

Centers for Medicare and Medicaid Services
Hospital
Open Door Forum
Moderator: Jill Darling
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1:00 pm CT

Coordinator: Welcome and thank you for standing by. At this time, 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. All participants will remain in a listen-only mode for the duration of the call until the question and answer session. At that time if you would like to ask a question, you'll press start one. I would now like to turn the conference over to Miss Jill Darling. You may begin.

Jill Darling: Great. Thank you (Rebecca). Good morning and good afternoon everyone. I'm Jill Darling in the CMS Office of Communication and welcome to today's Hospital Open Door Forum. As always, we appreciate your patience. We try to get as many folks in as we can prior to the start of the all but we know those always can't make the call times so we'll kind of just get right into the agenda.

But as always, 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 inquiries, please contact CMS at press@cms.hhs.gov. So first, I'll hand it over to (Tiffany Swygert) who will begin for the Hospital OPPS payment Proposed Rule.

(Tiffany Swygert): Thanks Jill. Everyone, this is (Tiffany Swygert). Welcome to the call today. We'd like to provide an overview of the calendar year 2020 hospital outpatient perspective payment system and ambulatory surgical center payment proposed rule.

The proposed rule went on display at the federal register on July 29th and the proposed rule has a 60-day public comment period as usual. The proposed rule contains a number of policies many of which we will highlight today.

These policies further advance the agency's commitment to increasing price transparency, strengthening Medicare, rethinking rural health, unleashing innovation, reducing provider burden and strengthening program integrity.

As I mentioned, we'll be briefly highlighting some of the proposed policies that were included in the rule however we remind everyone that please to submit your public comments via one of the methods outlined in the proposed rule for consideration in the development of the final rule.

The public comment period deadline closes on Friday, September 27, 2019 and additionally, just as a reminder, since we are within the public comment period and the final rule has not yet been issued, we will not be sharing any information that is not already publicly available in the proposed rule.

However, we are happy to listen to your comments, questions and concerns and again, the official way to state your questions, comments and concerns for the record is through the public comment submission process.

So, we look forward to an engaging discussion today and with that, I will turn it over to (Steven Johnson) to provide the first couple of updates.

(Steven Johnson): Thanks (Tiffany). In the proposed statute, CMS is updating the OPPS payment rate by 2.7%. This update is based on hospital basket increase of 3.2% minus 0.5 percentage point adjustment for the multi-factor productivities.

Section 340B of the Public Health Service Act allows participating hospitals and other providers to purchase certain covered outpatient drugs at discounted prices from manufacturers.

In the CY2018 OPPTS/ASC final rule CMS is re-examining the appropriateness of the average sale price plus 6% payment methodology for drugs acquired through the 340B program given that the hospitals acquired these drugs at steep discounts.

Beginning January 1, 2018 (unintelligible) ASP minus 22.5% for certain payable drugs or biologicals that are acquired through the 340B program that hospitals paid under the OPPTS that is not accepted from the payment adjustment policy.

For CY 2020, CMS is proposing to continue the payment adjusted amount of the ASP minus 22.2% for certain (separately) payable drugs or biologicals that are acquired through the 340B program.

CMS also acknowledges the ongoing litigation pertaining to the 340B payment adjusted and solicits comments on alternative payment options for CY2020 and potential remedies for CY2018 and CY2019 payment in the event of an adverse ruling on the 340B payment policy by the United States Court of Appeals.

At this time, I would like to turn it over to my colleague (Elise Barringer) who will talk about the increase in utilization of outpatient services.

(Elise Barringer): Thank you (Steven). As finalized in the 2019 OPPTS final rule, CMS discussed completing the two-year phase in of a method to reduce unnecessary

utilization in outpatient services by addressing payments for clinic services furnished in the off campus hospital outpatient setting.

Clinic services are the most common billed under the OPPS. Currently Medicare and its beneficiaries often pay more for the same type of clinic visit in the hospital outpatient setting than in the physician office setting.

This change would result in lower copayments for beneficiaries and estimated savings for the Medicare program of \$810 million for calendar year 2020. For example, for a clinic visit accepted in an off-campus provider based apartment, the average beneficiary cost sharing is currently \$16 in calendar year 2019 but would be \$23 absent this policy.

With the completion of the two-year phase-in that cost sharing reduces to \$9 saving beneficiaries an average of \$14 each time they visit an off-campus department for a clinic visit in calendar year 2020.

Now I'll turn it over to my colleague (Scott Talaga) to talk about the 2019 ASC rate update.

(Scott Talaga): Thank you (Elise). In previous years, CMS has update the annual payment rates for ambulatory surgical centers, ASCs, by the percentage increase in the consumer pricing index for all urban consumers also known as CPIU.

In the calendar year 2019 OPPS/ASC final rule comment period we finalized our proposals to apply the hospital market basket update to the ASC payment system rates for an interim period of five years, calendar year 2019 through calendar year 2023

CMS is not proposing any changes to its policy to use the hospital market basket update for ASC payment system rates for calendar year 2020 through 2023.

Using the hospital market basket, CMS proposes to update ASC rates for calendar year 2020 by 2.7% for ASC's meeting relevant quality reporting requirements.

This change is based on the projected hospital market basket increase of 3.2% minus a 0.5% percentage point adjustment for multi-factor productivity. Now I'll discuss finalized changes to the ASC list of covered surgical procedures.

The ASC covered procedures list, CPL, is a list of covered surgical procedures that are paid by Medicare when furnished in an ASC. Covered surgical procedures are those procedures that are separately paid under the OPPS which would not be expected to pose a significant list to beneficiary safety and would not typically be expected to require active medical monitoring care at midnight following the procedure

Under current policy, covered surgical procedures include those prescribed by common procedural terminology, CPT codes that are within the surgical code range and other codes that directly crosswalk or are clinically similar to CPT codes within the surgical code range.

For calendar year 2020 CMS is proposing to add total knee (arthroplasty)) TKA, knee mosaicplasty and three coronary intervention procedures to the ASC/CPL that may be paid in both the hospitals in ASC setting.

CMS is soliciting comment on whether there should be any additional limitations on the provision of TKA or other procedures in the ASC setting.

Additionally, CMS is soliciting comments on how the agency could redesign the role of the ASC/CPL to encourage physician's ability to determine the setting of care as appropriate for a given beneficiary situation. And now I'll turn it over to my colleague (AuSha Washington) to discuss changes to the inpatient only list.

(AuSha Washington): Thank you (Scott). CMS is proposing to remove total hip arthroplasty from the inpatient only list making it eligible to be paid in both the hospital inpatient and outpatient settings.

We are also soliciting comments on whether several other procedures should be removed from the IPO list. These include two Arthrodesis procedures and four Laminectomy procedures. Now I will hand it over to my colleague, (Lela Strong) to discuss changes to review procedures removed from the IPO list.

(Lela Strong): Thanks (Asha). CMS is proposing to establish a one-year exemption of certain medical review activity for procedures removed from the inpatient only list beginning in calendar year 2020 and subsequent years.

Specifically, we're proposing that procedures that have been removed from the inpatient only list would not be eligible for referrals through recovery audit contractors or RACS for non-compliance with the two midnight rules within the first calendar year of their removal from the inpatient only list.

This proposal is not an exemption from the two midnight benchmark which states that basically services are appropriate for inpatient admission payment under Medicare Part A when a physician expects the patient to require a stay that crosses at least two midnights and admits the patient to the hospital based upon their expectations.

During the one-year exemption period procedures removed from the inpatient only list would also not be considered by the beneficiary family centered care quality organizations or BFCCQIOs in determining whether a provider exhibits persistent non-compliance with the two midnight rule for purposes of referral to the RACs nor would these procedures be reviewed by RACs for patient status.

BFCCQIOs would have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the two-midnight rule but claims identified as non-compliant would not be denied due to the site of service under Medicare Part A.

Now I'm going to turn it over to (Josh McFeeters) to discuss outpatient therapeutic services.

(Josh McFeeters): Thank you (Lila). For CY2020 CMS is proposing to change the generally applicably minimally required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished for all hospitals and CAHs.

Direct supervision means the physician must be immediately available to furnish assistance and direction throughout the performance of a procedure however the physician does not need to be in the room where the procedure is performed.

General supervision means the procedure is furnished under the physician's overall direction and control but that the physician's presence is not required during the performance of the procedure. This proposal would ensure a standard minimum level of supervision for each hospital service per incidence of physician service in accordance with the statute.

Also conditions of participation and state regulations related to physician supervision would continue to be in effect. Next, I will discuss the wage index.

As in previous years CMS is proposing to use the IPPS wage index as the wage index for the OPPS. In fiscal year 2020 the IPPS – in fiscal 2020, the IPPS proposed rule, CMS proposed a number of policies to address wage index disparities between a high and low wage index hospitals.

CMS is finalizing these policies in the FY2020 IPPS final rule so these wage index policies will be reflected in the final IPPS wage index starting in calendar year 2020. Now I'll discuss skin substitutes.

Skin substitute products are packaged with their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure.

Under current policy skin substitute products are either placed into a high cost or low cost group if they exceed either the mean unit cost otherwise referred to as the MUC or the per day cost, otherwise referred to as the PDC for these products.

Some stakeholders have raised concerns about significant fluctuations in both the MUC threshold and the PDC threshold from year to year. The fluctuations in the threshold may result in the re-assignment of several skin substitutes from the high cost group to the low cost group which under current payment rates may result in a significant payment difference for the same procedure.

CMS is proposing to continue our policy established in calendar year 2018 to assign skin substitutes to the low cost or high cost group. In addition, CMS presented (our) ideas to change how skin substitute products are going to be paid under the OPPS including (unintelligible) and establishing a single payment category such as a comprehensive APC between 4 and 12 weeks would be appropriate.

CMS solicits comments on these ideas and welcomes new ideas on how to pay for skin substitute products. I will now turn over the discussion back to my colleague (AuSha Washington).

(AuSha Washington): Thank you (Josh). Under the OPPS a device is typically packaged into the payment of the created surgical procedure however Medicare law provides for a temporary additional payment for devices that are approved for Medicare transitional device past due status for a period of up to three years

The intent of transitional device past due payment is to facilitate access for beneficiaries to new and innovative devices before the Medicare payment rate for the procedure is updated to reflect claims data that include the cost for such devices.

We received seven devices past due applications for the CY2020 proposed rule. Information on each of these applications is included in the proposed rule. There are no procedures to approve or deny any of the applications in the CY2020 proposed rule however we are soliciting comments before making final determinations on the application and the final rule.

Additionally, for transformative devices that meet the FDA breakthrough device designation CMS is proposing an alternative pathway under which qualifying and breakthrough devices would meet the substantial clinical

improvement beginning with applications received on or after January 1, 2020.

This is similar to a proposal implemented in the inpatient perspective payment system, IPPS final rule, where CMS also responded to public comments on how to revise the definition of substantial clinical improvement criterion for the device pass-through payments.

This proposal and comment solicitation are aimed at ensuring that Medicare beneficiaries have timely access to new therapies and reduce the uncertainty that interface with payment for these therapies.

Now I will be handing it over to my colleague (Anita Bhatia).

(Anita Bhatia): Thank you (AuSha). Good afternoon. I'm program lead for the hospital outpatient reporting program. CMS is proposing changes for this pay for reporting program to further meaningful measurement and reporting quality of care in the outpatient physical setting while limiting burden to support patients over paperwork.

CMS is requesting comments on utilizing a set of patient safety measures currently adopted for the ambulatory surgical center quality reporting program as this is an important area of clinical concern and would serve to increase program alignment.

Specifically, for the hospital outpatient quality reporting or OQR program, CMS is proposing to remove one web-based measure for the calendar year 2022 program year.

This is the external beam radio therapy or EBRT for bone metastases, the measure designated at OP-33. This removal is proposed on the basis that the cost associated with the measure outweighed the benefit of its continued use in the program as the complexity of reporting this measure places substantial administrative burden on hospitals.

CMS is requesting comments on adding to this program four patient safety measures previously adopted for the Ambulatory Surgical Center Quality Reporting Program. These are ASC-1, patient fall, ASC-2, patient burn, ASC-3, wrong site, wrong side, wrong procedure, wrong implant and ASC-4, all cause hospital transfer/ admission.

Thank you. I can now turn the presentation over to (Scott Lawrence) to speak on the prior authorization process in requirements for certain hospital department services.

(Scott): Thank you (Anita). Recently CMS has observed significant increases with respect to various outpatient department services that are likely cosmetic surgical procedures with limited Medicare coverage.

CMS is proposing to implement a prior authorization requirement using its authority in 1833(t)(2)(F) the following types of services – blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation – to assure these services are only billed when medically necessary.

Access is preserved by having set timeframes for contractors to complete reviews of prior authorization requests (ten days), and in expediting processing where the estimated timeframe in additional delays in care could seriously jeopardize the life or health of beneficiaries (two days).

Additionally, this proposal does not change any medical necessity documentation requirements.

We believe a prior authorization process for these outpatient department services would ensure that Medicare beneficiaries continue to receive medically necessary care while protecting the Medicare trust funds from improper payments and at the same time keep the medical necessity documentation requirements unchanged for providers.

We are proposing to begin the prior authorization requirement for these services in July 2020 to ensure sufficient outreach and education efforts for physicians, practitioners, and providers who perform and bill for these services.

And now, I'd like to pass the microphone to (Alpha Wilson) who will be discussing the requests for information regarding potential changes to the organ procurement organization and transplant center regulations. Thank you.

(Alpha Wilson): Thank you (Scott). Good afternoon everyone. The calendar year 2020 OPPS ASC proposed rule includes one proposed change to the organ procurement organization. That is OPO additions for coverage, EFC, and requests for information, RFI, regarding potential changes to the OPO and transplant center regulations.

Specifically, we propose to revise the definition of expected donation rate to match the scientific registry of transplant recipients. That's the SRTRs definition. In addition, we stated that we are considering a comprehensive proposal to update the CFCs for OPOs and possibly the conditions of participation. That is the COPs for transplant centers.

We therefore issued a request for information on what revisions may be appropriate for the OPO CFCs and the transplant center's COPs. We specifically asked that the public submit comments on certain key areas including the OPO outcome measures and whether the current measures accurately and reliably reflect an OPOs performance.

The impacts and consequences of the current OPO measures on an OPOs performance and the availability of transplantable organs, whether the certification and decertification processes for OPOs have an impact on organ procurement and transplantations.

Recommend on potential empirically based outcome measures for OPOs other than the currently existing measures, whether there are other indicators of quality that can be used for OPOs in the CFCs in addition to the outcome measures. And whether there are any transplant center COPs that conflict with or should be harmonized with other OPO CFCs.

We also requested comments on two potential OPO outcome measures. These specific measures are a measure of the actual deceased donors as a percentage of inpatient deaths among patients 75 years of age or younger with a cause of death consistent with organ donation and a measure of the actual organs transplanted as a percentage of inpatient deaths among patients 75 years or younger with a cause of death consistent with organ donations.

We are especially interested in the validity and reliability of these measures, appropriate parameters for these measures, how to determine what percentage indicates that an OPO performance is acceptable or successful, the benefits and unintended consequences of these measures and the impact of these measures on OPOs, transplant centers or organ donations and transplant recipients.

Finally, we're seeking comments on how revising the OPO outcome measures would benefit or negatively impact patient outcomes, access and quality of life. And now I'll pass it back to our moderator, Jill.

Jill Darling: Thank you (Alpha). Last on the agenda we have (Tiffany Jackson-Dickey) who will give transition updates on the beneficiary and family centered care quality improvement organizations.

(Tiffany Jackson-Dickey): Thank you Jill. Hello everyone. My name is (Tiffany Jackson-Dickey). I am the CMS representative for the case review work of the beneficiary and family centered care quality improvement organizations also known as the BFCCQIO. The case review work includes the BFCC-QIO handling of complaints and quality of care reviews, appeals of service terminations and hospital discharge notices and other types of case reviews for Medicare beneficiaries.

During last month's Open-door forum, I reported on the issues that have arisen based on the transition into a new contract period with the BFCCQIO contract with both KEPRO and Livanta. I specifically touched on the customer service issues with KEPRO.

They unfortunately were experiencing delays in responding to providers and beneficiaries as well as experiencing extreme call center wait times. I'm here today to provide another status update as it relates to the BFCCQIO transitions of states, their associated concerns and overall impact to the provider community.

We want to continue to provide transparent communication throughout this process and we remain committed to working with you in addressing your concerns as quickly as possible.

To-date, CMS in conjunction with BFCC-QIO KEPRO continues to take a number of steps to mitigate the situation. On August 14th of 2019 KEPRO held a conference call with the New England Hospital Association. This was an area that was greatly impacted by the transition.

During this conference call they formally introduced themselves as well as helped to bridge any gaps that may have still be in existence at the start of the transition. CMS continues to allow KEPRO for use of their online tracking system until CMS can replace it with similar functionality. All cases open as at July 14th can be tracked online for status updates.

As a result, KEPRO's timeliness rate has improved to 99% since we've last met. KEPRO is making significant progress on eliminating the backlog for executing the memorandums of agreement with providers.

I'm happy to report that the number of complaints has drastically decreased; however if there are any issues that may arise, providers may send their inquiries via email to qioconcerns@cms.hhs.gov. Thank you for your time and I'll turn it back over to Jill.

Jill Darling: Thank you (Tiffany) and thank you to all of our speakers today. (Rebecca), please open the queue for Q&A please.

Coordinator: Absolutely. If you would like to ask a question, press star one from your phone, unmute your line and record your first and last name clearly when prompted.

If you would like to withdraw your question, press star two. One moment while we wait for questions to queue. Our first question comes from (Ronald Hirsh). Your line is now open.

(Ronald Hirsh): Hi guys. First, I thought we'd get an update on who's going to do the short state reviews but since we haven't, I want to note that (Lela) mentioned that – the changes about the inpatient only list with the RACs and the QIOs and the first year changes.

But she also mentioned that it doesn't waive the requirement until the admissions meet the two-midnight benchmark. On a previous call (David Rice) did the same thing where he ignored the fact that there's an exception for patients who have a one midnight expectations but who are deemed high risk on a case by case basis.

And this exception is commonly used with total joint arthroplasty. Now I'm wondering if exclusion of mentioning that means that we cannot use that case by case exception for total joint arthroplasty?

And then my second question is, I'm wondering why the prior authorization program is not going to include physician processes or ambulatory surgery centers where there's much less oversight for medical complexity by compliance officers and such. Thank you.

(Tiffany Swygert): Hi Dr. (Hirsh). It's (Tiffany Swygert). I'll take the first question and if (Scott Lawrence) is still on the line, perhaps he can take your second question.

Regarding the first question, we did not propose a change to the case by case exception where when the physician believes in her clinical judgement that a one-day admission, inpatient admission, would be appropriate, that that is still

allowed. So, there were no proposed changes to that. That's why we didn't mention it.

(Scott), if you're still on the line, did you want to take the second question about program integrity from the physician office in ASC setting perspective?

(Scott): Certainly. Thank you. So, as part of our responsibility to protect Medicare trust funds, CMS will continue to review and analyze Medicare data and determine if and which additional outpatient department services exhibited unnecessary increase in volume for which prior authorization would be appropriate.

And we will propose any new additional services through rulemaking. So, we haven't necessarily finished the project. This is just where we're starting out. These were pretty clear options for us to test the system.

(Ronald Hirsh): Thank you.

Coordinator: As a reminder, if you would like to ask a question, please press star one from your phone, unmute your line and record your first and last name clearly when prompted. Our next question comes from (Sandy Sage). Your line is now open.

(Sandy Sage): Hi, this is a comment on price transparency. I know it really wasn't discussed today. But I did want to make a comment that it is stated several times in the proposed rule that contract information will be easily available for hospitals to access.

This is pretty much inaccurate for rural and critical access hospitals that do not have that information loaded into their systems. To post negotiated rates

from insurance companies will definitely be a burden on these hospitals and will also be costly.

So, if the goal is to reduce burden and cost to the Medicare program this will be contrary to that goal. If you consider that critical access hospitals that are reimbursed based on cost and spend an average of \$10,000 on apps or software just to accomplish the new guidelines; that alone would cost the Medicare program millions of dollars in cost reimbursement for those hospitals.

I think that the publishing of negotiated rates should be the responsibility of the insurance companies to let their beneficiaries know what their financial responsibility will be at a designated hospital and what out of network costs would be. ‘

Medicare has already published their information for the beneficiary. I think commercial insurers should have the burden to do the same with all the different variables. I think that it would be much more accurate that way but we do appreciate your transparency and openness with us.

And I just – I really didn’t have a question. I just wanted to mention that.
Thank you.

Tiffany Swygert: Thank you Miss (Sage). We do appreciate your comment and would encourage you to submit your comments and concerns via the public comment process.

We did not allocate time to discuss the price transparency provisions on today’s call because there was an earlier call that went into great detail on those provisions and that was a two-hour call.

So, we don't have folks here who can address that specific concern, but we do hope that you'll submit a public comment.

(Sandy Sage): Okay, thank you.

Tiffany Swygert: Thank you.

Coordinator: Our next question comes from (Ronald Hirsh). Your line is now open.

(Ronald Hirsh): Wow, nobody else has questions. Okay, so my first question. Okay, so what's the status of the short state QIO reviews? So it appears that (LaVanta) got a separate contract awarded but we don't know what that's for.

And then second, going back to the prior authorization process, it appears from the description in the final rule that all related claims will be denied if one of these surgeries occurs without prior authorization.

And will that go back to denying the radiologists, the pathologists, the anesthesiologists, et cetera or will it just be the surgeon and the facility performing the procedure?

Tiffany Swygert: Dr. (Hirsh), regarding your first question, (Tiffany), are you still on the line to address the question about the status of the short stay in patient reviews?

(Tiffany Jackson-Dickey): I am on the call however, do we have (Malini Krishan) on the line?

(Malini Krishan): Hi, yes, this is (Malini Krishan). And Dr. (Hirsh), thank you for your question regarding the status. Please do send your question on the short stay review

mailbox. I believe you've sent questions there before and we will respond to you. Thank you.

(Ronald Hirsh): Okay.

Tiffany Swygert: Okay, and I think the second question – you had a question about whether related claims would be denied under the prior authorization proposal. I'm going to go ahead and take that one just because it sounds like you're asking a question that wasn't articulated in the proposed rule itself.

So, (Scott Lawrence) can certainly make note of your question but that's not something that we could answer outside of the rulemaking process so that would be a great one to submit via public comment.

(Ronald Hirsh): You bet. Thank you.

Jill Darling: Thank you.

Coordinator: There are no other questions in queue at this time. As a reminder, if you would like to ask a question, please press star one from your phone, unmute your line and record your first and last name clearly when prompted. Just a moment while we wait for questions to queue.

(Tiffany Swygert): Hi. It sounds like there are no further questions. This is (Tiffany Swygert) chair of the Open Door Forum so we do appreciate everyone's participation today.

If you had a burning questions that you didn't get to ask, please send an email to the hospital Open-door forum mailbox at hospital_odf@cms.hhs.gov. And again, if your question is related to the proposed rule, the proposed OPPS

ASC 2020 calendar year rule, please do submit a public comment through one of the methods outlined in the proposed rule by the comment deadline which again is September 27.

Thank you everyone.

Coordinator: Thank you for your participation in today's conference. All parties may disconnect at this time. Leaders, please stand-by.

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