Centers for Medicare & Medicaid Services
Open Door Forum: Hospital/Quality Initiative
November 17, 2021
2:00 pm ET

Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen-only mode until the question -and-answer session of today's conference. At that time, you may press star 1 on your phone to ask a question. I would like to inform all parties that today's call is being recorded. If you have any objections, you may disconnect at this time. I would now like to turn the conference over to Ms. Jill Darling. Thank you. You may begin.

Jill Darling: Great, thank you, (Chelsea). Good morning and good afternoon, everyone, and welcome to today's Hospital Quality Initiative Open Door Forum. As always, we greatly appreciate your patience waiting for the open door forum to begin. Many factors are involved in trying to make sure we have everyone and folks coming from meetings. So again, we appreciate your patience.

I am Jill Darling in the CMS Office of Communications. Before we get into the 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 do have any inquiries, please contact CMS at Press@cms.hhs.gov.

And I'd like to hand the call off to Emily Forrest.

Emily Forrest: Thanks, Jill. Hi, everyone, this is Emily Forrest. Thanks for joining us today.

We have a full agenda today. We'll be providing an overview of the final policies that were in the CY 2022 OPPS/ASC-PPS Final Rule, which was issued on November 2nd.

If anyone has any COVID-related questions, we're also happy to address those to the extent that we're able. Also, on today's call - and finally, I wanted to highlight that on November 4th, CMS issued an emergency regulation requiring COVID-19 vaccination of eligible staff at healthcare facilities that participate in the Medicare/Medicaid program. Facilities covered by the regulation must establish a policy that ensures all eligible staff have received the first dose of a two-dose vaccine or a one-dose COVID-19 vaccine prior to providing any care, treatment or other services by December 5th of this year.

So, if folks have any questions related to that emergency regulation, I would encourage you all to review the FAQ document and Webinar slides that are also available on our website.

We have a full agenda, as we mentioned. But we will reserve some time at the end to take some questions on issues that we presented today, along with any hospital-related COVID questions.

So, without further ado, I'll turn it over to our first speaker, (Susan Janeczko), for an overview of the CY 2022 OPPS/ASC policies. But also, I would ask that each speaker state which topic they're briefing on prior to going into their remarks.

So, Susan --

(Susan Janeczko): Thanks, Emily.

So, I'll go ahead and start with a quick review of the OPPS payment rates and then turn it over to the team to discuss some of the policies included in the rule in just a little more detail.

So, in accordance with the Medicare statute, CMS is updating the calendar year 2022 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 5.7 percentage points for the productivity adjustment.

Now, a quick note on data here. For both the OPPS and ASC rate setting processes, we use the best available data so that the payment rates can accurately reflect estimates of the cost associated with furnishing outpatient services. Ordinarily, the best available claims data is the most recent set of 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, as the most recent complete calendar year of data prior to the public health emergency, are generally a better approximation of expected cost for calendar year 2022 hospital outpatient services for rate setting purposes.

As a result, CMS is generally using the calendar year 2019 claims data to set the calendar year 2022 OPPS and ASC payment system rates.

So, I'll go ahead and turn it over at this point to (AuSha Washington) to discuss the Inpatient-only list.

(AuSha Washington): Thanks, (Susan). Hi, this is (AuSha Washington) and I'll be covering the Inpatient-only list.

Since the beginning of the OPPS, CMS had maintained the Inpatient-only or IPO list, which is a list of services that due to their medical complexity, Medicare will only pay for it when performed in the inpatient setting. In the CY 2021 OPPS-ASC Final Rule, CMS finalized the policy to eliminate the Inpatient-only list over a three-year period, removing 298 services from the Inpatient-only list in the first phase of the elimination.

Throughout this process, CMS received the large number of stakeholder comments and following issuance of the final rule with comment period that opposed the elimination of the Inpatient-only list, primarily due to patient safety concerns, stating that the Inpatient-only list serves as an important programmatic safeguard.

In the CY 2022 OPPS-ASC Final Rule, CMS finalized the policy to halt the elimination of the Inpatient-only list and add back to the list the services removed in 2021, except for CPT codes 22630, Lumbar Spine Fusion, 23472, Reconstruct Shoulder Joint, and 27702m Reconstruct Ankle Joint, and their corresponding anesthesia codes.

We believe that this change in policy promotes transparency and ensures that any service removed from the Inpatient-only list has been reviewed against Medicare's longstanding IPO list criteria to determine if it is appropriate for Medicare to pay for the provision of the services in the outpatient setting.

Additionally, in the CY 2021 OPPS-ASC Final Rule, CMS established a policy in which procedures removed from the Inpatient-only list beginning in January of 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 Inpatient-only list beginning in CY 2021, due to the proposed elimination.

For CY 2022, because CMS finalized a proposal to halt the elimination of the Inpatient-only list and to return the majority of services removed in CY 2021 back to the list, CMS also finalized 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. That is a two-year period.

Now I will actually pass it over. And I believe that would be (Alison).

(Alison): Yes, thank you, (AuSha). So, this is for transitional pass-through for devices and drugs. So, in calendar year 2022, we received eight applications for a device pass-through, one of which we reviewed and approved through our quarterly review process. And it's consistent with our regular policy. We solicited public comment on all eight of those applications in the proposed rule. And we approved three of those devices for pass-through status in the final rule.

Additionally, we're continuing pass-through payment status for 46 drugs and biological. And that includes 27 drugs in biologicals for which we're using our equitable adjustment authority under Section 1833(t)(2)(E). And we're doing that because we're - since calendar year 2019 data rather than 2020 claims data is used to inform the 2022 rates, that's why we're using that equitable adjustment authority. And that is going to provide us the four quarters of separate payments for those drugs that would expire between December 31, 2021 and September 30, 2022.

And I will turn it back to (Susan).

(Susan Janeczko): Thanks, (Alison). So here I'll just discuss a quick update 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 ASC payment system rates for an interim period of five years. And that was 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 ASCs that meet applicable quality reporting requirements.

And next stop is - (Mitali) is up next.

(Mitali Dayal): Thanks, (Susan). This is (Mitali Dayal), and I'll be covering the changes to the ASC Covered Procedures List, or CPL.

So, in calendar year 2021, CMS revised the longstanding safety criteria that has historically been used to add covered surgical procedures to the ASC CPL and adopted a notification process for surgical procedures that the public believed could be added to the CPL under the criteria retained. Using the revised criteria, CMS added 267 surgical procedures to the CPL in calendar year 2021.

For calendar year 2022, CMS is reinstating the criteria that were in place in calendar year 2020 for adding procedures to the CPL. In the calendar year 2022 OPPS-ASC Proposed Rule, CMS requested comment on whether any of the 258 procedures proposed for removal from the CPL met the proposed reinstated criteria. CMS received 140 procedure recommendations, which included new procedures, as well as some procedures that were already on the CPL and not proposed for removal.

Based upon the review of these recommendations, CMS finalized retaining six procedures, three that were already on the CPL and three that were proposed for removal. CMS also finalized removing 255 of the 258 procedures proposed for removal. Additionally, CMS finalized the adoption of a nomination process beginning in March 2022 to allow external parties to nominate surgical procedures to be added to the CPL. If CMS determines that a surgical procedure meets the requirements to be added to the CPL, we would propose to add the procedure to the CPL for January 1, 2023. CMS intends to provide details on how procedures can be nominated early next year in order for commenters to be able to send in their nominations by March 2022.

Now I'll pass it along to (Cory Duke) for the Non-Opioid Section 6082 Summary.

(Cory Duke): Great. Thank you, (Mitali), and hello everyone. Again, this is (Cory Duke), and I will now cover our policy on payment for non-opioid pain management drugs and biologicals as authorized by Section 6082 of the SUPPORT Act.

The Section 6082 of the SUPPORT for Patients and Communities Act requires that the Secretary review payments under the Hospital Outpatient Prospective Payment System, as well as the Ambulatory Surgical Center Payment System for opioids and evidence-based non-opioid alternatives for pain management in order to ensure there are not financial incentives to use opioids instead of non-opioid alternatives.

For calendar year 2022, CMS is modifying its current policy to provide separate payments for non-opioid pain management drugs and biologicals that function as surgical supplies in the ASC setting when these products meet certain criteria as finalized in this rule.

For calendar year 2022, CMS is finalizing its proposal that a non-opioid pain management drug or biological that functions as a surgical supply in the ASC setting would be eligible for separate payment when such product is FDA-approved, FDA indicated for pain management or as an analgesic and has a per day cost above the OPPS drug packaging threshold. Accordingly, CMS finalized four HCPCS codes to receive separate payment when furnished in the ASC setting for calendar year 2022, as these products meet the criteria of this finalized policy.

So, thank you and this concludes my overview. And I will now turn it over to the next speaker, Terri Postma, to discuss hospital price transparency.

Terri Postma: Thanks, (Cory). This is Terri Postma, I'll be going over the CY 2022 OPPS and ASC Final Rule updates to the hospital price transparency regulations.

In final rule - well, by way of reminder, CMS finalized rules for hospital price transparency in 2019. Those rules became effective earlier this year on January 1st. In this final rule, CMS is making modifications to the hospital price transparency regulation that are designed to increase compliance with the requirements. They include the following: first, we finalized a policy to increase 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 $5500.

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 we 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 is updating the regulation's prohibition of certain activities that present barriers to access to the machine-readable files, specifically, requiring that the machine-readable file be accessible to automated searches and direct downloads.

And with that, I will turn it over to (Marcie O'Reilly).

(Marcie O'Reilly): Thank you, Terri. Hello everyone. In review, the Radiation Oncology Model will test whether prospective site-neutral modality-agnostic, episode-based payments made to physician group practices, including freestanding radiation therapy centers and the hospital outpatient department for radiotherapy episodes of care reduces Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries.

The CY 2022 OPPS-ASC Final Rule includes finalized modifications related to the Radiation Oncology Model. We have finalized that the five-year model performance period will start on January 1, 2022 and end December 31, 2026. The final rule also includes the following finalized modifications: we've

adjusted the pricing methodology by updating the baseline period to 2017 through 2019 and lowering the discounts to 3-1/2% and 4-1/2% for the professional component and technical component, respectively. We've removed brachytherapy from the included modalities and removed liver cancer from the included cancer types.

We finalized that in cases where a beneficiary switches from traditional fee-for-service to Medicare Advantage during an episode before treatment is complete, we will consider this an incomplete episode and RT services will be paid fee-for-service as opposed to the bundled payment.

We are excluding only those hospitals participating in the Pennsylvania Rural Health Model, or PARHM, not just PARHM-eligible hospitals. And we will be excluding hospital outpatient departments participating in the Community Transformation Track of the Community Health Access and Rural Transformation, CHART Model, and that the RO Model will follow the same policy for overlap between the RO Model and the Medicare Shared Savings Program, ACOs, for the CHART ACO Transformation Track.

And in light of the current public health emergency, or PHE, and several recent natural disasters, we finalized the addition of an extreme and uncontrollable circumstances, or EUC policy. This policy will give CMS the ability to offer flexibilities to reduce administrative burden of RO Model participation during an extreme and uncontrollable circumstance.

Please note that CMS announced on November 2nd that we have determined that there is currently an EUC based on the ongoing COVID-19 PHE. And unless the Secretary terminates his renewal of the COVID-19 PHE prior to January 1, 2020, CMS intends to invoke provisions of the EUC policy on the effective date of this final rule, which is January 1, 2022.

The flexibilities include the following: the requirement that RO participants collect and submit quality measures and clinical data elements will be optional in 2022; and because this requirement will be optional, the 2% quality withhold will not be applied to RO Model professional episode payments in 2022.

The requirement that RO participants actively engage with an AHRQ-listed patient safety organization, or PSO, will be optional in 2022. And the requirement that RO participants conduct peer review on treatment plans will also be optional in 2022.

It's important to note that opting out of these requirements in (PR-1) will not jeopardize an RO participant's advanced APM status. And CMS has also included clarifications in the final rule to answer questions from stakeholders and future participants about the relationship between RO Model and the Quality Payment Program. And I want to point you to a Webinar on December 15th that will further discuss the RO Model in QPP.

For more information, please reference the RO Model Web site at the URL included on today's agenda. And please note that the following items are now on the RO Model Web site. The RO Model-specific HCPCS codes and their trended national base rates are there. And the data dictionary for the data request and attestation, or DRA, that is available in the Radiation Oncology Model portal is there.

And speaking of the RO Administrative Portal, a ROAP, please log in there to see your participant-specific adjustments and your eligibility for the low volume opt-out. And it's important to note that you must choose, if you're eligible for the opt-out, you must choose to do so for Performance Year 1 by

December 31st. And also, in ROAP, you can submit a DRA to obtain your RO Model-specific claims data.

And for any questions related to the model's policy or RO participants seeking to get their RO Model ID, please contact the RO Model's Helpdesk at RadiationTherapy@cms.hhs.gov. And that email is also on the agenda.

Thank you. And, Jill, back to you.

Jill Darling: All right, thanks, (Marcie), and thank you to all of our speakers today.

(Chelsea), will you please open the lines for Q&A?

Coordinator: If you'd like to ask a question, please press star 1. Unmute your phone and record your name clearly when prompted. Again, please press star 1. Unmute your phone and record your name clearly when prompted. Our first question is from (Ronald Hirsch). Your line is now open.

Dr. (Ronald Hirsch): Thank you. And not surprisingly, I'm going to ask about the Inpatient-only list. And since CMS determined that performing those 290-whatever procedures is not yet shown to be safe to be performed as an outpatient and you're putting them back on the list, for the next 43 days, should hospitals only perform them as inpatient even though the guidelines for the admission under the Two-Midnight rule are not met?

Jill Darling: (Susan), is that something you're able to address today?

(Susan Janeczko): (Ausha), do you have any ideas on that one? I'm - the rule doesn't go into effect until January 1st, but potentially I'm misunderstanding what you're saying here.

Dr. (Ronald Hirsch): Well, what I'm saying is if you think that - and it might be (unintelligible) but if CMS thinks it's unsafe to perform these as an outpatient, and that's why you're putting them back on, then if we perform as an outpatient today when it's not on the Inpatient-only list, aren't we endangering a patient's life and safety by doing that? So therefore, shouldn't we do all of these as inpatient only immediately?

(Ausha Washington): So, Dr. (Hirsch), this is (Ausha) speaking. I think that is where we again impart to (Susan's) part - point the changes to the Inpatient-only list that were discussed today take place as of January 1st. In regards to the safety, we've always maintained that that clinical decision and that judgment of the appropriate site of service location is up to the physician and that patient beneficiary, in consideration of their specific needs in that moment.

I think with that, to answer your question at this time, those services that were not on the Inpatient-only list are allowed with their clinical determination for that specific beneficiary at this time.

Dr. (Ronald Hirsch): Okay. You're contradicting yourself but I'll accept it. Thank you.

Coordinator: The next question is from (Ina Bender).

Your line is now open.

(Ina Bender): Hi. Is CMS going to be holding any - is there any kind of a Webinar regarding GFE requirements? You know, we were like on several different calls today and there's a lot of, you know, technical questions about different scenarios when GFE will apply, how is it going to play out with Charity Care. Is CMS

planning to do any kind of training or service or sessions so people can ask questions?

Emily Forrest: Can you repeat what specific issue there you're referring to? I think my phone cut out when we were…

((Crosstalk))

(Ina Bender): The latest price transparency rules, the, you know, notifications that we have to provide to patients, there are a lot of technical questions around those rules. So, is CMS planning to have any kind of frequently asked questions sessions to go over these rules?

((Crosstalk))

(Ina Bender): Usually, CMS has done that in the past for new regulations.

Emily Forrest: Thank you. Yes, thank you for the question.

Terri, do you know if you guys are doing any Webinars on the price transparency policies in this rule?

Terri Postma: Hi. No, we're not planning on any. We have three open door forums that you can find online and we have a dedicated Web site related to the requirements of the hospital price transparency rule that has a lot of information about the rules...

((Crosstalk))

(Ina Bender): Well, not just price transparency; it's also about the estimates, the good-faith estimates we have to give to patients. Is that going to be covered in these open forums or is that something you will schedule some kind of a session?

Terri Postma: We - the No Surprises Act is a separate but related issue. And we don't have those experts on the line today.

((Crosstalk))

Emily Forrest: ...if you don't mind e-mailing us at hospital_odf@cms.gov, we can direct that question to the folks that work on the No Surprises Act requirements.

(Ina Bender): Okay, thank you. Yes.

Coordinator: I'm showing no further questions.

Jill Darling: All right. Well, thanks everyone for joining, unless Emily, do you have any closing remarks?

Emily Forrest: No closing remarks other than thanks everyone for joining. And please do reach out to us via e-mail if you do have any questions. Again, it's hospital_odf@cms.hhs.gov.

Thank you again. And this concludes today's call.

Coordinator: This concludes today's conference. All participants may disconnect at this time. Speakers, please stand by for the post-conference.

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