

Centers for Medicare & Medicaid Services
Hospital Open Door Forum
Thursday, July 25, 2024
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Jill Darling: Good morning and good afternoon, everyone. My name is Jill Darling, and I am in the CMS Office of Communications, and welcome to today's Hospital Open Door Forum (ODF). Before we begin with our agenda, I just have a few announcements. For those who need closed captioning, I will provide a link for you in the chat function of today's webinar. The webinar is being recorded. The recording and transcript will be available on the CMS Open Door Forum podcast and transcript webpage. That link is on the agenda. If you are a member of the press, please refrain from asking questions during the webinar. If you do have any questions, please email press@cms.hhs.gov. All participants are muted upon entry. For today's webinar, you will see this agenda slide up on your screen, and during the Q&A portion of the webinar, I will share a resource slide. We will be taking questions at the end of the agenda today. We note that we will be presenting and answering questions on the topics listed on the agenda for today. We ask that any live questions relate to the topics presented during the ODF webinar. If you have any questions unrelated to these agenda items, we may not have the appropriate person on the call to answer your questions. As such, we ask that you send any of your unrelated questions to the appropriate policy component, or you can send your email to the ODF resource mailbox, and we will try to get your question to the appropriate component for a response. You may use the raise hand feature at the bottom of your screen, and we will call on you when it's time for Q&A. Please introduce yourself and what organization or business you are calling from. When the moderator says your name, please unmute yourself on your end to ask your question and one follow-up question, and we will do our best to get to all of your questions today. And now, I will turn the call over to our Chair, Joe Brooks.

Joseph Brooks: Good afternoon, everyone. This is Joe Brooks and thank you very much for joining us today. As you can see on your screen, if you're joining us through your computer, during this Open Door Forum we'll be providing an overview of proposed policies in the calendar year 2025 OPSS (Outpatient Prospective Payment System) and ASC (Ambulatory Surgical Center) proposed rule, which was issued in July, and hopefully you've had a chance to take a look at that. I also wanted to make sure to emphasize that the public comment period for the CY (calendar year) 2025 OPSS and ASC proposed rule closes on September 9. Also, the Physician Fee Schedule proposed rule, which includes payment policies that impact services occurring in both the inpatient and outpatient settings, has a public comment period that closes on the same date, September 9. We encourage folks to get their comments submitted to us as early as possible to aid in our review of those comments, which also helps us get the responses and the final rule out as timely as we're able to. We'll also be discussing the CY 2025 ESRD

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(End-Stage Renal Disease) proposed rule and an upcoming conversion of grouper encoder code editor software. I also wanted to mention that we'll be reserving some time at the end to take some questions on the issues presented today. So, with that, I'll turn it over to the first presenter today, David Rice, to begin with providing an overview of the proposed payment rate updates from the calendar year 2025 OPPS proposed rule. David.

David Rice: Thanks, Joe. This is David Rice from the Division of Outpatient Care. To start off by talking about the 2025 OPPS ASC proposed rule, I'll be talking about the OPPS and ASC annual update. In accordance with Medicare law, CMS is proposing to update OPPS payment rates for hospitals by 2.6%. This update is based on the projected hospital market basket percentage increase of 3%, reduced by 0.4 percentage points for the productivity adjustment. In the 2019 OPPS and ASC final rule, CMS finalized the proposal to apply the productivity-adjusted hospital market basket updates to ambulatory surgical center payment system rates for an interim period of five years, which was from 2019 to 2023. In the 2024 final rule, we extended this for an additional two years through 2024 and 2025. So, accordingly, using the hospital market basket update, CMS is proposing to update ASC rates for 2025 by 2.6%. At this point, I'll pass it over to Cory Duke.

Cory Duke: Great, thanks, Dave. Hi everyone, this is Cory Duke with the Division of Outpatient Care. I will be covering the next several topics and the OPPS rule starting with Access to Non-Opioid Treatments for Pain Relief: Section 4135 of the Consolidated Appropriations Act (CAA) implementation. CMS is proposing to implement Section 4135 of the CAA 2023 in this proposed rule, which provides temporary additional payments for certain non-opioid treatments for pain relief in the hospital outpatient department, as well as the ambulatory surgical center settings starting January 1, 2025, through December 31, 2027. This proposal would implement several statutory provisions, including evidence requirements for medical devices, and the FDA-approved indications that meet the statutory requirements. To implement the statutory payment limitation under which the additional payment must not exceed the estimated average of 18% of the OPPS payment for the OPPS service or group of services with which the non-opioid treatment for pain relief is furnished, CMS is proposing to utilize the top five OPPS procedures by volume for each non-opioid drug or device in order to calculate the payment limitation. We are proposing that six drugs and one device qualify as non-opioid treatments for pain relief, and we propose these products be paid separately in both the HOPD (hospital outpatient department) and ASC settings starting in calendar year 2025. We are also soliciting comment from interested parties on additional products that may qualify for separate payment under this provision starting in calendar year 2025.

So next, I will cover the payment for specialized diagnostic radiopharmaceuticals. Starting with a bit of brief background, under the OPPS, the costs associated with the diagnostic rate of pharmaceuticals are packaged into the payment for the nuclear medicine tests in which they are used. While this payment approach generally works appropriately to support efficient care, in the proposed rule, we recognize that in some specific circumstances, the payment amount for the

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nuclear medicine tests may not adequately account for the cost of certain specialized diagnostic radiopharmaceuticals. In order to ensure Medicare payment policy is not providing a financial disincentive to using high-cost, low-utilization diagnostic radiopharmaceuticals, especially when those agents may be the most clinically appropriate, and to ensure appropriate access, we believe a subset of diagnostic rate of pharmaceuticals with higher per day cost should be paid separately and not packaged into the diagnostic procedure in which the radiopharmaceutical is used.

Consequently, we are proposing refinements to the existing packaging policy to improve the accuracy of the overall payment amounts by proposing to pay separately for any diagnostic radiopharmaceutical with a per day cost greater than \$630. This number is approximately two times the volume weighted average cost associated with diagnostic radiopharmaceuticals billed with nuclear medicine APCs (Ambulatory Payment Classifications). We would then remove these costs from the payment amounts for the nuclear medicine tests under our proposal. Any diagnostic radiopharmaceutical with a per day cost equal to or below that threshold would continue to be policy packaged with costs incorporated into the payment rates for the nuclear medicine tests. We proposed that 26 diagnostic radiopharmaceuticals will exceed this threshold and would be paid separately under this proposal. We propose to base the payment rate for diagnostic radiopharmaceuticals on mean unit cost data derived from hospital claims, and we are seeking comment on the use of average sales price data for determining the per day cost and setting the payment rate for diagnostic radiopharmaceuticals in future rulemaking.

Next, I will cover the gene and cell therapy exclusion from comprehensive APCs, or C-APCs. So, C-APCs and the OPSS create payment bundles for common surgeries and procedures performed in the hospital outpatient departments. A single payment is made for the C-APC, which includes ancillary items and services used to support that primary service, which includes drugs, regardless of their cost. In rare instances, the payment for very high-cost drugs, namely chimeric antigen receptor T-cell, or CAR T therapies and gene therapies, could be inadvertently packaged into the comprehensive APC even though the cell or gene therapy is not functioning as integral, ancillary supportive, dependent, and adjunctive to the primary C-APC service. Therefore, in our proposal, we are proposing to exclude payment for nine cell and gene therapies from being packaged when furnished with primary C-APC procedures. Additionally, we seek comment on whether there are other changes needed for C-APC payment or other classes of products provided with C-APC services we should consider under this policy for future rulemaking.

Lastly, I will cover the payment policy for devices and Category B and Investigational Device Exemption (IDE) clinical trials and drugs and devices with a Medicare coverage with evidence development designation. So, in the calendar year 2023 OPSS final rule comment period, we finalized the policy to make a single blended payment for devices and services and Category B Investigational Device Exemption studies in order to preserve the scientific validity of these studies by avoiding differences in Medicare payment methods that would otherwise reveal the group, treatment or control, to which a patient had been assigned. In this proposed rule, we

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clarified that CMS would pay for Category B IDEs with no control arm, provided the studies meet the coverage criteria. In those circumstances, Medicare payments would be made using the usual Medicare payment methodologies. Specifically for calendar year 2025, we are proposing to utilize a payment methodology that is similar to the one developed for Category B IDE clinical trials, but for drugs and devices covered under a national coverage determination (NCD) that uses the coverage with evidence development paradigm and requires a payment adjustment in order to preserve the scientific validity of that study.

Specifically, we propose to develop alternative methods of payment under Medicare Part B for drugs and devices being studied in clinical trials under a CED (coverage with evidence development) NCD. These CED NCDs will be listed on the CMS CED website, and similar to our policy on devices and Category B IDE trials for drugs or devices under a coverage with evidence development, we propose to make a single blended payment rate that would be dependent on the specific trial protocol and would account for the frequency with which the investigational drug or device is used. So next, I'll hand it over to Mitali Dayal to discuss the changes to the ASC CPL (Ambulatory Surgical Center Covered Procedures List).

Mitali Dayal: Thanks, Cory. I'll be covering the changes to the ASC Covered Procedures List, or CPL. The CPL specifies the list of procedures that can be safely performed in an ASC setting. CMS evaluates the ASC CPL each year to determine whether procedures should be added to or removed from the list. In the calendar year 2025 OPSS ASC proposed rule, CMS is proposing to add 20 medical and dental surgical procedures to the list. Now, I'll pass it back to David Rice for remote services.

David Rice: Thanks, Mitali. So, for remote services, CMS is clarifying in this proposed rule that for OPSS payment for services furnished remotely by hospital staff to individuals in their homes, including remotely furnished outpatient therapy services, diabetes, self-management training and medical nutrition therapy services and mental health services that we would anticipate aligning our requirements with those associated with Medicare telehealth and billed under the Physician Fee Schedule.

Moving next to the add-on payment for domestically produced Technetium-99 (Tc-99). Technetium-99, which is the radioisotope used in most diagnostic imaging services, is historically derived from legacy reactors outside of the United States using highly enriched uranium. Beginning in 2023, we finalized a policy to provide an additional payment of \$10 for the marginal cost of Technetium-99 produced by non-highly enriched uranium sources. 2025 is the final year of the add-on payment for Technetium-99 when it's produced without the use of highly enriched uranium (HEU), as the Secretaries of Energy and Health and Human Services have issued a certification that there's a sufficient global supply of Technetium-99 without the use of highly enriched uranium available to meet the needs of patients in the United States.

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However, the Department of Energy and other interested parties have identified another issue that is affecting the domestic supply chain for Mo-99 (Molybdenum-99), the source material for Technetium-99, that could cause payment inequity among outpatient hospital providers. Foreign Mo-99 production has historically been subsidized by their governments, resulting in prices below the true cost of production. We propose to address this payment inequity in this rule by establishing a new add-on payment of \$10 per dose for radiopharmaceuticals that use Technetium-99 derived from domestically produced Mo-99 starting on January 1, 2026. We believe this \$10 add-on payment for domestically produced Tc-99 would ensure equitable payments by providing providers who use domestically produced Tc-99 radiopharmaceuticals, when available, an amount that reflects the anticipated higher costs of these products. The \$10 add-on payment will help to preserve provider and beneficiary access to domestically produced Technetium-99 radiopharmaceuticals by addressing the additional cost of domestically produced Technetium-99 radiopharmaceuticals. At this point, I will pass it over to Elise Barringer.

Elise Barringer: Thanks, Dave. Today, I'll be discussing the all-inclusive rate add-on payment for high-cost drugs provided by Indian Health Services (IHS) and tribal hospitals. Under current regulations, IHS, or Indian Health Service, and tribal hospitals are excluded from payment under the OPSS. Instead, IHS and tribal outpatient departments are paid the Medicare outpatient hospital AIR, or all-inclusive rates, for each encounter that provides outpatient services. IHS calculates and updates the AIR yearly based on a review of the previous year's cost reports. Additionally, the calendar year all-inclusive rates are published in the Federal Register. For calendar year 2024, the outpatient AIR is \$667 in the lower 48 states and \$961 for Alaska. IHS and tribal hospitals have continued to expand the breadth of services that they provide to their communities. Increasingly, this has meant providing higher-cost drugs along with more complex and expensive services such as cancer-related treatments.

There are IHS and tribal hospitals providing specialty services where the AIR might not be an adequate representation of the hospital's cost to provide services to people with Medicare. This could be a significant equity and beneficiary access concern if IHS and tribal hospitals are not able to provide high-cost drugs or other services to the populations they serve. To improve the payments to IHS and tribal hospitals and to better account for the costs of high-cost drugs furnished to people with Medicare seeking care at these facilities, we are proposing a separate or additional payment to IHS and tribal facilities for high-cost drugs furnished in a hospital outpatient department. This payment would be in addition to the AIR. In order to receive the additional payment, we are proposing that qualifying drugs must exceed the threshold of two times the lower 48 AIR. Using the 2024 AIR as an example, for the calendar year 2024, the drug would have to have per day costs over \$1,334 or two times \$667 in order to receive an additional payment. In Addendum Q of the calendar year 2025 OPSS ASC proposed rule, we have modeled a list of 325 qualifying drugs using the two times the calendar year 2024, lower 48 AIR as the cost threshold. We were proposing to price the additional payment amount for each qualifying drug at the average sales price, or ASP. This is consistent with OPSS payment for most drugs, which uses the ASP payment methodology of ASP plus six but recognizes the fact that IHS and

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tribal facilities primarily obtain their drugs through the federal supply schedule, whose rates are significantly lower than ASP. In addition to these proposals, we are seeking comments on how to set the payment threshold, aligning this policy with the treatment of biosimilars under the OPSS, and if it will be appropriate to pay ASP plus 6% for qualifying drugs above the threshold. And now I'll turn it over to Molly Anderson.

Molly Anderson: Thanks, Elise. Today, I'll be going over the proposed health and safety standards for obstetrical (OB) services in hospitals and critical access hospitals that appeared in the OPSS proposed rule. As part of CMS' ongoing efforts to address the nation's maternal health crisis, we are proposing revisions to the Hospital and Critical Access Hospital (CAH) Conditions of Participation (CoP). Specifically, we have proposals across five topic areas, including a new obstetrical services CoP as well as revisions to the current quality assessment and performance improvement, or QAPI, requirements and current emergency services requirements. These proposals were informed by our request for information (RFI) on maternal health in the IPSS proposed rule, as well as other stakeholder outreach.

To begin, we have our OB organization staffing and delivery of services proposal. We are proposing a new obstetrical services CoP, which would require that if a hospital or CAH (critical access hospital) offers OB services, such services must be well organized in accordance with acceptable standards of practice, match the facility's scope of services, be consistent with the needs and resources of the facility, and be integrated with the other departments of the facility. We also proposed that the OB patient care units be supervised by an individual with the necessary training—specifically an experienced registered nurse, certified nurse midwife, nurse practitioner, physician assistant, or doctor of medicine or osteopathy. We additionally proposed that labor and delivery rooms have certain basic resuscitation equipment readily available, as well as adequate provisions and protocols for obstetrical emergencies.

Moving to obstetrical staff training. We are proposing that hospitals and critical access hospitals with OB services must develop policies and procedures to ensure that relevant staff are trained annually on key maternal health topics as identified by the facility's QAPI program. Further, we propose that facilities must use their QAPI program to inform ongoing staff training needs.

Revisions to QAPI for obstetrical services. Within the existing QAPI standards, we propose to add several enhancements related to obstetrical services. First, we proposed that for a hospital or CAH with OB services, OB leadership must be engaged in the facility's QAPI activities, and the facility must use its QAPI program to assess and improve outcomes and disparities among obstetrical patients, which would include analyzing data on OB patients by diverse subpopulations as identified by the facility and conducting at least one maternal health improvement project each year. Additionally, we propose that if a Maternal Mortality Review Committee, or MMRC, is available at the state or local jurisdiction in which the facility is located, the facility must have a process for incorporating MMRC data and recommendations into the facility's QAPI program.

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Next, we have emergency services readiness. Within the existing hospital and CAH emergency services CoP, we propose to require that facilities offering emergency services must have adequate provisions and protocols for the care of patients with emergency conditions, including but not limited to patients with OB emergencies, in accordance with the facility scope of services. For hospitals, we further propose the equipment and supplies used in treating emergency cases are kept at the hospital and are readily available. This proposal mirrors the existing conditions of participation for critical access hospitals and rural emergency hospitals for emergency supplies.

Lastly, transfer protocols. Within the existing discharge requirements for hospitals, we propose to require that hospitals have written policies and procedures for transferring patients under their care, inclusive of hospital inpatients, to the appropriate level of care, including to another hospital to meet the patient's needs. We welcome comments from a wide range of stakeholders on how these proposals could impact maternal health and safety. I'll now pass it to Amy Miller to cover the PHP (partial hospitalization program) and IOP (intensive outpatient program) rate updates. Thank you.

Amy Miller: Thanks, Molly. The calendar year 2025 OPSS ASC proposed rule would update Medicare payment rates for partial hospitalization program services and intensive outpatient program services furnished in hospital outpatient departments and community mental health centers. We are proposing to maintain the existing rate structure with two IOP APCs for each provider type and two PHP APCs for each provider type. One for four days with three services per day and one for days with four or more services per day. Consistent with the OPSS for this calendar year '25 rate setting, we are proposing to use the calendar year 2023 claims data and the latest available cost information from cost reports beginning three fiscal years - three years prior to 2025. We are also proposing to maintain the calculation of both hospital outpatient and community mental health center IOP payment rates and PHP payment rates for three services per day and four or more services per day based on cost per day using OPSS data that includes PHP and non-PHP days. We believe continuing to use the OPSS dataset will allow us to capture data from hospital claims that are not identified as PHP but that include the service codes and intensity required for a PHP day. I will now pass it to Abby Ryan to discuss the calendar year '25 End-Stage Renal Disease proposed rule.

Abby Ryan: Hi, thank you very much. I'm Abby Ryan, and I am the Deputy Division Director for ESRD PPS (Prospective Payment System) within the Chronic Care Policy Group. I'm here today to talk about one of our proposals that are included in the calendar year '25 ESRD PPS proposed rule. On June 27, CMS issued this proposed rule to update the rates and the policies, and it also included a request for information under the ESRD PPS for renal dialysis services furnished to Medicare beneficiaries on or after the first of January 2025. This rule appeared in the Federal Register on July 5. In this rule, CMS is proposing a new ESRD specific wage index that would be used to adjust ESRD PPS payment for geographic distances in area wages. The

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proposed methodology would combine data from the Bureau of Labor Statistics (BLS) Occupation Employment and Wage and Statistics and freestanding ESRD facility cost reports to produce an ESRD PPS specific wage index for use instead of using the hospital wage index values for each geographic area, which are derived from hospital cost report data. This rule may be viewed in the Federal Register and we are asking everyone that is on this call that if you choose to please comment on the rule. The comment period closes by August 26, 2024, and on the call, we have two subject matter experts, Russell Bailey, and Nicholas Brock, to answer any questions about this new proposal using the BLS as a basis for our new proposed wage index. Thank you and I will pass it to Wil Gehne.

Wil Gehne: Thanks, Abby. My name's Wil Gehne—I work in the Provider Billing Group. CMS provides case mix grouping and code editor programs to the public, including the Inpatient Hospital MS DRG Grouper, the Inpatient Medicare Code Editor, MCE, and the Integrated Outpatient Code Editor, IOCE. These programs use Java software and are currently based on Java version 8. Support for Java version 8 will end by November 2026. So, hospitals and software vendors who implement these programs in a mainframe environment will be impacted by this change. CMS is preparing now to convert these programs to Java version 17. For the upcoming fiscal year 2025 the MS DRG, MCE, and IOCE releases will include two COBOL (Common Business-Oriented Language) Java bridge programs instead of the one that is currently delivered. We'll continue to provide the existing bridge module that utilizes the 31-bit Java 8 Java Virtual Machine, or JVM, environment. We'll also provide a new bridge module that will utilize the 64-bit Java 17 JVM. The Java jar file for each book continues to be compiled using Java 8. This will preserve backwards compatibility for all existing mainframe deployments, both batch and CICS (Customer Information Control System). The installation guides for the programs will provide notice of the changes. This new Java bridge will allow users to test upgrades to their system over the next year to prepare for the move to Java 17. The fiscal year 2026 releases of these programs, effective October 2025, will be compiled with Java 17, and only the Java 17 64-bit COBOL calling module will be delivered. So, providers and their software vendors should begin planning this year to ensure they're prepared for this conversion in the fall of 2025. If you have questions about the Java 17 conversion, you can send them at any time to the resource mailbox that should be on your agenda. It's [GrouperBetaTesting](mailto:GrouperBetaTesting@cms.hhs.gov). That's all one word: GrouperBetaTesting@cms.hhs.gov. Thanks. Jill.

Jill Darling: Thank you, Wil, and thank you to all of our speakers today. We will be going into our Q&A. So, if you have a question or comment, please use the raise hand feature at the bottom of your screen for one question and one follow-up, and we will just wait one moment for any hands.

Jackie (Moderator): All right. Saeed, I think, is how I pronounce it. You're able to unmute, Saeed Ahmad. You're able to unmute.

Saeed Ahmad: That was my mistake, sorry.

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Jackie (Moderator): Oh, OK. No problem. That is the only hand I see right now, Jill.

Jill Darling: OK. We can just give it another moment. In the meantime, if you do, if you'd like us to send any of these helpful links to you through the chat, please raise your hand and let us know. I know it was sent out in the agenda for you. We do have one more hand. A couple more.

Jackie (Moderator): OK, let's do Ronald. I saw your hand first. You're able to unmute.

Ronald Hirsch: Hi there. It's Ron Hirsch with R1. I just want clarification on the non-opioid drug extra payment. That extra payment has been in place for ambulatory surgery centers for several years. So, the proposal really is just to add it to the outpatient hospital setting, or is there a change with the ASC payment other than adding the on-queue device?

Cory Duke: Hi Ronald, this is Cory Duke. Yeah, just to clarify here, the current non-opioid payment that you described in the ASC setting is authorized by Section 6082 of the Support Act. While similar, for 2025, we are implementing our proposal based on the statutory authority in Section 4135 of the Consolidated Appropriations Act.

Ronald Hirsch: Thank you. Now I get it.

Cory Duke: Yep. Thank you for your question.

Jackie (Moderator): All right. It looks like Emily, you are able to unmute.

Emily Phillips: Oh, yes, sorry. I was just looking for the list of these links to be sent out, so thank you for that and I appreciate the update today.

Jill Darling: Sure, I can send them out as the questions go on. Just give me a moment to get it all set up. OK.

Jackie (Moderator): All right. It doesn't look like we have any hands currently. If there's anyone else while Jill's doing that has questions?

Jill Darling: OK, there are no more hands, which is totally fine. That's wonderful. If you do have any other questions or comments, we have the Hospital ODF email up—this first one listed. So please send any questions or comments in. Again, we thank you for joining us, and we hope you all have a wonderful day. This concludes today's call. Thank you.

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