Centers for Medicare & Medicaid Services
Hospital/Quality Initiative Open Door Forum
Moderator: Jill Darling
July 19, 2022
2:00 pm ET

Coordinator: Welcome and thank you for standing by. All participants will be in a listen only mode until the question and answer session. During that time, if you'd like to ask a question, please press Star 1 and clearly record your first and last name for your question to be introduced.

I'd like to inform all parties that today's call will be recorded. If you have any objections, you may disconnect at this time. I'd now like to turn the call over to your host, Ms. Jill Darling. You may begin whenever you're ready.

Jill Darling: Great. Thank you, (Becca). Good morning and good afternoon everyone. I'm Jill Darling in the CMS Office of Communications and welcome to today's hospital quality initiative open door forum.

Before today's lengthy agenda, I have 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. Now I'd like to hand the call off to our chair, Emily Forrest.

Emily Forrest: Hey everybody. Thanks, Jill. This is Emily Forrest. Thank you for joining us today. As Jill mentioned, we do have a full agenda. I will be providing an overview of the proposed policies in the CY 2023 Hospital Outpatient and ASC proposed rule which was issued on July 15th.

And as a reminder, the comment period for that proposal does close on September 13th. I also wanted to highlight that CY 2023 PFS proposed rule was issued on July 7th and that's the comment period that closes on September 6th.

As many of you are aware this rule does include payment policies or --excuse me-- payment policy proposals for services that are furnished in multiple care settings. In particular, I just wanted to know that in this year's PFS proposed rule, we proposed to clarify and quantify certain aspects of our current payment policies for dental services along with a proposal to pay for other types of dental services such as dental exams, and necessary treatments, prior to organ transplants, cardiac valve replacements and valvuloplasty procedures.

In particular, I just want to note that the circumstances that we address in this proposed rule, we are proposing to pay for these services, whether they occur in either the inpatient or outpatient setting. So, I just wanted to note that to the group here.

We also are seeking comment on several other dental related issues including whether there are other types of clinical scenarios like dental services may be inextricably linked to the clinical success of a particular medical service. So, I just wanted to note that in particular.

I also wanted to highlight the proposed PFS proposal for folks to take a look at it as well. But as mentioned, we do have a full agenda, but we do plan to reserve sometime at the end to take some questions on the issues presented today.

So, without further ado I will turn it over to David Rice as he begins with our update on the CY 2023 of the PFS payments. Thank you.

David Rice: Thanks Emily. For the calendar year 2023, CMS is proposing to update the outpatient perspective payment system rates for hospitals that meet quality reporting requirements by 2.7%. This update is based on the projected hospital market basket percentage increase of 3.1% reduced by a 0.4% percentage point productivity adjustment.

For the ambulatory surgical center update, in the calendar year 2019 OPPS ASC final rule applied the productivity adjusted hospital market basket update to the ASC payment system rates for an interim period of five years, which covered calendar year 2019 through calendar year 2023. Using the proposed hospital market basket update, CMS is proposing to update the ASC rates as well for 2023 by 2.7%,

Moving to behavioral health services furnished remotely by hospital staff to beneficiaries in their homes. For calendar year 2023, CMS is proposing behavioral health services furnished remotely by clinical staff of hospital outpatient departments, including staff of critical access hospitals, through the use of telecommunications technology to beneficiaries in their homes be

considered as covered outpatient services for which payment is made under the OPPS.

Currently, this flexibility is available through the PHE, the Public Health Emergency specific policies referred to as hospital without walls, but the emergency waivers that enable this flexibility will expire when the Public Health Emergency for COVID 19 ends.

The beneficiaries cannot continue to receive these services in their home from hospital clinical staff. They may not be able to continue receiving behavioral health services, which may lead to a loss of access to care, particularly in rural and underserved areas.

CMS is proposing to require that payment for behavioral health services furnished remotely to beneficiaries in their homes may only be made if the beneficiary receives an in person service within six months prior to the first time hospital clinical staff provide the behavioral services remotely, and that there must be an in person service without the use of communication technology within 12 months of each behavioral health service furnished remotely by the hospital clinical staff.

We're proposing to permit exceptions to the in-person visit requirement when the hospital clinical staff member and beneficiary agree that the risk and burdens of in-person services outweighs the benefit of it, among other requirements.

CMS is also proposing that audio only interactive telecommunication systems may be used for -- to furnish these services and instances where the beneficiaries unable to use, does not wish to use or does not have access to two-way audio video technology.

Audio only communications are an important way to advance equities since many rural and underserved communities lack stable access to broadband services, making two-way audio/visual communication difficult.

At this point, I will pass it over to (Gil Ngan) who will discuss payment for drugs acquired under the 340B Program.

(Gil Ngan): Thank you. David. OPPS payment for drugs acquired through the 340B program. Section 340B of the Public Health Service Act 340B allows participating hospitals and other providers to purchase certain covered outpatient drugs from manufacturers at discounted prices.

In the CY 2018 OPPS/ASC final rule of comment period, CMS examined the appropriateness of paying the average sale price plus 6% for drugs acquired through the 340B Program, given that 340B hospitals acquired these drugs at steep discounts. Beginning January 1, 2018, CMS adopted a policy to pay an adjusted amount of ASP minus 22 1/2% for certain separately payable drugs or biologicals acquired through the 340B Program.

The OPPS 340B policy has been the subject of litigation resulting in the Supreme Court decision in American Hospital Association versus Becerra. On June 15, 2022, the Supreme Court held that HHS may not vary payment rates

for drugs and biologicals among groups of hospitals, in the absence of having conducted a survey of hospitals acquisition costs. The Supreme Court's decision concerned payment rates for CY 2018 and 2019, but it has implications for CY 2023 payment rates.

However, given the timing of the Supreme Court's decision, we were unable to adjust the proposed payment rates and budget (neutrality) calculations to cancel that decision before issuing this proposed rule. For CY 2023, we are formally proposing a payment rate of ASP minus 22.5% for drugs and biologicals acquired through the 340B program consistent with our prior policy, but we will fully anticipate applying a rate of ASP plus 6% to such drugs and biologicals in the final rule for CY 2023 in light of the Supreme Court's decision.

We're still evaluating how to apply the Supreme Court's recent decision to prior calendar years. Impacts for both policy options are included in the addendum to the proposed rule. I will be followed by (Abby Cesnik) on changes to the IPO list. Thank you.

(Abby Cesnik): Thank you, (Gil). Hi everyone this is (Abby Cesnik) and I will be covering the inpatient only or IPO list. The IPO list has existed since the start of the OPPS and is a list of services that due to their medical complexities Medicare will only pay for when provided in the inpatient setting.

The IPO list, it's reviewed annually using five established criteria to determine whether additions or deletions should be made to the list. For CY 2023, CMS

is proposing to remove 10 services from the IPO list after determining that these codes meet the current criteria for removal from the IPO list.

Next, I will turn it over to (Mitali) who will discuss the ASC covered procedures lists.

(Mitali Dayal): Thanks, (Abby). The ASC covered procedures list or CPL specifies a list of procedures that can be safely performed in an ASC. CMS evaluates the CPL each year to determine whether procedures should be added to or removed from the list.

In the calendar year 2023 OPPS/ASC proposed rule, CMS is proposing to add one procedure, a lymph node biopsy excision to the CPL, based upon our existing criteria for adding surgical procedures to the list.

Now I'll pass it on to Elise Barringer for the rural community hospital off campus clinic visit exemption.

Elise Barringer: Thanks (Mitali). CMS currently, pays the physician fee schedule equivalent payment rate for the clinic visits service when provided at an accepted off campus provider based department paid under the OPPS as a method to control the unnecessary increases and volume, CMS had observed for that covered outpatient department service.

The PFS equivalent payment rate is approximately 40% of the OPPS payment rate and the clinic visit is the most frequently billed service under the OPPS. In order to maintain access to care in rural areas, CMS is proposing to exempt

rural or community hospitals from this policy and pay for clinic visits, furnish and accepted off campus provider based departments of these hospitals at the full OPPS rate.

We believe that implementing this exemption would help to maintain access to care in rural areas by ensuring rural providers are paid for clinic visits services provided at off campus provider based departments at rates comparable to those paid by on campus departments.

This proposed exemption for rural or community hospitals is in keeping with CMS' prior policy to provide rural or community hospitals a 7.1% add on payment for OPPS services to account for their higher cost compared to other hospitals and to exempt rural or community hospitals from the 340B payment adjustment policy. Now I will turn it back to (Mitali).

(Mitali Dayal): Thanks Elise. So as required under Section 1833 T22A and I8 of the Social Security Act added by Section 6082 of the Support Act, the Secretary must review payments under the OPPS and ASC for opioids and evidence-based non-opiate alternatives for pain management to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives.

For calendar year 2023, CMS is proposing to maintain its current policy to provide for separate payment for non-opioid pain management drugs and biologicals that function of surgical supplies in the ASC setting. When those products are FDA approved, have an FDA approved indication for pain management or as an analgesic, do not have transitional pass through payment

status, are not separately payable already under the OPPS or ASC and have a per day cost above the OPPS drug packaging threshold.

CMS is proposing payment in the ASC setting for four products, including certain local anesthetics and ocular drugs that meet our criteria. CMS is also soliciting comment on additional drugs or biologicals that satisfy our criteria and should be paid separately in the ASC setting. Potential policy modifications or any additional criteria for this policy using statutory authority to create payment policy specific to non-opioid, non-drug or non-biological products, access barriers for non-opioid pain management products that may exist and how our payment policies could be modified to address these barriers and the expansion of this policy and associated criteria to the HOPD setting.

Now I'll pass It along to (Jim) to discuss payment adjustments to purchase domestically made N95 masks.

(Jim Mildenberger): Good afternoon, my name is (Jim Mildenberger) and I'll be discussing the proposed payment adjustment for domestically made N95 masks. In the fiscal year 2023 IPPS proposed rule, which was published on April 18th, CMS requested comments on potential payment adjustments under the IPPS and OPPS for domestically made NIOSH approved surgical N95 respirators.

In that rule, we acknowledged that there was a severe shortage of these masks during the early months of the pandemic, and that given their importance in protecting health care workers, we believe sustaining a level of domestic production would be important for future emergency preparedness. In that

rule, we also acknowledged that procuring domestically made masks over foreign masks can result in additional resource cost for hospitals. Therefore, we sought comments on the appropriateness of payment adjustments, that would offset these additional costs.

In the IPPS rule, we provided different frameworks for which these payments might be provided. We received many comments from hospitals and manufacturers, the vast majority of which supported a payment adjustment.

Therefore, in this 2023 OPPS proposed rule, we're proposing payment adjustments under the OPPS AND IPPS that reflect and offset the additional resource cost hospitals face in procuring domestically made NIOSH approved surgical N95 respirators. We are proposing that these payments will be provided on the hospital cost report, which was the preferred option of most commenters.

We're proposing that these payments would start for cost reporting periods beginning on or after January 1, 2023. On the cost report, we are proposing that a hospital would separately report the aggregate cost and quantity of masks it purchased that were domestically made, and those that were not. This information along with existing information already collected on the cost report will be used to calculate an IPPS and OPPS Medicare payment for the estimated cost differential.

CMS would use its exceptions and adjustments authority to make these payments under the IPPS in a non-budget neutral manner. CMS does not have the same authority under the OPPS to make these payments in a non-budget

neutral manner and therefore is proposing that the payments under the OPPS would be budget neutral.

So, I'm going to turn it over next to (Josh McFeeters) who will discuss rural emergency hospital proposals. Thank you.

(Josh McFeeters): Thank you. Jim. Starting on January 1, 2023, critical access hospitals (CAHs) and small rural hospitals with less than 50 beds that were in existence on December 27, 2020, will be eligible to convert to become Rural Emergency Hospitals otherwise known as REHs. REHs' will provide emergency outpatient and observation care services. The annual patient average time spent in a REH must be less than 24 hours. REHs will not provide inpatient hospital services.

REHs are required to have a transfer agreement with a Level I or Level II trauma center to provide care that would exceed the capacity of the REH. REHs will receive payment from two sources. The first source is payment for individual services performed. REHs will be paid at the OPPS payment rate for a service plus an additional 5% payment. This additional 5% payment will be excluded from beneficiary cost sharing.

In order not to limit the type of types of services that REHs can provide, CMS is also proposing that REHs may provide certain outpatient services beyond those paid under the OPPS which would be paid at the applicable fee scheduled amount without the additional 5% payment.

The second source of payment for REHs is a monthly facility payment. We estimate a proposed monthly facility payment of $268,294 which translates into an annual facility payment of approximately $3.22 million for calendar year 2023. This payment amount will be the same for all REHs. In subsequent years, the payment amount will be updated by the hospital market basket percentage.

The REH statue allows an entity that is owned and operated by an REH that provides ambulance services to receive payment for those services under the ambulance fee schedule. We are also proposing to update ambulance regulations to ensure that ambulances can service REHs.

The REH statute also allows REHs to include a unit that is a distinct part of a facility license of the facility. The unit that is a distinct part of the facility licensed as a skilled nursing facility to furnish post hospital extended care services. Payment for services provided by REHs and such a unit will be made through the skilled nursing facility perspective payment system. Next my colleague Frank Whelan will discuss enrollment.

Frank Whelan: Okay. Hi everyone. I hope everyone's doing okay. As many of you know providers and suppliers have to enroll in Medicare in order to receive payments for Medicare services and items. And the purpose of the enrollment process is to help confirm that providers and suppliers who are looking to bill Medicare that they meet all federal and state requirements to do so.

And in this proposal, we're proposing to update our existing Medicare provider enrollment regulations in 42 CFR Part 424 Subpart P to address enrollment requirements for REHs. There are three main components of this.

The first one is really more of a technical clarification and what we say in the proposed rule is that simply REHs have to comply with our enrollment requirements to the same extent as all other providers and suppliers.

The second thing is that we state that no application fee will be required for REHs who are looking to enroll to become REHs. The third piece of this and this is probably the most significant one that as many of, you know a provider that's looking to enroll in the Medicare program, has to submit an initial full application, but what we're proposing in this rule is that they would only need to submit a change of information application.

And this is kind of an abbreviated application, it's not a full application and the purpose of this is to help expedite the enrollment process, given the January 1, 2023 date, So that's really probably the key change in this that we outlined in the proposed rule. That's all I have. Passing it on to Lisa to talk about physician self-referral.

Meredith Larson: Thanks Frank. Lisa is actually not able to join us today. My name is Meredith Larson and I will be discussing proposed changes to the physician self-referral law related to Rural Emergency Hospitals. As a reminder, the physician self-referral law prohibits a physician from making a referral for certain designated health services to an entity with which the physician or an immediate family member of the physician has a financial relationship.

In addition, the entity is prohibited from billing Medicare or any other party for designated health services that it furnishes pursuant to a prohibited referral. However, the statute and our regulations provide exceptions to the referral and billing prohibitions.

As anticipated, Rural Emergency Hospitals will provide designated health services for purposes of the physician self-referral law and without an applicable exception, the physician self-referral law would prohibit referrals of REH services that are also designated health services by physicians who have financial relationships with Rural Emergency Hospitals.

To ensure that the physician self-referral law does not thwart the underlying goals of ensuring access to care in rural areas through the establishment of the new rural emergency hospital provider type we're proposing a new exception for ownership in a Rural Emergency Hospital. We are also proposing modifications to some existing exceptions to make them applicable to compensation arrangements between Rural Emergency Hospitals and physicians or immediate family members of physicians.

Essentially, these proposals support the policies established for Rural Emergency Hospitals elsewhere in the OPPS and conditions of participation. And with that I will pass it to Shaili Patel.

Shaili Patel: Hi good afternoon. Per section 125 of the Consolidated Appropriations Act of 2021, the Secretary is required to establish quality measurement reporting requirements for REHs. REHs are required to submit quality measure data to

the Secretary and the Secretary shall establish procedures to make the data available to the public on ACM's website.

In the calendar year 2023, the OPPS proposed rule would establish the Rural Emergency Hospital Quality Reporting or the REHQR program by proposing a fundamental standard administrative policy to require facilities to obtain a quality net account and security official for the purposes of data submission and access to facility level reports.

I would like to note that facilities that are eligible to convert to an REH are already eligible and participating in the Hospital Outpatient Quality Reporting program. CMS is also requiring comment -- requesting comment on quality measures to be included in REHQR program, excuse me, specifically measures for the OQR program and other measures requested by the National Advisory Committee on Rural Health and Human Services to address the special characteristics of this new Medicare provider type.

Lastly, CMS is also requesting comment on various other topics such as behavioral health, maternal health, telehealth, health equity, and addressing concerns regarding case volumes. Next program on the agenda is the hospital Outpatient Quality Reporting or the OQR program.

Mandated by the Tax Relief and Healthcare Act of 2006, the hospital OQR program collects quality measure data from short term acute care hospital paid under the OPPS for the care rendered in the hospital outpatient setting. Facilities must meet program requirements, including quality measure data submission, or be subject to a 2% reduction in their annual payment update.

Each year, there are over 96% of eligible hospitals that have successfully submitted quality data under the program since its initial reporting year in 2009. This year there is one measure related proposal, which is the cataract measure, improvement in patients, visual function within 90 days following cataract surgery, also known as an OP31 measure. CMS is proposing to change the OP31 measure from mandatory to voluntary beginning with 2025 reporting period.

Note, currently this measure is voluntary in the program and is scheduled for mandatory reporting, starting with calendar year 2025. Since the publication of last year's final rule, many stakeholders have expressed concerns about the reporting burden given the COVID-19 public health emergency, which has resulted in national staffing and medical shortages coupled with unprecedented changes in the patient case volumes.

This measure is uniquely different compared to other measures in the program as it requires cross-cutting coordination among different specialties.

Next, CMS is proposing administrative requirements. The first one is the proposal to align our patient encounter quarters to calendar year. Our current annual payment determinations are not aligned with calendar year as they are in other programs which has resulted in a lot of confusion regarding the deadlines and reporting quarters.

Second proposal is to add additional targeting criterion for validation purposes, as the current validation policy does not address an event where the

facility does not have all four quarters of data to be validated due to receiving and (ECE) for one or more quarters which could lead to 2% payment reduction and unfair treatment between facilities.

CMS is also requesting cross-cutting program request for comment that was in the IPPS proposed rule regarding guiding principles for health equity to seek comment relevant to outpatient settings.

Lastly for the OQR program, CMS is requesting comment on the potential re-adoption of the hospital outpatient department volume data on selected outpatient surgical procedures or other volume indicators in the OQR program.

Moving on to the Ambulatory Surgery Center Quality Reporting or ASCQR program. Similar to the OQR program, the ASCQR program collect measure data from ambulatory surgical center ASC settings. Facilities must meet program requirements including quality measures submission or be subjected to a 2% payment reduction in their annual payment update.

CMS is proposing one measures related proposal, which is again the (carrot) measure known in this program as ASC11. CMS is proposing to change the ASC11 measure from mandatory to voluntary beginning with the calendar year, 2025 reporting period for the same reasons outlined for the OQR program that I just covered previously.

Next, CMS is seeking comment on various topics such as re-adoption of the ASC volume data on selected ASC surgical procedures or other volume

indicators for this setting. Potential future implementation of measures, value pathways, status of electronic health record, implementation and utilization in the ASC care program. And lastly the cross program reference to the request for information that was in the IPPS proposed rule regarding guiding principles for the health equity to seek comment relevant to ASC setting,

I will not turn it over to Tyson Nakashima to discuss proposals related to hospital star ratings program. Thank you.

Tyson Nakashima: Hi. Thank you. For the overall hospital quality star ratings program, we have three items. First, we are providing information on the analysis performed concerning the inclusion of the Veterans Health Administration hospitals in overall hospital quality star ratings.

At this time, we do intend to include the VHA in the 2023 overall hospital quality star ratings refresh. Second, we are, we were advised that the existing language on frequency of publication for star ratings could be interpreted as requiring CMS to publicly -- to use publicly available measure results from the previous calendar year. So, we are proposing to amend the policy to allow for the use of publicly available measure results from the previous 12 months.

Third, we wanted to convey that although CMS intends to publish overall hospital quality star ratings in 2023, the calendar year 2021 OPPS/ASC rule established suppression policy criteria allowing for suppression of overall hospital quality star ratings including if the COVID 19 public health emergency affects the underlying measure data.

We are continuing at this time to monitor the data and as it is received, but we do intend to refresh the star ratings in 2023. Thank you. I will now hand it off to the partial hospitalization program. (Jenna Linguists) and Nic Brock.

Nick Brock: Hi, this is Nick, thank you. Good afternoon.

Partial hospitalization is an intensive structured outpatient program as an alternative to psychiatric hospitalization. Partial Hospitalization Programs (or PHPs) consist of a group of mental health services paid on a per diem basis under the OPPS based on PHP per diem cost. Medicare pays for PHP services furnished by hospital outpatient departments and Community Mental Health Centers (or CMHCs) with a single PHP ambulatory payment classification for each provider type for days with three or more services per day.

For CY 2023, CMS is proposing to maintain the existing rate structure. Additionally, CMS is clarifying that the proposal to pay under the OPPS for certain behavioral health therapy services furnished remotely by hospital staff using communications technology to beneficiaries in their homes would not be recognized as partial hospitalization services but would be available to those patients in a partial hospitalization program.

Specifically, CMS is clarifying that under the proposal a hospital could bill for non-PHP outpatient services furnished to PHP patients including remote therapy services furnished by a hospital outpatient department. Hospitals would be permitted to build for these non-PHP remote behavioral health services, but would need to continue to comply with documentation requirements that apply to PHP patients.

Lastly CMS is soliciting comments on the use of remote behavioral health services for PHP patients during the COVID 19 PHE. In addition, because CMHCs are only a provider of services for PHP by statute and therefore could not bill for remote services, we're soliciting comments on potential pathways to allow CHMCs to provide remote behavioral health services. Now, I'll pass it over to (Amy) to talk about prior authorization.

(Amy Cinquegrani): Hi, this is (Amy Cinquegrani) from the CMS Center for Program Integrity.

For this proposed rule, we're proposing the addition of a new service category to the hospital outpatient department prior authorization process that was finalized several years ago. The proposed new service category is Facet Joint Interventions, which includes 10 CPT codes - six codes for facet joint injection services and four codes for facet joint nerve destruction services. If finalized, prior authorization for this new hospital outpatient department service category would be required as a condition of payment beginning for dates of service on and after March 1, 2023.

We did not propose any changes to either the program or process requirements that have been finalized in previous years' rules. And that's it for me.

And now I'll turn it over to Heather Grimsley to speak on the competition and transparency.

Heather Grimsley: Thank you. President Biden's Executive Order on Promoting Competition in the American Economy developed a whole-of-government effort to promote

competition. It also specifically identified that hospital consolidation has left many areas, especially rural communities, without good options for convenient and affordable healthcare services, and that hospitals in consolidated markets charge far higher prices.

In response this year, CMS released data for the first time on hospital and skilled nursing facility mergers, acquisitions, consolidations and changes in ownership going back to 2016, and will update the data quarterly going forward. The intent of this data release was to add transparency for the public and researchers to better understand the effects of mergers, acquisitions, consolidations and changes in ownership on health care, affordability in their communities.

In this rule, CMS seeks comment on if there is additional data that should be released to further promote transparency and competition. And if there are additional provider types where information regarding mergers, acquisitions, consolidations, and changes in ownership should be released to the public. Amanda Michael will now discuss the organ acquisition payment proposals.

(Amanda Michael): Thanks Heather. Good afternoon, this is (Amanda Michael). CMS is proposing two policies and including a request for information on organ acquisition payments. The first proposal is relative to counting research organs. In the fiscal year 2022 inpatient prospective payment system rule, we proposed the policy for counting research organs to calculate Medicare's share of organ acquisition costs.

We did not finalize certain provisions of last year's proposal because commenters indicated our proposal would have a negative impact on the availability and affordability of research organs. To address commenters concerns, in the 2023 OPPS proposed rule, we are proposing a method of accounting for research organs that will improve payment accuracy and lower the cost to procure and provide research organs to the research community.

The second proposal is relative to the organ acquisition cost of potential organ donors. We are proposing to cover as organ acquisition costs, certain hospital costs incurred for services provided to patients for potential organ donors when death is imminent but prior to the declaration of death. This is typical in cases involving donation after cardiac death. These costs are for services that are necessary for organ donation but cannot be provided after death and would otherwise be billed to the donor's family.

This proposal would remove a potential financial barrier to organ donation, honor the patient's wishes to donate organs and support organ procurement.

Lastly, we are including a request for information on an alternative methodology for counting Medicare organs. In the fiscal year 2022 inpatient prospective payment system proposed rule, we proposed an alternative methodology for counting Medicare organs that required transplant hospitals and organ procurement organizations to track organs they excised and provided to other transplant hospitals or organ procurement organizations.

This would have required them to do determine if the organ was transplanted into a Medicare beneficiary to accurately account for Medicare’s share of

organ acquisition costs. We did not finalize this proposal due to the number and nature of the comments received and indicated we may review this issue in future rulemaking.

In this calendar year 2023 OPPS proposed rule, we are requesting information on possible alternative methodologies for counting organs to calculate Medicare's share of organ acquisition cost. The information received from interested parties in response to this request for information will inform our future organ acquisition payment policies, and will afford us time to analyze the effects of an alternative organ counting policy on the transplant ecosystem.

Now I will turn it over to (Kianna Banks) to discuss the Rural Emergency Hospital CCSQ/COP rule.

(Kianna Banks): Hi. Thank you. So just for clarity, I'd just like to highlight that the Rural Emergency Hospital proposed conditions of participation were published in a separate rule from the payment rule and that rule is titled Medicare and Medicaid programs, Conditions of Participation for Emergency Hospitals and Critical Access (OCOP) Hospital updates.

We do have a couple of critical access hospital (OCOP) of proposed provision in this rule, but I'll go over briefly towards the end. So just to provide some background, I know you already heard some of the statutory requirements on this call for Rural Emergency Hospitals, and I'm just going to repeat some of them.

So, in accordance with the statute, a facility is eligible to be a Rural Emergency Hospital if it was a critical access hospital or rural hospital with not more than 50 beds on or before the date of enactment of the Consolidated Appropriations Act, and that date of enactment was December 27, 2020. The statute does allow REHs to receive payment for items and services furnished on or after January 1, 2023. We intend to finalize all of the REH provisions before that date.

Rural Emergency Hospitals must provide emergency services and observation care, and they may not provide inpatient services. Rural Emergency Hospitals may provide skilled nursing facility services, and separately certified, distinct part skilled nursing facility unit. Rural Emergency Hospitals may also provide additional outpatient medical and health services as specified by the Secretary through rulemaking and the statute allows the Secretary discussion to establish additional requirements of Rural Emergency Hospitals in the interest of health and safety.

So, with that said, in order to address the growing concern over closures of rural hospitals, this proposed rule will create a pathway for conversion for certain critical access hospitals and rural hospitals to this new provider type, in accordance with the statute,

The overall policy goal of the Rural Emergency Hospital proposed COP rule is to establish the health and safety standards for Rural Emergency Hospitals in the most efficient manner possible and in accordance with the statute, while considering the access and quality of the care needs of the patient population that they serve.

Also, as I noted earlier, the proposal (unintelligible) for critical access hospitals and aims to provide clarity and consistency for critical access hospitals, regarding compliance with the location and distance requirements, and increased flexibility for critical access hospitals who are part of a larger health system.

So to touch specifically on some of the proposals and sort of our policy development approach, we closely model the proposal emergency hospital requirements after the critical access hospital, conditions of participation, based on comments we received on the request for information that we published last year and those comments generally encouraged us to align the conditions of participation for Rural Emergency Hospitals with the existing conditions of participation for critical access hospitals and those comments just encourage CMS to consider the challenges associated with the provision of health care services to rural communities.

The Rural Emergency Hospital proposal for staffing, medical records, emergency preparedness, laboratory services, infection central, discharge planning, and quality assessment and performance improvement program requirements generally reflect the critical access hospital standards, but in some cases there less than the critical access hospital (OCOP).

This is due in some cases to the statutory requirements, but it's also based on the fact that this is brand new and different providers type, and we have to consider the fact that critical access hospitals provide inpatient services while Rural Emergency Hospitals are outpatient only provider.

Some of the key differences between the critical access hospital requirements and the proposed Rural Emergency Hospital requirements are again that Rural Emergency Hospitals are prohibited from providing inpatient services. Rural Emergency Hospitals are required by the statute to have an agreement with a Level 1 or Level 2 trauma center and Rural Emergency Hospitals must have someone onsite at all times 24/7.

The existing critical access hospital, emergency services conditions of participation, requires out of practitioner with training or experience in emergency care be on call and immediately available by telephone and radio and be available on site at the critical access hospital within 30 minutes or within 60 minutes for a critical access hospital that is located in the (frontier) area.

We propose the same requirement for Rural Emergency Hospitals in accordance with the statutory requirement which states that Rural Emergency Hospitals have to meet the same critical access hospital emergency services requirements.

We've also included a request for comment on the appropriateness of the level of onsite presence for practitioners in the Rural Emergency Hospitals and the feasibility of implementing more stringent requirements in rural communities.

Rural Emergency Hospitals may provide additional outpatient services, and we specifically note in the proposed rule that these services may include but are not limited to radiology, laboratory, outpatient rehabilitation, surgical

behavior health, which includes substance use disorder treatment, and maternal health services. And we are seeking comment on the appropriateness of allowing Rural Emergency Hospitals to provide lower risk labor and delivery services.

CMS is proposing to establish specific Rural Emergency Hospital requirements as separate conditions of participation for medical staff, radiologic services and pharmaceutical services. I only highlight that because it is a difference in the way that the critical access hospital conditions of participation are laid out.

However, with that said, for these requirements, we aren't expecting the Rural Emergency Hospital to be providing any services or meeting any requirements that aren't already requirements for critical access hospitals.

CMS is proposing updates to the critical access hospital (COPs) to provide additional flexibility and clarity in the requirements, for the location and distance requirements, specifically, we're adding the definition of primary (roles) to the (CAH) location and business requirements to allow for a consistent method of measuring distance between the critical access hospital and another hospital, critical access hospital.

We are proposing to establish a patient's right of conditions of participation for critical access hospital to mirror the hospital's patients right condition of participation, and we've also made the same proposal for Rural Emergency Hospitals.

And lastly, we're allowing a (COB) that is a part of a multi-facility health system to use a unified and integrated model for its organized medical staff, as well as for its infection prevention and control and antibiotics stewardship programs and for its quality assessment and performance improvement program.

And in this case, the health system must have a single governing body that is legally responsible for all of the facilities in the system.

And just to touch on the timing of the proposed rule. So, the proposed rule was published if I'm not mistaken on, I believe about a week ago. And then all of the final policies for Rural Emergency Hospitals including the conditions of participation -- for including those for the conditions of participation, enrollment payment, and quality measures, and quality reporting requirements will be published in the calendar year 2023 outpatient and ambulatory service center and a final payment rule in the fall. And the proposed critical access hospital policies will also be finalized in that same rule.

And the comment period for the Rural Emergency Hospital proposed rule closes on August 29th and that's all I have. So, I'll pass it back to Jill Darling.

Jill Darling: Great, thank you, (Kianna) and thank you to all of our speakers today. We do have some time for Q.&A. So, will you (Becca), please open for Q&A.

Coordinator: If you'd like to ask a question at this time, please press Star 1. Again, that is Star 1. One moment please to see if we have any questions. Our first question comes from (Ronald Hirsh), your line is now open.

(Ronald Hirsh): Hi Jill. My question is about the Rural Emergency Hospital. Actually, two things. One is the 24-hour limit annually. Does that include the patient who walks into the lab and has a blood drawn and leaves, and that would be a 15-minute visit along with the observation patients or is it limited to just patients who end up staying in a bed of some type.

And then is the $268,000 to be divided amongst all hospitals or is that per hospital, no matter how many hospitals like this end up being opened?

Josh McFeeters: Kianna, do you want to answer Dr. (Hirsh's) first question?

Kianna Banks: Sure. So, we are still developing the some of the policies and especially for things like the length of stay. We will have flushed out further in the sub-regulatory guidance. The sub-regulatory guidance for the COP rule will be released after the publication of the final rule, so you will be able to find details of what the requirements are and how it's being determined in the regulatory guidance.

(Ronald Hirsh): Thank you.

Kianna Banks: Let me encourage you if you have comments to comment on the proposal accordingly.

(Ronald Hirsh): Okay. And the money issue?

(Josh McFeeters): This is (Josh McFeeters). To address your question about the monthly facility payment, that monthly facility payment of $268,000 again proposed to $268,294 for each REH that comes into existence. So, it's the same payment rate for each REH.

(Ronald Hirsh): Got it. And since I'm on the line for the OPPS plus 5%, is that the OPPS adjusted for the wage index or is it the base rate that's posted on Addendum B.

(Josh McFeeters): Like anything else it would be adjusted for wage index and other appropriate adjustments.

(Ronald Hirsh): Thank you very much. Bye Jill.

Coordinator: Our next question is from Heather Hill. Your line is now open.

Heather Hill: Hi. I have a question about the partial, I'm sorry, the prior authorization for hospital outpatient services. The speaker got very garbled when she was saying what those services were, I was just wondering if you could repeat that please? I caught just joint and something about 10 CPT codes, but I missed the beginning.

(Amy Cinquegrani): Hi. This is Amy Cinquegrani. Can you hear me better now?

Heather Hill: I sure can. Thank you.

(Amy Cinquegrani): Sure. So, the service category is facet joint interventions. Facet F-A-C-E-T. And the 10 CPT codes include six codes for facet joint injection services and four codes for facet joint nerve destruction services.

Heather Hill: Thanks very much.

(Amy Cinquegrani): Thank you.

Coordinator: Our next question comes from (Mary Adamia). Your line is now open.

(Mary Adamia Manjong): Yes. Hi, this is (Mary Adamia Manjong). I'm calling from Mount Sinai Medical Center. My question was just related to the payment for behavioral health remote services for outpatient behavioral health.

My question is whether or not there is going to be any consideration to have licensed mental health counselors and licensed marriage and family therapists have the ability to bill Medicare for outpatient services for counseling. I just wanted to ask whether or not that's even something that's on the table or being considered.

David Rice: Hi this is David Rice. Are you talking about separately through the physician's fee schedule or are you talking about the facility payment through CPS?

(Mary Adamia Manjong): Right. So, for facility payment if we have like for example, right now we have active services that we provide for PHP and then for (IOP). Our program is staffed fully by LMHCs and LMFTs. Many of our patients when

they're stepped down from these services, they're seeking to do follow up with us.

But as individual providers, as we all know, historically under Medicare, they will only reimburse an LCSW or licensed clinical psychologist. I just didn't know if there was any conversation about expanding this because we're just -- we're bombarded by request, and you know, I'm just looking to find out whether that's even something that is somewhere in some discussion.

David Rice: Yes. I don't think we have any folks from the division of practitioner services on the call, that could address that question but if you submit a question to the hospital open door forum mailbox, we can direct that to the division of practitioners services.

(Mary Adamia Manjong): Okay, perfect. Thank you so much.

David Rice: Thanks.

Coordinator: As a reminder, if you'd like to ask a question, please press Star 1. Our next question comes from (Eric Hyden).

(Eric Hyden): Yes. Thank you. Just for clarification on the critical access updates and clarification language, it's my understanding that you are looking at redefining a primary road as a road that has two lanes going in both directions to the next nearest hospital.

And then also, updating and providing some clarification to the updates where the national highway system language was introduced a few years back, where federal highways, again indicating that federal highways should also be two lanes going in each direction, and then all of the roads would be considered secondary roads. Is that correct? Is that the proposed language?

((Crosstalk))

Lela Strong: The proposed definition is that a primary road is a number of federal highways that includes interstates and expressways or a number of state highways with two or more lanes each way, and we're also soliciting comments in the rule on the number of federal highway -- the definition should include number of federal highways with two or more lanes each way.

(Eric Hyden): Yes. I would suggest you consider that. Obviously, a lot of federal highways that we have in the rural areas are one lane each direction, and they're not well maintained and probably are more challenging to navigate than some of the secondary roads that we have.

Lela Strong: Thanks. We welcome your comments on that.

Coordinator: Our next question comes from (Melanie Grant). Your line is open.

(Melanie Grant): Hi. Thank you. I was just looking for some clarification around the -- what you consider a Rural (full) Community Hospital as far as being exempt from the site neutral payments for the general clinics.

Could you just specify a little bit more of how you're defining that because I know you do have the rule (SCH) 7.1% adjustment in the rule? So, do you consider hospitals that are redesignated as rural to be in that category to be exempt for this purpose?

Emily Forrest: Hi Elise, is that something you can address or should we take the question offline.

Elise Barringer: I think if you could write it in just so that we can capture the nuances of our response, that would be great.

(Melanie Grant): Okay, where do I send that to?

Elise Barringer: (Melanie), the inbox is hospital_ODF@CMS.HHS.gov.

(Melanie Grant): Thank you.

Coordinator: Our next question comes from (Dale Gibson), your line is now open.

(Dale Gibson): Yes, I think my kind of answered my own question. You were talking about the critical access hospital being part of the rule, emergency help hospitals. But every now and then someone would only say the word rural and there's you know there's a classification of rural hospitals, and I'm assuming that those facilities will not be eligible for the Rural Emergency Hospital classification.

(Kianna Banks): Hi, this is (Kianna). So, the statute states that a facility would be eligible to seek conversion to a Rural Emergency Hospital if it was a critical access hospital or if it was a rural hospital with not more than 50 beds, and it has to have those classifications on it before the date of enactment of the Consolidated Appropriations Act which is December 27, 2020.

(Dale Gibson): Okay, so rural hospitals would be eligible.

(Kianna Banks): Rural hospitals with not more than 50 beds.

(Dale Gibson): Thank you.

(Kianna Banks): Mm-hmm.

Coordinator: Our next question comes from (Matt Sheldon) and your line is now open.

(Matt Sheldon): Hello. My questions may be slightly off-topic, but I was wondering if there's been any word if there will be any additional payments coming out from HRSA on the COVID patients.

Emily Forrest: Hi Matt, this is Emily Forrest. You don't have anybody on the line to address that particular question, but happy to direct you to the folks who work on that particular issue to get some clarification on your particular circumstance.

So, we would recommend that you email us at a hospital_ODF@CMS.HHS.gov and we can address the questions through that means.

(Matt Sheldon): Thank you.

Emily Forrest: Thank you.

Jill Darling: And we'll take one more question, please.

Coordinator: Our last question comes from (Marc Hartstein). Your line is now open.

(Marc Hartstein): Thanks, and so in response to the woman who asked the question previously about marriage and family counselors and licensed professional counselors, I think it's clear that they can their serve -- they cannot bill for their own services under the physician fee schedule, there would need to be a new benefit category for that.

But I think a question that she's raising that perhaps you can answer Dave is would they be -- would their services be billable as incident to service under the mental health benefit in the proposed rule for -- by the hospital as hospital outpatient services, if they were employed by the hospital?

David Rice: Thanks. Marc. Yeah, the question is if you know family and marriage counselors who are providing services for the hospital under the proposed codes that we talk about in the proposed rule, then the hospital can receive a payment under the OPPS for those service is assuming all the other requirements are met.

(Mark Hartstein): Right.

David Rice: Yeah. Assuming that question before, about a separate physician schedule payment of which we all -- is not discussed in the proposal, but the under the policy proposed in the OPPS rule, there is a facility side payment as described. Thanks, Mark.

(Mark Hartstein): Yeah, yeah, I agree. Just -- CMS can't expand the benefit under the physician schedule, that would require changes a lot but those kinds of practitioners, I agree, they could be paid under the incident to requirements when their employees of the hospital and the services are billed by the hospital, as long as they meet all of the requirements. So, thank you for the clarification.

Jill Darling: All right. Well, thanks everyone for joining us today. I'll pass it to Emily, for any closing remarks.

Emily Forrest: Thanks Jill and thanks to our speakers and all the folks on the line for all the questions today and being engaged on this rule. I just wanted to remind folks the comment period for the OPPS/ASC proposed rule closes on September 13th and the comment period for the Rural Emergency Hospital, Conditions of Participations rule closes on August 29th.

So, I would encourage folks to turn in comments as early as possible and appreciate everyone's participation on the call today. That concludes the call and I hope you have a great rest of your day.

Coordinator: Thank you for your participation. That concludes today's call. You may disconnect at this time. Speakers, please stand by. END