on January 1, 2024. We are proposing a $250,000 one-time upfront payment and then quarterly payments based upon beneficiary assignment.

The quarterly payments would be capped at 10,000 beneficiaries and would increase when more beneficiaries who are dually eligible for Medicare and Medicaid or who live in areas with high deprivation measured by the area deprivation index, the ADI, are assigned to the ACO.

We will make the payments for the first two years of an ACO's agreement and then recoup any monies paid through their shared savings payments through the remainder of their five-year agreement and future agreements.

We would also recoup if an ACO's agreement is terminated early. If the ACO does not earn any shared savings, we will not recoup the advance investment payments.

Under the proposed approach, ACOs must use advance investment payments to improve health care provider infrastructure, increase staffing or provide accountable care for underserved beneficiaries, which may include addressing social needs.

ACOs would also publicly report on their Web site the amount of any advance investment payments and the actual amount spent in each of the spend plan categories. We believe that this would encourage ACOs to partner with

providers in treating rural and underserved populations that have been underrepresented in the Shared Savings Program.

We've also heard from ACOs that they need more time in order to modify their care practices to be successful in delivering value-based care.

For agreement periods beginning on January 1, 2024 and in subsequent years, we are proposing to allow ACOs that are inexperienced with performance-based risk to have one five year agreement that is one-sided shared savings only.

We are proposing to allow ACOs currently participating in Level A or B of the BASIC track the option to elect to continue in one-sided only for the remainder of their agreement. And for agreement periods beginning on January 1, 2024 and in subsequent years, participation in the ENHANCED track would be optional.

In this proposed rule we are building on the existing Shared Savings Program benchmarking methodology by proposing modifications to strengthen financial incentives for long-term participation by reducing the impact of ACOs' performance on their benchmarks to address the impact of ACO market penetration on regional expenditures that are used to adjust and update benchmarks and to support the business case for ACOs serving high risk and high dually eligible populations to participate.

These policies would be applicable for agreement periods beginning on January 1, 2024, and in subsequent years, and would align with our

consideration of the more long-term benchmarking concepts that would move towards the use of administratively set benchmarks in order to grow and sustain long-term program participation as discussed in the related request for information.

To improve financial incentives for ACOs to continue to reduce spending in regions with increasing ACO market penetration, we are proposing to modify the methodology for updating the historical benchmark to use a three-way blend of one-third, a prospectively projected administrative growth factor, which would be a variant of the United States Per Capita Cost and two-thirds the existing national-regional blend.

The Accountable Care Prospective Trend, or ACPT, as we are referring to it, would be calculated as one or more annualized growth rates for per capita spending for a five-year period projected near the start of the ACO's agreement period and would be risk-adjusted and expressed as a flat dollar amount.

To prevent high performing ACOs from being penalized for past performance, we are proposing to incorporate an adjustment for prior savings that would apply in the establishment of benchmarks for renewing ACOs and re-entering ACOs to account for savings generated by the ACO in the performance years corresponding to the benchmark years for the ACO's new agreement period.

We are proposing changes to limit the impact of negative regional adjustments on an ACO's historical benchmark. We are proposing to make the negative regional adjustment amount gradually decrease as the ACO's weighted

average renormalized CMS-HCC risk score increases or its proportion of dual eligible Medicare and Medicaid assigned beneficiaries increases or both, and to reduce the cap on negative regional adjustments.

We anticipate that the combination of proposals, including updating the benchmark using a three-way blend that includes the ACPT, adjusting the benchmark for prior savings and reducing the impact of the negative regional adjustment, would be more favorable for ACOs in markets with high program penetration, that serve high proportions of dual eligible and disabled populations, and ACOs operating in rural areas, and would also provide additional incentives for participation among ACOs serving high cost, medically complex populations.

An additional benchmarking proposal includes modifying the calculation of regional fee-for-service expenditures to align calculations with the ACO's chosen assignment methodology and eliminate a bias in existing calculations.

We are proposing to revise how we apply the existing 3% cap on positive CMS-HCC risk score growth to better account for medically complex high cost populations, by accounting for all changes in demographic risk scores for the ACO's assigned beneficiary population between benchmark year three and the performance year and applying the 3% cap in aggregate across Medicare enrollment types. Under this approach, it would be less likely for populations of ESRD, disabled, or aged/dual eligible beneficiaries to exceed the cap.

We are also proposing to expand opportunities for certain low revenue ACOs participating in the BASIC track to share in savings, even if they do not meet

the minimum savings rate to allow for investments in care redesign and quality improvement activities among less capitalized ACOs.

We are proposing changes to the quality reporting and quality performance requirements that are responsive to interested parties' feedback and designed to support the transition of ACOs to all payer quality measure reporting.

These proposals include reinstitution of a sliding scale methodology for ACOs that meet the minimum quality reporting and performance requirements but fall below the level of performance required to receive the maximum sharing rate for their track in order to avoid the all or nothing approach to shared savings and to revise the approach for determining shared losses for ACOs participating in the ENHANCED track.

We are proposing to implement a health equity adjustment of up to 10 bonus points to an ACO's MIPS quality performance category score when reporting all payer eCQMs / MIPS CQMs and based on high quality measure performance and providing care for a higher proportion of underserved or dually eligible beneficiaries.

The proposal would add bonus points to the ACO's MIPS quality performance category score if the ACO scores in the top third or middle third of performance for each quality measure. This proposal would only positively impact ACOs and not penalize them.

We are also proposing changes to reduce ACO administrative burden as part of our efforts to balance reducing administrative burden on ACOs with our continued focus on program integrity.

We are proposing to modify the requirement for ACOs to provide a beneficiary notice to reduce the frequency with which an ACO or ACO participant must furnish standardized written notices to beneficiaries to once per agreement period instead of annually with a beneficiary engagement interaction taking place within 180 days after the beneficiary notice is provided.

ACOs would still be required to provide the notice prior to or at the first primary care service. The goal of this interaction is to promote beneficiary comprehension around the standardized written notice by ensuring they understood its content and providing an opportunity for beneficiaries to ask any outstanding questions they may have.

Lastly we are proposing revisions to the definition of primary care services that are used for purposes of beneficiary assignment, including to incorporate new prolonged services codes and new chronic pain management codes to ensure that the Shared Savings Program assignment methodology remains consistent with billing and coding guidelines.

And that concludes the highlights of select proposals related to the Medicare Shared Savings Program. And I will pass it to Alex Chong and Hilary Cavanagh with the Enhancing Oncology Model. Thank you.

(Alex Chong): Great. Thanks so much, (Rachel). I'm Alex Chong from the CMS Innovation Center. And outside of the proposed rule, we wanted to use this forum to spread awareness about the Enhancing Oncology Model, or EOM.

On June 27, CMMI announced EOM, which is a new voluntary value-based medical oncology model. It is a total cost of care model for chemotherapy episodes that aims to improve patients under care for Medicare fee for service beneficiaries.

As an overview for EOM, the goals are to put the patient at the center of a care team that provides high value, equitable evidence-based care and improved care coordination and quality as well as health outcomes.

We are also interested in examining behaviors of oncologists to hold them financially accountable for their total cost in quality to assess whether or not they increase their use of high value care, such as making the decisions to prescribe lower cost drugs, which includes generics and biosimilars.

For the timeline for EOM, it is scheduled to run from July 1, 2023 and end on June 30, 2028. The application period for EOM is open now. And the deadline to apply is September 30, 2022.

Just to note that the development of EOM draws from the pillars of the CMMI strategic refresh to drive accountable care, advanced health equity and also address affordability. And closely related to the strategic refresh but separately EOM also supports the priorities by President Biden's Cancer Moonshot Initiative.

EOM addresses the Cancer Moonshot priority of improving the patient experience for cancer patients, their caregivers and their families.

For the scope of target participants, we are targeting oncology physician group practices and other payers through multi-payer alignment, such as commercial payers and state Medicaid agencies. And the target beneficiary populations are Medicare beneficiaries with a cancer diagnosis that are undergoing active chemo therapy treatment.

The focus is on patients undergoing treatment for these included cancer types, which are lung, breast, multiple myeloma, lymphoma, colorectal, prostate and chronic leukemia.

We have a care transformation aspect of EOM to address health equity and again hit the goal of improving the patient experience. These required practice redesign activities include a robust patient navigation in order to support improved outcomes.

A subset of those required practice redesign activities are defined as enhanced services. Again these enhanced services focus on patient navigation, care coordination, screening for health- related social needs, quality improvement efforts and also a collection of patient reported outcomes.

And the payment for these enhanced services is a monthly enhanced oncology service payment, or MEOS payment. The base amount is a $70 per beneficiary per month. And for any Medicare and Medicaid dually eligible

beneficiary, the participant may bill an additional $30. And that $30 would not be included in the total cost of care.

As a part of the financial incentive, there is also an opportunity to earn a lump sum performance-based payment, or they may need to owe CMS a performance-based recruitment. Providers are responsible for all episodes for their patients. This includes the cost of drugs.

These episodes of expenditures are then compared to a benchmark. And then the determination is made for a performance-based payment or a performance-based recoupment based on a risk arrangement.

Participants are required to take on financial liability or down sided risk for their performance of these expenditures and utilizations from the start of the model. Performance on quality metrics is linked with payment to determine the full amount of a performance based payment or recoupment.

And under participation for EOM, both of the risk arrangements would qualify as a MIPS ATM. And one of the risk arrangements, the one with the more progressive downside of risk, we expect to qualify as an advanced APM.

I think that concludes the overview of EOM. And I'm going to turn it back to Jill to for a few minutes of Q&A.

Jill Darling: Great. Thank you, (Alex) and thank you to all of our speakers today. We do appreciate everyone's patience as there was much information provided.

We are about four minutes to the top of the hour, so we will do our best to get your questions. If you are not able to ask your question, please feel free to send your question/comment into the partnership email that is listed on the agenda. It's partnership@cms.hhs.gov.

Denise, please open the lines for questions.

Coordinator: Absolutely. Thank you. If you would like to ask a question at this time, please press star 1 on your phone, be sure your line is unmuted and record your name so that you may be introduced. Again to ask a question, please press star 1.

Our first question today comes from (Mark Hartstein). Go ahead, please. Your line is open.

(Mark Hartstein): Hi, thanks. I think this question is for Zehra Hussain. On the wound care products on Page 419 of the proposed rule, it says treating these products as Incident 2 supplies would mean that the resource cost for these products would be included in establishing the PERUs associated physician services with which they would be furnished.

So that suggests that the skin substitutes would be packaged or the wound care products would be packaged into the physician payment.

But then on Page 420 it says we further propose to establish a code for all skin substitutes meeting the criteria for a HCPCS Level 2 code and propose contractor pricing these services effective January 1, 2024.

So that suggests that these codes are going to be contracted priced and not bundled into the physician fee scheduled payment. Can you clarify what CMS's proposal is? Is it to bundle the payment into the physician fee schedule service payment or pay separately for these wound care products as contracted price beginning January 1, 2024?

And I also have one more question after Zehra answers on a different topic if I may.

Gift Tee: Hey, (Marc). This is Gift. Zehra, I'll take this one. Thanks for the question. And I definitely will follow-up to offer more clarity.

(Mark Hartstein): Okay. Thanks, Gift. I appreciate it. Then my second question it has to do with the specimen collection fee. On Page 541 of the proposed rule, CMS says the nominal specimen collection fee for COVID-19 testing for homebound and non-hospital inpatients is $23.46 cents. And for individuals in a SNF and individuals who samples are collected by a laboratory on behalf of an HHA is $25.46.

I'm not sure what's the difference between a non-hospital inpatient and an individual and a SNF, if you could clarify. I mean, a non-hospital inpatient specimen collection is paid at $23.46 for COVID-19 and then for a SNF it's at $25.46.

And I really never understood this language, but if you could explain what a non-hospital inpatient is if it's not an individual in a SNF.

Gift Tee: (Rachel), do you want to take this one or do we want to just have (Mark) send us the question to the mailbox and then we can follow-up?

(Rachel): I would definitely say to follow-up. Thank you.

Gift Tee: Okay. Thanks, (Mark). Just please again just send us an email and we'll certainly - we'll follow-up and clarify.

(Mark Hartstein): All right. Thank you.

Jill Darling: Hi, Denise. How many questions do we have left in the queue?

Coordinator: We have three remaining questions currently.

Jill Darling: Okay. So, folks, we are at the top of the hour and we do realize that there was much information provided and we had a little bit of time for questions. So those three in the queue, if you don't mind, would you please email partnership@cms.hhs.gov. And I will forward it to the correct party.

So this will conclude today's Physicians Open Door Forum. We appreciate your time in calling and listening in. We thank you and have a wonderful day.

Coordinator: That will conclude today's conference. And we thank you for participating. You may disconnect at this time.

[End]