Centers for Medicare & Medicaid Services

Rural Health Open Door Forum

Moderator: Jill Darling

November 18, 2021

2:00 pm ET

Coordinator: Welcome and thank you for standing by. At this time all participant lines are in a listen-only mode. After today's presentation, you will have the opportunity to ask questions and you may do so at that time by pressing star then 1 on your phone keypad. Today's conference call is being recorded. If you have any objections to this, please disconnect at this time. And now I would like to turn the call over to your host for today, Ms. Jill Darling. Ms. Darling, you may begin.

Jill Darling: Great. Thank you, (Brad). Good morning and good afternoon, everyone. I'm Jill Darling in the CMS Office of Communications. And welcome to today's Rural Health Open Door Forum.

We have a really great agenda today, so I will just give my one brief announcement. 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 have any inquiries, please contact CMS at press@cms.hhs.gov.

And I'd like to hand the call off to our Co-Chair, John Hammarlund.

John Hammarlund: Thanks so much, Jill. Well, thank you all for joining us today for the Rural Health Open Door Forum Call. We are delighted to have you. And today's call is kind of special. It's special because we have a very robust agenda for you today; very timely policies to cover.

As always, we endeavor to highlight those sections that are the most salient for rural and frontier providers. And I want to thank the subject matter experts from our headquarters who are presenting today, as well as call out the regional rural health coordinators who have joined this call today. There are your points of contact in the regional offices for any follow up.

Second, this is a special call because it is National Rural Health Day, and that gives those of us at CMS a chance to acknowledge and thank you for your dedication in providing high quality healthcare to citizens of rural America. We honor you on this day.

And thirdly, it's special because we have a special guest to offer welcoming remarks. And that's Jon Blum, the Principal Deputy Administrator and Chief Operating Officer at CMS. So, without any further ado, I'm going to introduce Jon. This is his second time serving as a senior leadership role at CMS. He previously served as the Deputy Administrator and Director of the Center of Medicare for - during 2009 and 2014, leading the agency's Medicare payment and delivery reform strategies.

Jon has more than 25 years of public and private sector experience working in health care policy and administration. In addition to his positions at CMS, he has worked as a strategy and management consultant, a vice president for

medical affairs at care first Blue Cross Blue Shield, professional staff at the Senate Finance Committee and a program analyst at the Office of Budget - Management and Budget.

He has a Master's of Public Policy from the Kennedy School of Government at Harvard University and a Bachelor of Arts from the University of Pennsylvania. I've known Jon for quite a number of years, and he is very dedicated to the - to rural care and rural America.

Jon, it's a pleasure to have you on today's Open Door Forum call. Thank you for joining us. And with that, I'll hand over the microphone to you.

Jonathan Blum: Great. Thank you, John. Thank you to the whole CMS team today, and thank you for folks that have joined us throughout the country.

One of the things that we've been really thinking hard about here at CMS is how we build and really support the entire health care system in a post-pandemic world. And we know from our conversations that we know from data that the pandemic has been truly consequential, a tremendous task to respond to, particularly in those areas that are rural, that are frontier, that we know from our various work that challenges to find care that is safe for our citizens.

We know that it's a challenge to find sufficient staff. We know that those that live in those parts of the country that are more rural, it tends to be older. They tend to have higher incidence for chronic disease. They tend to be higher

proportion tend to be too eligible for both Medicare and Medicaid. And those are the populations that were most affected by the current pandemic.

And one of the things that we think is critically crucial for us going forward is that CMS become a much more trusted partner to the whole health care system for how we think about this post-pandemic world that is hopefully safer, that is hopefully better supported, that is hopefully more resilient to whatever comes next.

And we have a lot of policy work to do really to respond to the current pandemic, but also to think about how we build, how we think about staffing, how we think about facilities and how we think about better services for all populations, particularly those that were most affected.

And one of the things that we really want to do going forward here at CMS is think about policy development differently. And so, it's probably true and probably, you know, probably history that CMS tends to make policy and then talk about it. We tend to propose policy. We tend to then finalize policy that we educate. Then we talk about it.

But we really want to change that model going forward where we have forums like this, where we have an opportunity to really communicate before policy is made, before we think about the rulemaking processes that happen every year. But to really listen, to really take in perspective and the work that John Hammarlund and his whole team do is to really bring that perspective.

And so, one thing that we're going to work harder at going forward is to create

more opportunities, to engage, to take more opportunities, to truly listen and to take more opportunities to really understand how CMS can be the trusted partner going forward.

And so, while it's hard for us to travel right now due to the pandemic, we will surely create forum resumes through telephone calls today, but really again want to thank everybody for joining. These conversations are so important to us to learn to have the best we can in today's world, you know, true interaction that's more authentic. And that leads to better support going forward.

So, on this day today that we celebrate, we also thank you and the CMS team here, please know works incredibly hard to ensure that we get it right and that we truly serve as a trusted partner that we want to be going forward.

So, John, thank you and your team for organizing us today. And I'll turn the floor back to Jill to start the - run the show today.

Jill Darling: Wonderful, thank you so much, Jon. We appreciate you joining us today. First on the agenda, we have Jean Moody-Williams, who will talk about the COVID-19 Omnibus Vaccine Rule, the IFC-6.

Jean Moody-Williams: Thanks so much, Jill. And please let me add my thanks to all of you during this happy Rural Health Day. I think every day is Rural Health Day, but it's always nice to set aside a time for special recognition. The one thing about a conference call, at least on my end, is that I can't see who's on, but I'm pretty sure many of my colleagues that I've worked with over the years on rural health issues are likely listening.

I just want to thank you for all you've contributed to CMS as we work, but more importantly, to those persons that you serve. So, I do want to just take a minute, I know we have a full agenda, to give a few brief remarks about the CMS Omnibus COVID-19 healthcare staff vaccination rule.

And I want to emphasize, as Jon has mentioned, that patient safety is a foremost priority of CMS, and it really is a fundamental principle of everything we do but in particular, this regulation. The staff vaccination requirement applies to Medicare and Medicaid certified facilities that are regulated under the foundational Medicare health and safety standards known as the conditions of participation or CoPs and the conditions of coverage or the requirements of these patients.

On the next couple of points, I want to raise, I'm going to walk through the primary question that we have received from these various stakeholders' which is, "Am I included?" And so, I'm going to give you at a high level who is excluded, but there's always, various nuanced scenarios, what if I do this and what if I only go here three days?

We've compiled a list of those kind of more specific scenarios and we'll be able to point you to where you can get through these frequently asked questions. But at a high level, as I said, if you are covered by the CoP or the Conditions for Coverage, and you're a Medicare and Medicaid facilities, then you are likely covered.

The CoPs of course, have been established to protect individuals receiving

health care services at certified facilities. So, this regulation keeps in mind, of course, the health care workers that provide their services every day, but with a distinct focus on patient and resident care.

We have included both provider and supplier types and I will briefly mention those: ambulatory service centers, clinics, rehab agencies, public health agencies as providers of outpatient physical therapy and speech-language pathology services, community health centers, comprehensive outpatient. We have facilities critical access hospitals, end-stage renal disease facilities, home health agencies.

We've gotten a couple of questions about home health agencies, but again Medicaid service side, Medicaid service side, they are directly facing these patients and they are in fact included. Home infusion therapy, supplies, hospice, hospitals, innovative care facility for individuals with intellectual disabilities, long term care facilities and then the (PACE) program, psychiatric residential treatment facilities and, rural health clinics and certain federally-qualified health centers.

And as I said a few minutes ago, you'll understand why they are in fact included. I'll note that we don't have statutory authority for certain types of facilities, such as assisted-living facilities. I know we've gotten some questions on that. And, CMS does not have regulatory authority.

Most assisted-living facilities are regulated by state or the local jurisdiction, which states that we don't have authority similar to group homes or physician offices. If a physician or clinician is affiliated with one of the Medicare-

certified facilities they may be subject to requirements under that facility, but we don't regulate physician offices.

This is key when trying to determine who this applies to. There are three basic requirements to be able to meet the regulation. Number one, a process or a plan for vaccinating eligible staff. This is important because no matter the size of the facility, knowing how you're going to outreach is needed? What kind of questions are you going to get?

The process of the plan for vaccinating eligible staff and that would be those that don't qualify for a medical or religious exemption or if it (unintelligible) telework, then that would apply.

The second thing is they must have a process or plan for providing exemptions and accommodations for those who are exempt. We have requirements in the rule of how you can tell what guidance to use as far as exemptions and accommodations. If you have somebody that's exempt, you can make accommodations such as, but not limited to, testing, source control, physical distancing and those kinds of things could be considered.

And the third thing, you must have a process or plan for tracking and documenting staff vaccination. So, when we are coming out to validate that the regulations have been met, these pieces of documentation and process for plan for tracking it will be reviewed.

So how is it going to be documented? The regulation establishes two important phases. Phase one requires that within 30 days after the regulation is

published and so we know it's been published and that would make it by December 6, 2021 facilities have all processes and plans in place for vaccinating staff, providing exemptions and protecting staff vaccination. So, you have your plan in place for 30 days.

Again, the regulation requires that staff at all health care facilities, must have received, at a minimum, the primary series or a single dose of the COVID-19 vaccine prior to staff providing care, treatment or other services for the facility.

Phase two requires that within 60 days after the regulation is published, and that would be about January 4, 2022, the staff must have received the shot to be fully vaccinated again with those exceptions and exemptions that will be met. So, we believe the 30- and 60-day supplies variance are reasonable and allows for facilities to implement staff vaccination plan.

The vaccine requirements apply to all eligible current and new staff, again, those that are not exempt, and working at a facility regardless of whether they had direct or indirect patients contact.

The basic rule of thumb is that any staff member who is on-site at the facility interacting with others and providing direct patient care, must be fully vaccinated. Again, this is another area where we're getting questions.

So, a nurse - may go between a nursing home and assisted-living facilities may only be on-site part-time but who have fulltime responsibilities in another

facility not regulated by CMS. For example, an independent physician's office with hospital - working in a hospital with admitting - treating patients outside the physician's offices is not regulated.

But being on-site at the facility included in this regulation means that physician staff are subject to the requirements. CMS currently considers staff fully vaccinated if it has been two weeks or more since they completed a primary vaccination series for COVID-19

But we do note, that the staff who have received out shots at January 4, 2020 to a clinic, we have met this requirement, although they still may be waiting for their 14-day waiting period that they must have received the shot; another question that comes up.

Staff who receive vaccines listed by the World Health Organization (WHO) for emergency use that are not approved or authorized by the FDA or as a part of a clinical trial are also considered to have completed the vaccination series in accordance with CDC guidelines.

Now at this time, we are not requiring staff to receive additional doses beyond the primary vaccination series or boosters to be considered fully vaccinated. We'll continue to monitor that. CMS requires facilities to allow for both medical and religious exemptions in accordance with the federal law, and you have to have a process in place that’s clear to staff of how they go about - apply for this exemption.

There are specific requirements as it pertains to what level of documentation

is needed for either a medical or religious exemption. So, we encourage you to review the Equal Employment Opportunity Commission Compliance Manual on religious exemptions for more information. I know that you likely have to be familiar with these regulations for things even outside of COVID or vaccines.

Finally, CMS recognizes that there are several vaccinated-related requirements for health care workers. So, we've established a hierarchy for you to follow. If the facility is Medicare or Medicaid certified and subject to the CMS conditions of participation, then they should adhere to the requirements at line in the CMS Omnibus COVID-19 health care staff vaccination regulation.

The CMS rule says proxy above other federal vaccination requirements, as CMS' oversight and enforcement will exclusively monitor and address compliance for provisions outlined in this regulation. ***(please disregard this statement)***

So those are some of the high-level questions. Again, I know you may have very specific questions about your scenario, so please check out FAQs - Jill will give information on those FAQs.

And your question isn't answered there, we encourage you to continue to send in your questions. That's how we develop our list by listening to those who had questions, and we're always happy to update them and post them fairly frequently. So again, thank you for all you do and appreciate this opportunity. Jill?

Jill Darling: Great, thank you, Jean. Like Jean mentioned, we won't be taking questions today, however, for additional information, we have some helpful resources. I just did a quick Google search for CMS IFC-6 recording. And there is a YouTube video. It's about 39 minutes.

And then also for the FAQs and slides I just typed in CMS Omnibus vaccination requirements and it was the first and the third result. So, we gear you towards those helpful resources. So, we thank you and thank you to Jean.

Up next, we have (Susan) and (Terri) who will talk about the 2022 Hospital Outpatient Prospective Payment System, OPPS, and the Ambulatory Surgical Center, ASC Payment System Final Rule update.

(Susan Janeczko): Hi, my name is (Susan Janeczko). So, the OPPS, ASC final rule went on display at November 2nd and I believe it finally published the 16th. So, we'll go ahead and start with a quick review of the OPPS payment rates, and then I'll discuss a couple of the OPPS policies included in the rule and just a little more detail. And then I'll do the same for the ASC payment rates and policies.

So, beginning with an update to the OPPS payment rates, in accordance with the Medicare statute, CMS is updating the calendar year 2020 OPPS payment rates for hospitals that meet applicable quality reporting requirements by 2%. This update is based on the projected hospital market basket increase of 2.7%, reduced by 0.7 percentage points for the productivity adjustment.

Now, a quick note on data, for both the OPPS and ASC rate-setting processes,

we use the best available data so that payment rates can accurately reflect estimates of the costs associated with furnishing outpatient services. Ordinarily, the best available claim data is the most recent set data, which is from two years prior to the calendar year. That's the subject of rulemaking.

However, due to a number of COVID 19 public health emergency related factors, we believe the calendar year 2019 data has the most recent complete calendar year of data prior to the public health emergency, are generally a better approximation of expected costs for calendar year 2022 hospital outpatient services for rate-setting purposes.

As a result, CMS is generally using calendar year 2019 claims data to set the calendar year 2022 OPPS and ASC payment system rates. And the first policy issue we'll discuss in our changes to the in-patient only list.

So, since the beginning of the OPPS, CMS has maintained the in-patient only list, IPO list, which is the list of services that due to their medical complexity Medicare will only pay for when performed in an in-patient setting. In the calendar year 2022, I'm sorry in the calendar year 2021, OPPS ASC final rule, CMS finalized the policy to eliminate the IPO list over a three-year period, starting by removing 298 services from the IPO list in the first phase.

CMS received a large number of stakeholder comments throughout the calendar year 2021 rulemaking cycle and following issuance of the final rule that uphold the elimination of the IPO list primarily due to patient safety concerns. So, for calendar year 2022, CMS is finalizing its proposal to halt the elimination of the IPO list and add that to the list the services removed in

2021, except for CPT codes for lumbar spine fusion, reconstruction of shoulder joints and ankle joints and their corresponding anesthesia codes.

This change in policy promotes transparency and ensures that any service removed from the IPO list this has been reviewed against Medicare's long standing IPO list criteria to determine if it's appropriate for Medicare to pay for the provision of the service in the outpatient setting.

Our second OPPS issue is the two-midnight rule for medical review activities, and it's closely related to the IPO list. In the calendar year 2021, OPPS ASC final rule, CMS established a policy in which procedures removed from the IPO list beginning January 1, 2021 would be indefinitely exempted from certain medical review activities related to the two-midnight policy.

This policy change was made to accommodate the unprecedented number of procedures being removed from the IPO list beginning in calendar year 2021 due to the elimination of the IPO list. For calendar year 2022 however, because CMS is finalizing the proposals to halt the elimination of the IPO list and return the majority of the services removed in calendar year 2021 back to the list, CMS is also finalizing the proposal to revise the exemption for procedures removed on or after January 1, 2021 from the IPO list to the exemption period that was previously in effect, and that was a two-year period.

Now we move on to ASC issues, and we'll start with updates to the ASC payment rates. In the calendar year 2019, OPPS ASC final rule with comment period, CMS finalized a proposal to apply the Hospital Market Basket update

to ASC payment system rates for an interim period of five years. Those are calendar years 2019 through 2023.

Using the final productivity-adjusted hospital market basket update, CMS is updating the ASC payment rates for calendar year 2022 by 2% for ASC's that meet applicable quality reporting requirements.

And on to policies. The first one is changes to the ASC covered procedures list. In the calendar year 2021 OPPS ASC final rule, CMS revised the longstanding safety criteria that were historically used to add covered surgical procedures to the ASC covered procedures list for the ASC CPL and adopted the notification process for surgical procedures the public believes can be added to the ASC CPO under the criteria we retained.

Using these revised criteria, CMS added 267 surgical procedures to the ASC CPL beginning calendar year 2021. For calendar year 2022, CMS is reinstating the criteria for adding procedures to the ASC CPO that were in place in calendar year 2020.

In the calendar year 2022, OPPS ASC proposed rule, CMS requested comment on whether any of the 258 procedures proposed for removal from the ASC CPO met the proposed reinstated criteria. CMS received 140 procedure recommendations, including new procedures and procedures that were already on the PPO and not proposed for removal.

Based upon review of these procedure recommendations, CMS is keeping six procedures; three that were already on the ASC PPO and three that will

propose removal and removing 255 of the 258 procedures proposed removal. CMS is also finalizing the adoption of a nomination process, which will begin in March 2022 to allow an external party to nominate a surgical procedure to be added to the ASC CPL.

CMS determines that a surgical procedure meets the requirement to be added, including a surgical procedure nominated by an external party. It would propose to add the surgical procedure to the ASC CPL for January 1s, 2023. And finally, payment for non-opioid pain management, drugs and biologicals under Section 6082 of the SUPPORT Act.

Under this act, the Secretary is required to review payments under the OPPS and ASC for opioid and evidence-based opioid alternatives for pain management to ensure they're not financial incentives to use opioids instead of not opioid alternatives. For calendar year 2020, CMS is modifying its current policy to provide for separate payment for non-opioid pain management, drugs and biologicals that function as surgical supplies in the ASC setting when those products meet certain criteria finalized this rule.

Specifically, CMS is finalizing its proposal that beginning January 1, 2022, a non-opioid pain management drug or biological that functions as a surgical supply in the ASC setting would be eligible for separate pain and when such product is FDA approved, FDA indicated for pain management or as analgesic and has a per day cost above the OPPS drug packaging threshold.

And that's all I have, so I'll go ahead and turn it over to (Terry Postma).

(Terri Postma): Thanks, (Susan). This is (Terri Postma), I'll be going over the updates to the hospital price transparency regulations that were finalized in the CY 2022 OPPS and ASC final rule.

By way of reminder, CMS finalized rules for hospital price transparency in 2019. Those rules became effective earlier this year on January 1st. And then this final rule, the CY 2022 OPPS and ASC final rule, CMS is making modifications to the hospital price transparency regulations that are designed to increase compliance with the requirements.

They include the following: First, we finalize the policy to increase the civil monetary penalties for noncompliance. CMS is setting a minimum CMP of $300 per day that will apply to smaller hospitals with a bed count of 30 or fewer and a penalty of $10 per bed per day for hospitals with a bed count greater than 30, not to exceed a maximum daily dollar amount of $5,500.

Under this approach, for a full calendar year of noncompliance, the minimum total penalty amount would be $109,500 per hospital, and the maximum total penalty would be $2,007,500 per hospital. This approach to scaling the CMP amount retains the current penalty amount for small hospitals, increases the penalty amount for larger hospitals, and affirms the administration's commitment to enforcement and public access to pricing information.

The second policy that was finalized was to deem state forensic hospitals as having met requirements. CMS modified the hospital price transparency regulations deeming policy to include state forensic hospitals as having met the requirements so long as such facilities provide treatment exclusively to

individuals who are in the custody of penal authorities and do not offer services to the general public.

Third, CMS finalized a policy to prohibit specific barriers to access to the machine readable file. CMS updated the regulation's prohibition of certain activities that present barriers to access to machine readable file, specifically requiring that the machine readable file be accessible to automated searches and direct downloads.

That completes my update for hospital price transparency, and I'll turn it back over to Jill.

Jill Darling: Great. Thanks, (Susan) and (Terri). Next, we have some updates from the - for the 2022 Physician Fee Schedule, final rule updates, and we'll start off with (Michael).

(Michael): Hi, everyone. So, I'm going to talk a little bit about the conversion factor for the physician fee schedule and our clinical labor pricing update, and then I'll pass it over to some of my colleagues.

First up, for the conversion factor, the conversion factor for the physician fee schedule is the number that we use to translate our views into dollars. It's the amount of dollars that one (RVUD) is equal to. We update this number annually based on a couple of different things such as statutory update formula, a budget neutrality adjustment and then any other statutory provisions that might apply.

Section 108a of the Medicare Access and Chip Reauthorization Act of 2015, repealed the previous statutory update formula and specified the update for 2015 and beyond. And what that means is that for the current year, for 2022, the scheduled statutory update is 0%. So, no change in terms of the statutory update as 0% for 2022.

We also have a requirement of a budget neutrality adjustment. The Social Security Act requires that increases or decreases in our views may not cause the amount of expenditures for the year to differ by more than $20 million. And if they do, we apply a budget neutrality adjustment that gets triggered essentially every single year.

So, for the current year, for 2022, our budget neutrality adjustment was negative 0.1%, so 1/10 of 1 percentage point in the negative direction. There's also an additional statutory provision that is unique for 2022. During the current year in 2021, we had a one year provision from the Consolidated Appropriations Act that provided a temporary 3.75% increase in PFS payments that was only for 2021. So, for 2022, that temporary 3.75% increase is due to expire, and we will note that this is a statutory provision that CMS does not have regulatory authority to alter, so that 3.75% was a one year increase and it's going away for 2022.

So, after we apply all of those adjustments, which we're required by law, the 0% statutory update, that negative 0.1% from budget neutrality and then the removal of the 3.75% increase, the final 2022 PFS conversion factor is

$33.60, which is a decrease of about $1.30 from the 2021 PFS conversion factor.

But the other thing I'm going to cover is the clinical labor pricing update. One thing I will mention is we discussed both the conversion factor and also the clinical labor pricing update in more detail in the actual rule preamble. So, there's much more information on them if you want to take a look at the Physician Fee Schedule final rule.

Okay. Quick background on the clinical labor pricing update. Our clinical labor rates were last updated for 2002 using Bureau of Labor Statistics data, and we had stakeholders raise concern that the long delay since clinical labor pricing was last updated was creating a significant disparity between the rates that CMS was using and the actual market averages for clinical labor rates.

You can understand if they were last updated in 2002 that they were in many ways getting pretty, pretty out of date. The statute requires CMS to budget neutral payments for services under the PFS based on relative resource costs incurred by practitioners when furnishing services to Medicare beneficiaries. And so, because our payment system is based on relative resource costs, it's necessary for us periodically to update the information on which we base those costs.

So, we proposed in our proposed rule and then ultimately finalized our proposal that we would update the clinical labor rates starting in 2022. We propose to do this right away and then ultimately in our final year, when we finalize it, we would do this using a four-year transition period.

So, our finalized proposal is that we will update clinical labor over a four-year transition period. This is similar to what we've done to incorporate new pricing data in the past. We've done that with our supply equipment pricing update. We did that with some of our indirect DT data in the past.

And so, we think that using this four-year phase transition will help promote payment stability and also maintain beneficiary access to care. As far as the effects on payments, the impact on clinical labor rate update on PFS payments is largely driven by the share that clinical labor costs represent of the direct PE inputs for each service.

Specialties and services that have a substantially lower or higher than average share of direct cost attributable to clinical labor will experience decreases or increases, respectively. What we mean by that is services and specialties that have a lot of their valuation tied up in clinical labor are likely to see increases in valuation from this update, since the clinical labor date was kind of outdated.

And if you use a lot of clinical labor, you're more likely to go up in pricing. Similarly, services and specialties that use less clinical labor are more likely to see decreases as applied to our budget neutrality formula. For example, a service that is very heavy on supply and equipment cost doesn't use as much clinical labor is more likely to see decreases just due to the fact that everything in terms of practical expense is budget neutralized under the PFS.

So, we note that as we update the clinical labor pricing data, payment for

some services will be reduced due to the PFS budget neutrality requirements that I mentioned. These services include proportionately more supplies and equipment than clinical labor. However, other services, such as those primarily furnished by family practice and internal medicine specialties, involve proportionately more clinical labor and will be positively affected by the pricing updates.

Like we said, we understand that there are some services that will go down as a result of this pricing update, but conversely, many of those services also benefited from the supply and equipment pricing update that we've been doing over the last four years.

So, our basic principle here has been to update all of the data so that we can have the most accurate information possible to use in our pricing. We note that this pricing update is scheduled to take place over the next four years; 2022 will be the first year, and then it will be a four-year phase transition.

So, we appreciate any additional information that stakeholders can supply, both in terms of direct clinical labor wage data, as well as help helping us identify the most accurate types of (VLS) categories that can be used for clinical labor pricing. We will continue to consider additional pricing data that can be used to update the clinical labor race during the remaining three years of the transition period, which, as mentioned, will start in 2022 and then continue up until 2025.

So that's an overview of those two topics, and I'm happy to pass the line over to my colleague (Ann Marshall).

(Ann Marshall): Thanks, Michael. I'm going to talk briefly about some of the policies we finalized for evaluation and management visits, and I'm just going to run through it because I want to leave time for Q&A at the end.

We have policies in three areas. The first is for split or shared visits. We've explicitly defined these as E&M visits in a facility setting by a physician and a non-physician practitioner in the same group or incident to payment is not available, and the visit will be billed by the physician or practitioner who provides the substantive portion of the visit.

In general, substantive portion will have to be more than half of the total time that the practitioners spend cumulatively, except for a transitional year in 2022. We're expanding the types of visits that can be billed as split or shared will allow them for new or established patients, initial and subsequent visits, and also prolonged services. And we're going to be allowing critical care visits to be billed as split or share visits.

Also, nursing facility visits that are not required to be performed entirely by a physician, we created and will be requiring a new modifier, it's F as in Frank, and S as in Sam to identify, split or shared visits on claims and in the role, we lay out a brief set of documentation requirements.

We also had some policies about critical care services and the final rule, essentially, we're refining and codifying longstanding policies that these services are defined by the CPT editorial panel in the CPT code book, and we're adopting their listing of bundled services.

We will allow concurrent critical care services on the same day to the same patient. If a practitioner has a different specialty, I think that is a bit different than what is in CPT. Critical care services will be payable on the same day as another E&M visit. If the E&M visit was provided prior at a time when the patient did not require critical care and the services are not duplicative and that is largely consistent, but a little bit different for some settings than our former manual policy.

As far as critical care, in conjunction with global surgery, we will allow separate billing if the critical care is unrelated to the procedure and that is consistent with former manual and we created a new modifier. It will be F as in Frank and T, as in Tom, to identify this unrelated critical care visits on your claim. In interval, we also briefly address documentation for critical care services.

And finally, for teaching physician services for E&M visits that are furnished by teaching physicians in conjunction with residents. An insurer will work addressing some questions that came in as a result of the recent changes to E&M visit coding, where time or medical decision making can be used for visit level selection.

And we've clarified that one time is used to select visit level that only the time of the teaching physician is counted for purposes of visit level selection. And this kind of course include time that the teaching physician is present with the resident.

And then secondly for visits that are furnished under the primary care exception, in other words, the teaching physician is not present in these situations. Medical decision making must be used to select visit level since residents are less efficient with their time.

And that's all we wanted to go over for in the E&M policies for the final rule. I'll turn it back to Jill. Thank you.

Jill Darling: Thanks. And next, we have (Pam West).

(Pam West): Hi, this is (Pam West). And I'm going to talk a little bit about the therapy services through our 2022 rule making. We implemented the final part of Section 53107 of the Bipartisan Budget Act of 2018, which requires payment of 85% of the applicable payment amount for physical and occupational therapist and therapy providers for services furnished in whole or in part by physical and occupational therapy assistants effective for dates of service on and after January 1, 2022.

In response to stakeholders' questions and to promote appropriate care, CMS revised the de minimis standard that is the 10% time standard established to determine when the therapy service, a modifier CQ and CO are applied on therapy claims to trigger the reduced amount. The finalized policies include two exceptions to the de minimis standard. This year will not apply.

And to save time, can we go - not go over all of these examples of what we finalized in the rule. I wanted to let everybody know that the following billing

examples are up on the Therapy Services billing Web site. And also, CR12397 was issued today.

And I wanted to just briefly touch on the medical nutrition therapy services. And those are all for our registered dietitians and nutrition professionals who can provide therapy services, one that was followed by a physician that is a doctor of medicine or osteopathy for the management of patients with diabetes or renal disease.

In response to stakeholders' concerned about parity with other types of nonphysician practitioners, we did establish regulations for the services of RDs in the final rule. We also updated the payment regulation for MNT services to clarify that the services are paid at 100% instead of 80% or 85% of the physician fee schedule amount since 2011, as required by the Affordable Care Act.

And in the final rule, CMS removed a requirement that limited who could refer people with Medicare to MNT services, allowing any physician that has an MD or (DO) to do so, not just the physician treating a person's diabetes or renal disease. Finally, we updated the glomerular filtration rate to reflect current practice and align with accepted chronic kidney disease staging.

Now, I'll turn the mic over to (Patrick Sartini) to party.

(Patrick Sartini): Thank you. I will be discussing telehealth and other services involving communications technology. So first of all, in the 2022 PFS final rule, we finalized a revised timeframe for inclusion of certain services added to the

telehealth list on a temporary basis, extending from the current timeline of December 31, 2021 to December 31st, 2023.

In addition, we're implementing provisions of the Consolidated Appropriations Act of 2021, including broadening the removal of the geographic restrictions and the inclusion of the patient's home as a permissible originating site to include telehealth services for the purposes of diagnosis, evaluation or treatment of a mental health disorder effective for services furnished on or after the end of (PHE) for COVID-19.

Also, the CAA prohibits payment for a mental health service via telehealth unless the physician or practitioner furnishes an item or service in person first, without the use of telehealth within six months before the first time they furnished a telehealth service to the beneficiary and thereafter with subsequent in-person services at such time as the Secretary determines appropriate.

Therefore, in the 2022 rule, we finalized a requirement for an in - for the in-person visit, be within 12 months of subsequent mental health telehealth services, and we are finalizing that exceptions may be made based on beneficiary circumstances, with the reason for the exception documented of the patient's medical record.

In addition, the CAA added rural emergency hospitals to the list of permissible telehealth originating sites effective beginning CY 2023. Also, in the 2022 PFS final rule, we finalized a revision to our regulatory definition of interactive telecommunications system to permit the use of audio-only

communications technology under certain circumstances for mental health services provided via telehealth beneficiaries who are in their homes.

We are implementing a requirement for documentation in the middle in the medical record of the reason for this use of audio-only technology. In addition, based on support from commentary, as we finalize our proposal to permanently adopt coding and payment for HCPCS Code G2252, which is a longer virtual check and visit as described in the CY 2021 PFS final rule.

Finally, we are finalizing that certain cardiac and intensive cardiac rehabilitation codes continue to be available through Medicare telehealth on a temporary basis until the end of December 2023.

And with that, I would like to hand it over to (Lisa Parker).

(Lisa Parker): Thank you, (Patrick). I will briefly talk about the proposal finalized for both health clinics and federally-qualified health centers. The first topic I will cover is mental health services furnished via telecommunication technology for (RHCs) and (FQHCs).

Consistent with the expansions for mental health services under the PFS, CMS finalized its proposal to revise the current regulatory language for RHCs or FQHC mental health visits to include visits furnished using interactive, real time telecommunications technology. This change will allow RHCs and FQHCs to report and receive payment for mental health visits firms via real-time telecommunications technology in the same way they currently do when

visits take place in-person, including audio-only visit when the beneficiary is not capable of, or does not consent to the use of video technology.

The next topic I would cover is the Rural Health Clinic payment limit per visit increase. Section 130 of the Consolidated Appropriations Act requires that beginning April 1, 2021, already enrolled independent RHCs and provider-based RHCs in larger hospitals receive an increase in their payment limit per visit over an eight-year period, with a prescribed amount for each year from 2021 through 2028.

Then, in subsequent years, the limit is updated by the percentage increase in the Medicare Economic Index or the MEI. Also beginning April 1, 2021, Section 130 requires that a payment limit per visit be established for most provider-based RHCs in a hospital with fewer than 50 beds enrolled before January 1, 2021 be subject to a payment limit based on their 2020 per visit rate, updated annually by the percentage increase in the MEI.

Lastly, Section 130 of the CAA subjects all newly enrolled RHCs, as of January 1, 2021, and after, both independent and provider-based, to a national payment limit per visit. CMS finalized the regulation text update to align with these changes.

The next topic is the payment for attending physician services furnished by RHCs or FQHCs to hospice patients. CMS finalized its proposal to implement Section 132 of the Consolidated Appropriations Act, which makes FQHCs and RHCs eligible to receive payment for hospice attending physician services when provided by an FQHC or RHC physician, nurse practitioner or physician

assistant who is employed or working under contract for an FQHC or RHC, but is not employed by a hospice program starting January 1, 2022.

The RHC or FQHC would bill for these services as they would for any other qualified service to be paid the RHC all-inclusive rate or the FQHC PPS rate, respectively. The last subject I will cover is concurrent billing for chronic care management services, or CCM and transitional care management services or TCM for RHCs and FQHCs.

CMS has finalized it proposal to allow RHCs and FQHCs to bill for TCM and other care management services furnished for the same beneficiary, during the same service period, provided all requirements for billing each code are met.

I will now pass it over to (Abigail Ryan) to cover the CY 2022 ESRD Prospective Payment system.

(Abigail Ryan): All right, this is (Abby Ryan). The ESRD PPS rule went on display October 29th and it was published on November the 8th. And what this is from - it was primarily this year a great update with several requests for information from our - from the public.

A quick review that we make payments to approximately 7700 ESRD facilities and that we pay for (inaudible) of Health Services, which means that we pay for the dialysis treatment, the drugs, the lab supplies, cap-related costs and we do this on a per treatment amount and it gets adjusted for wages and reflects payment and payment level - patient level adjustments and facility level adjustments, along with having add-on payments for when it's

appropriate for training for home and self-dialysis, for high cost outliers and for what we call TDAPA and TAPA stands for Traditional Drug Add-On Payment Adjustments and the Traditional Add-On Payment Adjustment for new and innovative supplies.

And we also have an adjustment for cost-related assets. The visit - we went through analysis this year to decide which set of data would be the most appropriate. And since ESRD patients have to have a lifesaving procedure through dialysis, this is not considered an elective procedure, and the data was not significantly impacted by COVID so we chose to use the calendar year 2020 claims data for this.

So, the overall - the final calendar year 2022 base rate has gone up in the $5 to 257.90 at the current. The base rate formerly was 253.13. And so, what we projected for calendar year 2022 is that there would be an increase in total payments for all ESRD facilities, including the rural by 2.5% compared with calendar year 2021.

Knowing that there are approximately 1,276 ESRD facilities that are in rural geographic region locations, and that they understand that they will provide 6.4 million treatments, there was a 0.6% increase due to the changes in the outlier policy and a 1.9% increase due to changes in the payment rate update. And overall, this yielded the total 2022 final change of 2.5%.

For acute kidney injury, which seemed to increase due to COVID, there were 850 - 875 rural facilities that provided AKI treatments to the tune of 49,400 treatments. And again, the same way, there was a 1.9% increase due to the

2022 change in the payment rate update, and this yielded a 1.9% in the total 2022 payments.

There were updates to the outlier policies, which is we have a 1% carve out and the FDL amount for pediatric beneficiaries decreased from 44.78 to 26.02 and the Medicare allowable payment decrease for the pediatric beneficiaries from $30.88 to $27.15. With regard to the adult population, for the adult beneficiaries, the FDL amount decreased from $122.49 to $75.39, and the Medicare level payment amount decreased from $50.92 to $42.75.

And as I mentioned at the beginning of the call, we have several requests for information and received substantial comment with regard to those topics. And those topics included the low volume payment adjusted comment.

The second topic was payment suggestions which included how we should think about allocate composite rate costs. The third was suggestions we've posted for any kind of refinement to the outlier payments. We also requested to notice - to comments, suggestions for pediatric dialysis and changes to the hospital cost reports.

And finally, during the public health emergency, there were a number of acute kidney injury patients as a result of COVID-19 and the request for allowing home dialysis to be done at home instead of having these patients go into the dialysis facilities. And we also requested information and feedback on what the public thought about having AKI patients have dialysis at home. And that's the summary for the ESRD PCF. Thank you.

John Hammarlund: Great. Thank you, all. Hi, everyone, this is John Hammarlund again, Co-Chair of the call. Well, I told you it was going to be a special call and it lived up to that billing. We've taken you about six minutes over time. Apologize for that. Apologize also for the late start. But we had a lot of really important information we wanted to make sure you had from us today, and I want to thank all of today's speakers for joining us and making this agenda truly robust.

What is does mean, unfortunately, though, is that we do not have time to take your questions now. However, we will definitely want to take your questions. So, let me offer you the way that you can submit them to us. Apologize for the airplane noise above me. You will want to write your questions and send them to the following email address. It is ruralhealthodf, that's all one word, ruralhealthodf@cms.hhs.gov and we will do our best to answer those questions as timely as possible.

Again, I want to thank you all for joining us today's call. Happy Rural Health Day and I will now turn it over to our operator to close out today's call.

Coordinator: Thank you all for your participation on today's conference call. At this time, all parties may disconnect.

END