Policy Update

CMS Releases CY 2025 Hospital Outpatient Prospective Payment and ASC Payment Systems Final Rule

On November 1, 2024, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2025 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Final Rule [CMS-1809-F], which includes finalized policies to update payment rates and regulations affecting Medicare services furnished in hospital outpatient and ambulatory surgical center (ASC) settings beginning in CY 2025.

For CY 2025, CMS increased payment rates under the Hospital Outpatient Prospective Payment System (OPPS) and the ASC Payment System by 2.9%. In continuation of an existing policy, hospitals and ASCs that fail to meet their respective quality reporting program requirements will be subject to a 2% reduction in the CY 2025 fee schedule increase factor.

CMS estimates, based on the policies, that total payments to OPPS providers and ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case mix) for CY 2025 will be approximately $87.7 billion and $7.4 billion, respectively. This growth represents an increase of approximately $4.7 billion and $308 million, respectively, from CY 2024 payment levels.

Key takeaways from the CY 2025 OPPS and ASC Payment System Final Rule:

- CMS did not expand the categories of services subject to prior authorization but finalized a policy to harmonize the timeline for review for non-urgent services and procedures.
- CMS finalized its proposal to make separate payment for non-opioid treatments (including drugs and devices) for pain relief.
- CMS finalized the revision to its current bundling policy for diagnostic radiopharmaceuticals to separately pay for high-cost radiopharmaceuticals with a per-day cost over a specific threshold.
- CMS finalized updates to the ASC covered procedures list (CPL) by adding 21 medical and dental surgical procedures to the list. CMS finalized a decision to remove one code – not originally noted in the proposed rule – from the inpatient only (IPO) list for CY 2025.
- CMS will continue to apply a productivity-adjusted hospital market basket update to ASC payments for CY 2025.
- CMS finalized the policy to expand coverage of colorectal cancer (CRC) screening tests.
- CMS finalized its policy to create exceptions to the Medicaid clinic services benefit four walls requirement.
- CMS finalized new conditions of participation (CoPs) for obstetric services and emergency readiness but will phase in the new requirements over two years.
- CMS finalized its proposals for new quality measures focused on health equity and social drivers of health (SDOH) and reviewed information on how to further address patient safety.

McDermott+ has developed a **dashboard** that shows total Medicare fee-for-service payment rates, volumes and geometric mean costs for outpatient stays by HCPCS and APC, as calculated by CMS for the 2025 OPPS final rule. This information can be used to identify the codes driving changes in cost at the APC level over time.

- The finalized regulations are available here.
- The press release is available here.
- The fact sheet is available here.

OPPS Major Policies

Changes in APC Groupings or Comprehensive APCs

Key Takeaway: CMS finalized its policy to exclude cell and gene therapies from C-APCs starting in CY 2025.

Under the OPPS, CMS assigns items, services, and procedures to ambulatory payment classifications (APCs) that are used to set payment rates. The APCs are organized such that each group is intended to be homogeneous both clinically and in terms of resource use. Starting in 2015, CMS began implementing comprehensive APCs (C-APCs) that include a primary service and all adjunctive services provided to support the delivery system of the primary service.

For CY 2025 and subsequent years, CMS finalized its policy to exclude cell and gene therapies from C-APC packaging. The basis for this policy is that, per CMS, these therapies are not supportive or adjunctive to the primary C-APC service; rather, these therapies are independent services. CMS finalized the policy with modifications by applying it to CY 2025 and subsequent years, and by adding CASGEVY to the list of cell and gene therapies excluded from C-APC packaging. This new policy will apply to the cell and gene therapies listed below that do not have pass-through status or whose pass-through status expires in CY 2025.

Trade Name	HCPCS Code	Long Descriptor
Yescarta	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Kymriah	Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Provenge	Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion
Tecartus	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Breyanzi	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Abecma	Q2055	Idecabtagene vicleucel, up to 510 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Carvytki	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose

Trade Name	HCPCS Code	Long Descriptor
Luxturna	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes
Zolgensm	J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes
CASGEVY	J3392	Injection, exagamglogene autotemcel, per treatment

Source: Table 4, CY 2025 OPPS Final Rule, Display Copy

CMS also finalized its policy to keep the five-level structure to the Neurostimulator APC Family, but did not finalize its proposal to assign 0266T and 33276 to APC 5465 for Level 5 Neurostimulator and Related Procedures. Procedure codes 0266T and 33276 maintain their assignment to APC 1580 for New Technology Level 43 ($40,001 – $50,000).

Non-Opioid Treatments for Pain Relief

Key Takeaway: CMS finalized a policy to make temporary separate payments for six drugs and five devices for non-opioid treatment of pain relief.

Section 4135 of the Consolidated Appropriations Act (CAA), 2023, provides for temporary separate payments for certain non-opioid treatments for pain relief in both the hospital outpatient department (OPD) and ASC settings from January 1, 2025, through December 31, 2027. These separate payments are available for qualifying drugs, biologicals, and devices that have their payment packaged into payment for a covered OPD service (or group of services), among other requirements. Under the law, these temporary separate payments must be made in a budget-neutral manner.

In defining the drugs and biologicals subject to the non-opioid policy, CMS finalized that drugs and biologicals that are currently subject to the ASC policy for non-opioid treatments authorized by Section 6082 of the SUPPORT Act (for CY 2024, these are Exparel®, Omidria®, Dextenza®, and Xaracoll®) will instead receive separate payments, subject to the limitation, for the duration of the payment period for Section 4135.

In this final rule, CMS finalized its proposed definition of a non-opioid treatment:

- For drugs and biologicals, the product must have “a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body’s opioid receptors.”
- For medical devices, the product:
  - Must be “used to deliver a therapy to reduce postoperative pain, or produce post-surgical or regional analgesia.”
  - Is defined as having “an application under section 515 of the Federal Food, Drug, and Cosmetic Act that has been approved with respect to the device, been cleared for market under section 510(k) of such Act, or is exempt from the requirements of section 510(k) of such Act pursuant to subsection (l) or (m) or section 510 of such Act or section 520(g) of such Act.”
  - Must have “demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal.”

For medical devices, CMS finalized that it will review all data submitted during the public comment period to determine if the device demonstrates the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids

CMS finalized its policy to only approve separate payment for non-opioid drugs and biologicals with a label indication approved by the US Food and Drug Administration (FDA) to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors. For medical devices, CMS finalized that while the device is not required to have an FDA-approved indication for delivering a therapy to reduce postoperative pain or producing postsurgical or regional analgesia, such an indication is one way to show that the device is used for such a purpose.

CMS finalized as proposed that, for drugs and biologicals for non-opioid pain relief, the separate payment amount is the amount of payment for such products determined under Section 1847A of the Social Security Act that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the product. For medical devices, the separate payment amount is the amount of the hospital's charges for the device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the device. CMS finalized its proposal to assign a payment offset of $0 for the qualifying drugs, biologicals, and devices for CY 2025.

With respect to the payment limitation to which non-opioid drugs, biologicals, and devices are subject, CMS finalized its policy to base the statutory 18% payment limitation on the volume weighted average of the CY 2025 payment rates of the top five primary procedures by volume into which a non-opioid treatment for pain relief would have their payment packaged, absent this policy.

In the proposed rule, CMS listed non-opioid treatments for pain relief for which separate payment would be made. Commenters suggested additional non-opioid products for that list. In the final rule, CMS reviewed eight of the suggested products and approved four. CMS discussed, but did not review, additional products suggested by commenters, stating that these medical devices did not need to be evaluated under its policy because they did not directly deliver pain management therapies.

CMS's final list of qualifying products for separate payment is as follows. Products added to the list in the final rule are in **bold**.

Brand Name	HCPCS Code	Long Descriptor
Exparel®	C9290	Injection, bupivacaine liposome, 1mg
Omidria®	J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml
Dextenza®	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg
Xaracoll®	C9089	Bupivacaine, collagen-matrix implant, 1 mg
Zynrelef®	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg
Ketorolac Tromethamine Injection	J1885	Injection, ketorolac tromethamine, per 15 mg
ON-Q Pump	C98X4/C9804	Elastomeric infusion pump (*e.g.*, ON-Q* Pump with Bolus), including catheter and all disposable system components, non-opioid medical device (must be a qualifying Medicare

Brand Name	HCPCS Code	Long Descriptor
		non-opioid medical device for postsurgical pain relief in accordance with Section 4135 of the CAA, 2023)
SPRINT Peripheral Nerve Stimulator System	C9807	Nerve stimulator, percutaneous, peripheral (*e.g.*, SPRINT Peripheral Nerve Stimulation System), including electrode and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for postsurgical pain relief in accordance with Section 4135 of the CAA, 2023)
Cryo Nerve Block Therapy	C9808	Nerve cryoablation probe (*e.g.*, cryoICE, cryoSPHERE, cryoSPHERE MAX, cryoICE cryoSPHERE, cryoICE Cryo2), including probe and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for postsurgical pain relief in accordance with Section 4135 of the CAA, 2023)
ambIT Electronic Infusion Pump	C9806	Rotary peristaltic infusion pump (*e.g.*, ambIT Pump), including catheter and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for postsurgical pain relief in accordance with Section 4135 of the CAA, 2023)
Iovera System	C9809	Cryoablation needle (*e.g.*, iovera System), including needle/tip and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for postsurgical pain relief in accordance with Section 4135 of the CAA, 2023)

Source: Table 158, CY 2025 OPPS Final Rule, Display Copy

Prior Authorization Process for Certain Services

Key Takeaway: CMS added no new service categories for the hospital outpatient prior authorization process for CY 2025. However, CMS finalized changes to its review timeline for non-expedited (standard) requests to align with the CMS Interoperability and Prior Authorization Final Rule.

Beginning with CY 2020, CMS established a process through which hospitals must submit a prior authorization request for a provisional coverage affirmation before an outpatient service is furnished to a beneficiary and before a claim is submitted. The change applied initially to only five categories of services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation.

In CY 2021, CMS expanded the services subject to prior authorization, adding two new categories of services (cervical fusion with disc removal and implanted spinal neurostimulators) for dates of service on or after July 1, 2021.

CMS did not change the list of services subject to prior authorization in CY 2022 or CY 2024, holding steady with the previously established seven categories. In the CY 2023 rulemaking cycle, CMS expanded the services subject to this requirement, adding facet joint injections, medial branch blocks, and facet joint nerve destruction.

In February 2024, CMS sought comments on a new demonstration project called the Prior Authorization Demonstration for Certain ASC Services. In the notice, CMS stated that it intended to develop and implement the demonstration with a targeted implementation date of November 1, 2024, in 10 states. CMS stated that the focus would be on the same services that were subject to prior authorization in the hospital OPD setting in 2020.

For CY 2025, consistent with its approach in CYs 2022 and 2024, CMS implemented no changes to the list of service categories subject to the prior authorization process in the hospital outpatient setting, holding steady with the existing categories. However, CMS changed its timeline for review of non-urgent review requests from 10 days to seven days so that the timeline can be harmonized with the timeline previously outlined in the CMS Interoperability and Prior Authorization Final Rule released in February 2024.

Transitional Pass-Through Payment for Medical Devices

Key Takeaway: CMS approved eight medical devices for pass-through payment beginning in CY 2025.

Transitional pass-through payment for new devices is intended to allow for adequate payment of new innovative technology during the interval in which CMS collects the data necessary to incorporate the costs for these devices into the accompanying procedure's payment rate. Hospitals using devices that meet the requisite qualification criteria are eligible to receive transitional pass-through payment. CMS also has established an alternative pathway for devices approved under the FDA Breakthrough Device Program; these devices do not have to show substantial clinical improvement (one of the requisite criteria for other devices).

As part of its quarterly review cycle, CMS evaluated 14 applications for device pass-through payments – 10 through the alternative pathway for breakthrough designated devices and four through the traditional pathway. The agency preliminarily approved three devices, all of which qualified under the alternative pathway, during the quarterly review process. In the final rule, CMS approved eight applications submitted through the alternative pathway; two applications were withdrawn prior to the final rule. Of the four devices seeking approval via the traditional pathway, CMS did not approve any of the devices. None of the devices met the substantial clinical improvement criteria, and CMS found that two of the applicants were appropriately described by existing device categories and thus also failed to meet the newness criteria.

Taking into consideration the utilization estimates of the devices newly approved for transitional pass-through and the devices previously approved for CY 2025, CMS estimates that it will spend $318.1 million in pass-through for medical devices.

Key Takeaway: Pass-through status will expire for two medical devices at the end of CY 2024.

Medical devices that qualify for transitional pass-through are eligible for pass-through payments for no more than three years. As of the publication of the final rule, 12 devices have pass-through payment status. Table 112 in the display copy of the final rule lists the two devices with expiring pass-through status.

CMS did not propose or make any changes to its qualification criteria for transitional pass-through payments for medical devices in this year's rulemaking cycle.

New Technology APC

Key Takeaway: CMS will continue to exempt services assigned to new technology APCs with fewer than 10 claims over the four-year lookback period used for the universal low-volume policy.

The OPPS utilizes new technology APCs to pay for certain new services until CMS gathers sufficient claims data to enable it to assign the service to an appropriate clinical APC. To be assigned to a new technology APC, the service must meet certain criteria. Once assigned, a service is paid under a new technology APC until sufficient claims data have been collected (generally two to three years) to allow CMS to assign the procedure to a clinical APC group that is appropriate in clinical and resource terms. CMS assigns the new service to a new technology APC whose cost band includes the estimated cost of the new service.

Some services assigned to new technology APCs have very low annual volume, which CMS considers to be fewer than 100 claims in the year of claims data used for rate-setting. When utilization of services assigned to new technology APCs is low, it can lead to wide variation in payment rates from year to year, resulting in even lower utilization and potential barriers to access new technologies. This ultimately limits CMS's ability to assign the service to the appropriate clinical APC. To mitigate these issues, CMS finalized a policy in the CY 2019 OPPS/ASC final rule to use its equitable adjustment authority at Section 1833(t)(2)(E) of the Social Security Act to adjust how it determines the cost for low-volume services assigned to new technology APCs. In the CY 2022 OPPS/ASC final rule, CMS replaced the new technology APC low-volume policy with the universal low-volume APC policy that applies to clinical APCs and brachytherapy APCs.

For CY 2025, CMS finalized its policy to exempt services assigned to new technology APCs with fewer than 10 claims over the four-year lookback period used for the universal low-volume policy. Instead of assigning these services to a different new technology APC based on the very few claims available, CMS maintained the new technology APC assignment for each service from the prior year. CMS believes that it is appropriate to apply this policy to new technology APCs because these services represent new technologies for which it may be more challenging to determine an appropriate cost compared to other more established services.

For CY 2025, CMS assigned 58 devices to a new technology APC, including four new devices assigned. CMS did not make any changes to qualification criteria for new technology APCs for medical devices.

Revisions to the Inpatient Only List

Key Takeaway: CMS finalized the addition of three newly defined procedures to the IPO list and removed one add-on code from the IPO list.

CMS maintains a list of services that it perceives to be safely provided only in an inpatient setting, and precludes payment for these services under the OPPS. In CY 2024, CMS added nine services that were newly defined by the American Medical Association (AMA) CPT Editorial Panel to the IPO list.

In advance of the CY 2025 rulemaking cycle, stakeholders asked CMS to remove specific services from the IPO list. Consistent with standard practice, CMS reviewed the evidence supporting these requests and compared it against the five criteria used for evaluating procedures for removal from the IPO list. In the proposed rule, CMS stated that it did not find sufficient evidence to remove any procedures from the IPO list for CY 2025. However, one commenter requested that CMS remove CPT code 22848 (Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (List

separately in addition to code for primary procedure)) from the IPO list. The commenter stated that the service described by CPT code 22848 met the following criteria for removal:

- Most OPDs are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be furnished in most OPDs.
- The procedure is related to codes that CMS has already removed from the IPO list.
- A determination is made that the procedure is being furnished in many hospitals on an outpatient basis.

CMS agreed with the commenter. CMS removed CPT code 22848 from the IPO list and reassigned it to status indicator "N" (Items and Services Packaged into APC Rates), since it is an add-on code and will always be packaged.

For CY 2025, CMS finalized its proposal to add three services to the IPO list. The AMA CPT Editorial Panel newly created codes for these services (0894T, 0895T, and 0896T) for CY 2025. After clinical review of these services, CMS found that they required a hospital inpatient admission or stay and were not appropriate for payment under the OPPS. Therefore, CMS finalized its proposal to assign these services to status indicator ''C'' (inpatient only) for CY 2025.

CY 2025 Finalized Additions to the IPO List

HCPCS Code	CY 2025 Long Descriptor
0894T	Cannulation of the liver allograft in preparation for connection to the normothermic perfusion device and decannulation of the liver allograft following normothermic perfusion
0895T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; initial four hours of monitoring time, including hourly physiological and laboratory assessments (*e.g.*, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment)
0896T	Connection of liver allograft to normothermic machine perfusion device, hemostasis control; each additional hour, including physiological and laboratory assessments (*e.g.*, perfusate temperature, perfusate pH, hemodynamic parameters, bile production, bile pH, bile glucose, biliary bicarbonate, lactate levels, macroscopic assessment) (List separately in addition to code for primary procedure)

Source: Table 137, CY 2025 OPPS Final Rule, Display Copy

CY 2025 Finalized Removal from the IPO List

HCPCS Code	CY 2025 Long Descriptor
22848	Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (List separately in addition to code for primary procedure)

Source: Table 138, CY 2025 OPPS Final Rule, Display Copy

Site-Neutral Payments for Clinic Visits at Off-Campus Provider-Based Departments

Key Takeaway: CMS will continue to pay clinic visits provided by off-campus hospital OPDs at 40% of the OPPS rate.

Beginning in 2019, CMS implemented a policy that reduced OPPS payments to a rate equivalent to the Physician Fee Schedule (PFS) rate for clinic visits described by HCPCS code G0463 and furnished at off-campus provider-based OPDs that previously were excepted or grandfathered from site-neutral payment policies. CMS set the PFS-equivalent rate at 40% of the OPPS payment rate. Beginning in 2023, CMS implemented a policy that excepted from this payment reduction services furnished at off-campus provider-based OPDs of rural sole community hospitals.

For CY 2025, CMS made no changes to this policy.

Hospital OPD Payment for Telemedicine Evaluation and Management Services

Key Takeaway: CMS finalized its policy to not recognize the new telemedicine evaluation and management (E/M) services created by the CPT Editorial Panel effective January 1, 2025.

For CY 2025, CMS finalized its position to not recognize the new codes describing audio/video and audio-only telemedicine E/M services that were created by the CPT Editorial Panel effective January 1, 2025. Given the similarities between the new telemedicine E/M code set and the office/outpatient E/M code set, CMS believes that the new telemedicine codes fall within the scope of the hospital outpatient clinic visit policy because the predecessor codes (office/outpatient E/M codes 99201 – 99205 and 99211 – 99215) would be reported using code G0463.

In the proposed rule, CMS sought comments on the hospital resources associated with the telemedicine E/M services, particularly any resource costs that would not be included in the payment for G0463. CMS also requested feedback on:

- Whether the agency should finalize separate payment for these new telemedicine E/M codes under the PFS.
- Whether the agency should develop separate coding to describe the resource costs associated with a telemedicine E/M service.

CMS noted that it will take the stakeholder feedback under consideration in future rulemaking.

Diagnostic Radiopharmaceuticals

Key Takeaway: For CY 2025 and beyond, CMS will separately pay for diagnostic radiopharmaceuticals with a per-day cost (PDC) greater than a specified threshold.

CMS packages several categories of non-pass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Many stakeholders have urged CMS to always pay separately for diagnostic radiopharmaceuticals, and not just when the products have pass-through payment status. Stakeholders have said that the packaged payment rate after the expiration of pass-through status is often inadequate, especially in cases where the diagnostic radiopharmaceutical is high cost and has low utilization. Stakeholders have also expressed concerns that packaging payment for precision diagnostic radiopharmaceuticals in the outpatient setting creates barriers to beneficiary access for safety net hospitals serving a high proportion of Medicare beneficiaries.

In the CY 2024 proposed rule, CMS invited comments on potential modifications to its packaging policy for diagnostic radiopharmaceuticals. Specifically, CMS sought comments on the following payment alternatives:

- Paying separately for diagnostic radiopharmaceuticals with PDCs above the OPPS drug packaging threshold of $140.

- Establishing a specific PDC threshold that may be greater or less than the OPPS drug packaging threshold.
- Restructuring APCs, including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals.
- Creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials.
- Adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

CMS ultimately chose not to change its policy for CY 2024, in part because of a lack of clear consensus on the best payment alternative.

For CY 2025, however, CMS finalized a significant policy change whereby diagnostic radiopharmaceuticals will be separately payable if the PDCs exceed $630. CMS implemented this policy to address perceived financial disincentives that hospitals currently face with regard to high-cost, low-utilization diagnostic radiopharmaceuticals that may be the most clinically appropriate agent for a diagnostic service. CMS calculated this threshold by determining the volume-weighted average policy packaged offset amount for the nuclear medicine APC series and multiplying by two. This approach is consistent with other OPPS policies such as the two-times rule violation and will ensure that only diagnostic radiopharmaceuticals whose costs significantly exceed the estimated amount of payment attributed to these radiopharmaceuticals in the procedures will be eligible for separate payment. CMS intends to update the separately payable threshold ($630 for CY 2025) each year by updating with the Producer Price Index for Pharmaceutical Preparations.

For the diagnostic radiopharmaceuticals that qualify for separate payment, CMS finalized its policy to set the payment based on the mean unit cost (MUC) data submitted by hospitals. CMS will use MUC rather than average sales price (ASP) because of concerns regarding the accuracy of reported ASP, in light of the limited number of manufacturers currently reporting it.

Based on the finalized policy, 26 diagnostic radiopharmaceuticals (listed in Table 9) qualify for separate payment in CY 2025.

Skin Substitutes

Key Takeaway: CMS finalized its proposal, with modification, to continue its historic policy with respect to packaged skin substitutes for CY 2025.

CMS has a longstanding policy of packaging skin substitutes with their accompanying surgical procedure. CMS divides skin substitutes into high-cost and low-cost groups to ensure "adequate resource homogeneity among APC assignments." For CY 2025, CMS continued this policy of assigning skin substitutes to high-cost or low-cost groups based on the product's geometric MUC or PDC relative to the MUC or PDC threshold. The finalized MUC threshold for CY 2025 is $50 per cm^2 (rounded to the nearest $1). The finalized PDC threshold for CY 2025 is $833 (rounded to the nearest $1), a slight decrease from the CY 2025 proposed threshold of $840. Table 135 in the display copy of the final rule includes the CY 2024 and CY 2025 cost category assignments for each skin substitute product.

CBSA Updates

Key Takeaway: CMS finalized its proposal to update labor market configurations using more current census data. CMS finalized, for CY 2025, a policy continuing the low wage index hospital policy under the OPPS.

Following a decennial census, the US Office of Management and Budget uses updated population and commuting pattern data to update core-based statistical area (CBSA) configurations. CMS uses these geographic regions to delineate urban and rural areas and calculate the wage index, among other things. In this rule, CMS finalized its adoption of the new CBSA configurations as finalized in the fiscal year (FY) 2025 Inpatient Prospective Payment System (IPPS) Final Rule.

CMS finalized its proposal to include the low wage index hospital policy as part of the CY 2025 OPPS wage index despite the US Court of Appeals for the District of Columbia Circuit's decision in *Bridgeport Hosp. v. Becerra* vacating the low wage index policy and CMS's interim final action with comment period to remove the low wage index hospital policy for FY 2025 IPPS purposes. While CMS acknowledged that this would create a divergence between the OPPS wage index values in CY 2025 and the ultimate effective FY 2025 IPPS wage index values for some hospitals, the agency stated that it believes that the concerns related to the wage index that led to the application of this policy to the OPPS wage index in previous years continue to apply, and that the OPPS authority for wage adjustment factors continues to give CMS the authority to implement a budget-neutral low wage index hospital policy. CMS said that it will explore options for realigning the IPPS and OPPS wage index values through future rulemaking.

CMS finalized its policy to apply a 5% cap on any decrease to a hospital's wage index from its wage index in the prior FY. CMS also finalized a 5% cap on wage index decreases for CY 2025 for the ASC Payment System.

ASC Major Policies

ASC Covered Procedures List

Key Takeaway: CMS finalized its proposal, with modification, to update the ASC CPL by adding 21 medical and dental surgical procedures to the list.

CMS maintains a list of procedures eligible for reimbursement in the ASC setting. Each year, CMS reviews the ASC CPL to determine if there are services that should be added or removed.

For CY 2025, CMS updated the ASC CPL by adding 21 procedures, including 19 dental surgical procedures, to the list (see Table 154 in the display copy of the final rule). CMS initially proposed to add four medical and 16 dental surgical procedures to the list. However, two medical procedures were removed from the list because the codes are not currently permitted to be performed in the ASC setting based on the procedures' coverage with evidence development (CED). In the final rule, CMS provided additional insight into its rationale for not adding the other 71 codes requested for addition to the ASC CPL for CY 2025.

ASC Rate Update Based on the Hospital Market Basket

Key Takeaway: CMS finalized its proposal to continue to use the productivity-adjusted hospital market basket update to increase ASC Payment System rates consistent with its policy finalized in the CY 2024 final rule.

For CY 2019, CMS finalized a policy to apply the productivity-adjusted hospital market basket update to ASC Payment System rates for an interim period of five years (CY 2019 through CY 2023). CMS stated that it would use this period to assess whether there was migration of the performance of procedures from the hospital setting to the ASC setting, or any unintended consequences.

Because CMS found it difficult to disentangle the effects of the COVID-19 public health emergency from its analysis of whether the higher update factor for the ASC Payment System caused migration of procedures to the ASC setting, in the CY 2024 final rule CMS extended the interim period for which the productivity-adjusted hospital market basket update will apply to the ASC Payment System rates for an additional two years, CYs 2024 and 2025.

Using the hospital market basket update, CMS finalized a 2.9% increase in ASC payments for CY 2025. The update applies to ASCs meeting relevant quality reporting requirements. This increase is based on a hospital market basket percentage increase of 3.4% reduced by a productivity adjustment of 0.5 percentage points. In continuation of an existing policy, hospitals and ASCs that fail to meet their respective quality reporting program requirements are subject to a 2% reduction in the conversion factor for CY 2025.

OPPS and ASC Quality Policies

Hospital Outpatient, ASC, and Rural Emergency Hospital Quality Reporting Programs

Key Takeaway: CMS finalized new measures focusing on health equity and SDOH.

Outpatient Quality Reporting and ASC Quality Reporting Programs

The Hospital Outpatient Quality Reporting (OQR) and ASC Quality Reporting (ASCQR) Programs are pay-for-reporting programs. Providers must meet quality reporting requirements or receive a 2% reduction in their annual payment update.

CMS finalized several new quality measures, focusing on health equity and SDOH:

- Hospital/Facility Commitment to Health Equity, beginning with the CY 2025 reporting period.
- Screening for SDOH, beginning with voluntary reporting in the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period.
- Screen Positive Rate for SDOH, beginning with voluntary reporting in the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period.
- For OQR, CMS also finalized the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, beginning with voluntary reporting in CY 2026, followed by mandatory reporting beginning with the CY 2027 reporting period.

CMS removed the following OQR quality measures beginning with the CY 2025 reporting period:

- MRI Lumbar Spine for Low Back Pain.
- Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery.

CMS also finalized proposals to:

- Modify the immediate measure removal policy to an immediate measure suspension policy for adopted Hospital OQR Program measures.
- Require that electronic health record technology be certified to all electronic clinical quality measures available to report in the Hospital OQR Program.

- Publicly report the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients measure – Psychiatric/Mental Health Patients strata on the Compare tool hosted by the US Department of Health and Human Services.

The final rule summarized comments on a request for information (RFI) on specialty-focused and minimum case number reporting for ASCs, but did not take further action.

Rural Emergency Hospital Quality Reporting

CMS updates measures applicable to rural emergency hospitals (REHs) with changes that align with the OQR and ASCQR Programs. CMS finalized adoption of the following new measures:

- Hospital Commitment to Health Equity, beginning with the CY 2025 reporting period.
- Screening for SDOH, beginning with voluntary reporting in the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period.
- Screen Positive Rate for SDOH, beginning with voluntary reporting in the CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period.

CMS also finalized a policy to extend the reporting period for the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure from one year to two years beginning with the CY 2027 program determination.

Finally, CMS finalized that REHs must begin to report data under the REH Quality Reporting Program beginning on the first day of the quarter following the date that the hospital is designated as converted to an REH.

Request for Information on Hospital Star Ratings

Currently, Medicare publicly reports star ratings for hospitals, assigning ratings between one and five stars, to help patients compare different hospital performance. Ratings are based on data on the following measure groups: Safety of Care, Mortality, Readmission, Patient Experience, and Timely and Effective Care.

Given recent concerns about patient safety, CMS solicited feedback on whether the star rating methodology should be adjusted so that a hospital that performs in the bottom quartile in the Safety of Care measure group would be ineligible for the highest (five-star) rating. The RFI outlined options that would:

- Reweight the Safety of Care measure group.
- Apply an adjustment that reduces the star rating of any hospital in the lowest Safety of Care quartile by one star.
- Reweight the Safety of Care measure group combined with a policy-based four-star rating maximum.

Consistent with its historical approach to RFI responses, CMS outlined the comments received and noted that any modification to the overall hospital quality star rating methodology – including changes based on feedback on this RFI – would be addressed through future notice-and-comment rulemaking.

Other Major Policies

Medicaid Continuous Eligibility

Key Takeaway: The final rule codifies the CAA, 2023, requirement to provide 12 months of continuous eligibility to children under age 19 in Medicaid and the Children's Health Insurance Program (CHIP).

Medicaid and CHIP provide critical health coverage to more than 82 million Americans, including pregnant people, people with disabilities, and more than 37 million children. However, many Medicaid beneficiaries each year lose their coverage because of the cycle of enrollment and disenrollment, temporary changes in income levels, or administrative issues. Many of these individuals are still eligible for Medicaid. This issue is commonly referred to as Medicaid eligibility churn. The CAA, 2023, required that states permanently provide 12 months of continuous coverage in Medicaid and CHIP for children under the age of 19. (Prior to the CAA, 2023, states had the option to provide children with 12 months of continuous coverage through Medicaid and CHIP.) This final rule codifies the CAA, 2023, requirement to provide 12 months of continuous eligibility to children under the age of 19 in Medicaid and CHIP. CMS also finalized as proposed the removal of the option to disenroll children from CHIP during a continuous eligibility period for failure to pay premiums.

Medicaid Clinic Services Four Walls Exceptions

Key Takeaway: CMS finalized three new exceptions to the Medicaid clinic services benefit four walls requirement.

Medicaid clinic benefit regulations prohibit Medicaid reimbursement for "clinic services" provided outside of the four walls of a facility. During the COVID-19 pandemic, in order to ensure access to services, CMS permitted Indian Health Service (IHS) and Tribal facilities to continue to claim Medicaid reimbursement under the clinic services benefit for services provided outside of the four walls of the facility. CMS continues to extend this authority, which was set to expire in February 2025.

In the final rule, CMS finalized its proposal to add three exceptions to the four walls requirements:

- Clinic services furnished by IHS/Tribal clinics.
- Clinic services furnished by a clinic that is primarily organized for the care and treatment of outpatients with behavioral health disorders, including mental health and substance use disorders.
- Clinic services furnished by a clinic located in a rural area that is not a rural health clinic (rural health clinics may already provide services covered under a separate Medicaid benefit).

The exception for IHS/Tribal clinics is mandatory, while the exceptions for behavioral health and rural areas are optional for states.

Of note, the final rule allows states to choose either a state or federal definition of rural that best captures the state's rural population that meets the four criteria outlined in the proposed rule. Specifically, under the final rule, states implementing the exception must include in their state plans a definition of rural area. This definition must be either a definition adopted and used by a federal governmental agency for programmatic purposes, or a definition adopted by a state governmental agency with a role in setting state rural health policy.

Payment Policy for Drugs/Devices Covered Under Certain Coverage with Evidence Development National Coverage Determinations

Key Takeaway: CMS decided not to finalize the proposal to make a single blended payment for both arms of a CED study with a control arm in which the device or drug is used.

CMS proposed to make a single blended payment, dependent on the specific trial protocol, that would account for the frequency with which the covered device or drug is used compared to the control arm where the device or drug is not used. This proposal was comparable to a policy implemented in 2023 for Category B Investigational Device Exemptions (IDE) trials with a control arm. As with Category B IDE trials, CMS proposed this policy for CED studies with control arms to preserve their scientific validity "by avoiding differences in Medicare payment methods that would otherwise reveal the treatment or control group to which a patient has been assigned." This method would have only been used when necessary to maintain the scientific validity of the study.

Under the proposal, if routine costs in the study were exactly the same in both arms, they would not have been included in the blended payment rate, but would have been billed and paid according to existing coding and payment mechanisms. Otherwise, routine costs would also have been included in the single blended payment rate.

CMS chose not to finalize the policy because of several concerns expressed by commenters. Commenters expressed concern that a single blended payment rate to hospitals in clinical trials covered under a national coverage determination (NCD) with CED may inhibit non-academic hospitals from participating in such trials because of the lower blended rate. Commenters noted that if only mostly academic hospitals participated in CED studies, beneficiary access to such technology would be limited, potentially causing further health equity disparities. Eighteen organizations (and other commenters) raised concerns about including FDA approved drugs in a CED study. CMS pointed out that this concern was out of scope of the proposed rule. However, CMS indicated that it needed additional time to further consider the concern raised by the 18 organizations about the ethics of making beneficiaries pay 20% coinsurance even if they receive a placebo in the control arm.

CMS will consider comments received if it decides to revisit this topic in future rulemaking.

Hospital Conditions of Participation for Obstetrical Services and Emergency Readiness

Key Takeaway: CMS finalized new CoPs for obstetrical services and emergency readiness but will phase in the requirements over a period of two years.

Given ongoing concerns about maternal health, in the FY 2025 IPPS proposed rule CMS sought public comment on potential solutions that could be implemented through the hospital CoPs. In the CY 2025 OPPS proposed rule, CMS outlined proposed new CoPs and modifications to existing CoPs. Based on feedback from stakeholders, CMS finalized these proposals with some modifications, including a phased-in implementation of the requirements.

Baseline Standards for the Organization, Staffing, and Delivery of Care Within Obstetrical Units

CMS finalized a CoP requiring that if a hospital or critical access hospital (CAH) offers obstetrical services, the services must be "well organized and provided in accordance with nationally recognized acceptable standards of practice for physical and behavioral (inclusive of both mental health and substance use disorders) health care of pregnant, birthing, and postpartum patients." CMS also

finalized that the organization of obstetrical services must be appropriate to the scope of services offered by the facility and must be integrated with other departments of the facility.

CMS modified its proposed CoP that obstetrical privileges must be specifically spelled out for all practitioners providing obstetrical care in accordance with the competencies of each practitioner. The final CoP references existing requirements of the medical staff bylaws for hospitals and the requirements for agreements for credentialing and quality assurance for CAHs.

With respect to the delivery of services, CMS modified its proposed CoP that labor and delivery room suites have certain basic resuscitation equipment readily available, including a call-in-system, cardiac monitor, and fetal doppler or monitor. CMS clarified that under this CoP, basic equipment for treating obstetrics patients (including a call-in-system, cardiac monitor, and fetal doppler/monitor) must be kept at the facility and be readily available to meet the needs of obstetrics patients in accordance with the scope, volume, and complexity of services offered by the facility.

CMS finalized its CoP requiring that the obstetrical service at each hospital have protocols consistent with evidence-based, nationally recognized guidelines, as well as readily available supplies and equipment for obstetrical emergencies, complications, immediate post-delivery care, and other patient health and safety events as identified as part of the facility's quality assurance and performance improvement (QAPI) program.

Training for Obstetrical Staff in Hospitals and CAHs

CMS finalized a core set of training requirements for hospitals and CAHs offering obstetrical services. Hospitals must develop policies and procedures to ensure that relevant obstetrical services staff are trained on select topics for improving the delivery of maternal care, including facility-identified evidence-based best practices and protocols to improve the delivery of maternal care within the facility. CMS finalized that hospitals and CAHs that provide obstetrical services should also use findings from their QAPI programs to inform obstetrical staff training needs and any additions, revisions, or updates to training topics on an ongoing basis. In the final CoPs, CMS added a requirement for hospitals and CAHs to provide relevant new staff with initial training. CMS also modified its requirements around staff identification and documentation of training. Under the finalized CoPs, the governing body must identify and document which staff must complete the initial training and subsequent biannual training on evidence-based best practices.

QAPI Programs

CMS revised the existing QAPI standards for hospitals and CAHs that offer obstetrical services to require them to use their programs to assess and improve health outcomes and disparities among obstetrical patients on an ongoing basis.

Emergency Services Readiness

CMS finalized an "emergency services readiness" CoP within the existing emergency services CoP for hospitals and CAHs. The emergency services readiness CoP applies to all hospitals and CAHs offering emergency services, regardless of whether a hospital or CAH offers additional specialty service lines (such as obstetrical services).

CMS finalized as proposed that facilities will be required to:

- Have adequate provisions and protocols to meet the emergency needs of patients in accordance with the complexity and scope of services offered. Hospitals must have protocols consistent with nationally recognized and evidence-based guidelines for the care of patients with emergency conditions. (CMS pointed to resources created by the American College of Obstetricians and Gynecologists and others on obstetrical emergencies.)
- Train their emergency services personnel on these standards. CMS did not indicate which emergency services staff should be trained.
- Maintain certain supplies and products necessary for treating emergency cases. These must include drugs, blood and blood products, and biologicals commonly used in life-saving procedures; equipment and supplies commonly used in life-saving procedures; and a call-in-system for each patient in each emergency services treatment area.

In the proposed rule, CMS considered extending these requirements to REHs, but the agency did not finalize that proposal.

Transfer Protocols

CMS finalized a requirement that hospitals have written policies and procedures for transferring patients under their care. CMS also finalized for hospitals (but not CAHs and REHs, which have similar requirements already) a requirement to provide annual training to the relevant staff (as determined by the facility) regarding policies and procedures for transferring patients under the hospital's care.

Effective Dates

In response to stakeholder comments expressing concern about facilities' ability to meet the new and revised CoPs, CMS finalized a phase-in timeframe for the requirements as follows:

Phase 1 (six months from effective date of final rule)
- Emergency services readiness for hospitals and CAHs.
- Transfer protocols for hospitals.

Phase 2 (one year from effective date of final rule)
- Organization, staffing, and delivery of services for hospitals and CAHs.

Phase 3 (two years from effective date of final rule)
- Obstetrical staff training in hospitals and CAHs.
- QAPI program for obstetrical services in hospitals and CAHs.

Expanding Colorectal Cancer Screening

Key Takeaway: CMS finalized proposals to expand coverage for CRC screening, with one modification.

In the CY 2023 PFS final rule, CMS expanded the regulatory definition of CRC screening to include a complete CRC screening, which includes a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result. CMS noted in the CY 2023 PFS final rule that many commenters asked CMS to further expand its approach to a complete CRC screening.

For CY 2025, CMS finalized the following proposals to update and expand coverage for CRC screening:

- Deletion of HCPCS codes G0106 and G0120 (screening barium enema) effective December 31, 2024.
- Addition of coverage for computed tomography colonoscopy procedure (CPT code 74263).
  - In this final rule, CMS reassigned CPT code 74263 to APC 5523 instead of APC 5522, as proposed.
- Expansion of the definition of a complete colorectal screening to include a follow-on screening colonoscopy when performed after a blood-based biomarker colorectal screening test covered under NCD 210.3

CMS included a more detailed discussion of the now finalized policy in the CY 2025 Medicare PFS proposed rule.

Medicare Fee-for-Service No Legal Obligation to Pay Payment Exclusion and Incarceration

Key Takeaway: CMS narrowed the description of "custody" for purposes of Medicare's no legal obligation to pay payment exclusion, to allow Medicare fee-for-service payments for services to individuals who are in custody.

In the CY 2025 IPPS proposed rule, CMS proposed to remove individuals who are under supervised release (for example, on bail, parole, or probation) or required to live under home detention from the description of "custody" in § 411.4(b). CMS proposed to strike the phrase "or confined completely or partially in any way under a penal statute or rule."

CMS received near-unanimous support for this proposal and finalized it with a few modifications. CMS removed the term "under arrest" and removed halfway house residents from the description. The agency also added an illustrative, non-exhaustive list of individuals who are not considered to be in custody for purposes of the no legal obligation to pay payment exclusion. Lastly, CMS finalized the choice of phrase and definition of "penal authority," as proposed, to be broad enough to include all agencies or institutions that might place or hold an individual in custody.

Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals

Key Takeaway: CMS revised the eligibility requirements in the special enrollment period (SEP) to align with the finalized no legal obligation to pay payment exclusion and added individuals living in halfway houses to SEP eligibility.

As proposed, CMS finalized the revision of the eligibility criteria for the SEP for formerly incarcerated individuals to remove the reference to "custody" and instead tie eligibility to the Social Security Administration's determination that an individual is no longer incarcerated. This change will facilitate access to Medicare coverage for individuals who become eligible through the new no legal obligation to pay payment exclusion. In response to public comment, CMS revised the proposal to allow for individuals who reside in halfway houses to be eligible for this SEP as well, because these individuals are generally responsible for paying for their own health services.

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