Issue Brief

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Update to the CY 2023 Hospital Outpatient and ASC Prospective Payment Systems

The Centers for Medicare and Medicaid Services (CMS) have issued a final rule that updates policies and payment rates for services to hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) beginning January 1, 2023 (CY 2023).

Further, the rule updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, and the ASC Quality Reporting (ASCQR) Program.

CMS is also updating requirements for Organ Acquisition, Prior Authorization, and Overall Hospital Quality Star Rating.

CMS is establishing a new provider type – Rural Emergency Hospitals (REHs), and is finalizing proposals regarding payment policy, quality measures, and enrollment policy for REHs. In addition, CMS is finalizing the Conditions of Participation (CoPs) that REHs must meet in order to participate in the Medicare and Medicaid programs.

This rule also finalizes changes to the Critical Access Hospitals (CAH) CoPs for the location and distance requirements, patient's rights requirements, and flexibilities for CAHs that are part of a larger health system.

Finally, CMS is finalizing as implemented a number of provisions included in the COVID-19 interim final rules with comment period (IFCs).

The document is scheduled to be published in the ***Federal Register*** on November 23. A copy of the 1,561-page document is currently available at: https://www.federalregister.gov/d/2022-23918

The Addenda relating to the OPPS are available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices

The Addenda relating to the ASC payment system are available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASCRegulations-and-Notices.

[With respect to the websites for the Addenda above, as of November 5, they either do not open or open to a wrong address.]

COMMENT

Be careful. On November 1 CMS issued its version of the final OPPS rule. However, the "official version" of the document was not posted at the ***Federal Register*** office until November 3. The ***Federal Register*** version's page numbering is different than the CMS version. The numbers below are those from the display copy at the ***Federal Register***.

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CMS notes the policies in this rule will affect approximately 3,500 hospitals and 6,000 ASCs.

There are many items in the rule not addressed in this summary and analysis. The material is just too long to cover all.

I. SUMMARY of SELECT PROVISIONS (Page 15)

The following is a summary of select items from the regulation's preamble text .

OPPS Update: (Page 15) (1,423)

CMS is increasing the payment rates under the Outpatient Department (OPD) fee schedule by a factor of 3.8 percent. This increase is based on the final Fiscal Year (FY) 2023 hospital inpatient market basket percentage update of 4.1 percent reduced by a final productivity adjustment of 0.3 percentage point.

Based on this update, CMS estimates that total payments to OPPS providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for calendar year (CY) 2023 will be approximately $86.5 billion, an increase of approximately $6.5 billion compared to estimated CY 2022 OPPS payments.

CMS is continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9807 to the OPPS payments and copayments for all applicable services.

CMS estimates that the total increase in Federal Government expenditures under the OPPS for CY 2023, compared to CY 2022, due only to the changes to the OPPS would be approximately $1.79 billion.

CMS also says it estimates "that the total increase in Federal Government expenditures under the OPPS for CY 2023, compared to CY 2022, due to the changes to the OPPS in this final rule with comment period, will be approximately $2.53 billion." (Page 1,423) This conflicts with the estimate above of $1.79 billion. Which is correct?

CMS says "that the final update to the conversion factor and other budget neutrality adjustments will increase total OPPS payments by 4.8 percent in CY 2023. (Page 1,424) Yet, CMS also says it estimates "that the rates for CY 2023 will increase Medicare OPPS payments by an estimated 4.5 percent." (Page 1,431)

CMS estimates "the total increase (from changes to the ASC provisions in this final rule with comment period, as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2023 compared to CY 2022, to be approximately $230 million.

COMMENT

The update amounts appear correct. However, the total amounts of spending have conflicts. It is obvious that this material is not being reviewed and verified. More importantly it suggests that there could be many other errors in this rulemaking.

Data used in CY 2023 OPPS/ASC Rate-setting: (Page 16)

CMS is using CY 2021 claims data with cost reporting periods prior to the Public Health Emergency (PHE) to set CY 2023 OPPS and ASC payment system rates.

Partial Hospitalization Update: (Page 16) (Page 637)

continued

For CY 2023, CMS is maintaining the CY 2022 CMHC APC payment rate of $142.70 as the CY 2023 CMHC APC final payment rate

Changes to the Inpatient Only (IPO) List: (Page 17) (Page 674)

CMS is removing 11 services from the IPO list.

340B–Acquired Drugs (Page 17) (Page 569)

For CY 2023, in light of the Supreme Court decision in American Hospital Association v. Becerra, 142 S. Ct. 1896 (2022), CMS is applying the default rate, generally average sales price (ASP) plus 6.0 percent, to 340B acquired drugs and biologicals for CY 2023 and removing the increase to the conversion factor that was made in CY 2018 to implement the 340B policy in a budget neutral manner.

CMS says it is still evaluating how to apply the Supreme Court's decision to prior calendar years.

Device Pass-Through Payment Applications: (Page 17) (Page 355)

For CY 2023, CMS received 8 applications for device pass-through payments.

Cancer Hospital Payment Adjustment: (Page 17) (Page 109)

CMS is continuing to providing additional payments to 11 cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data.

Section 16002(b) of the ***21st Century Cures Act*** requires that this weighted average PCR be reduced by 1.0 percentage point. Based on the data and the required 1.0 percentage point reduction, CMS is using a target PCR of 0.89 to determine the CY 2023 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments will be the additional payments needed to result in a PCR equal to 0.89 for each cancer hospital.

ASC Payment Update: (Page 18)(Page 805)

For CYs 2019 through 2023, CMS adopted a policy to update the ASC payment system using the hospital market basket update. Using the hospital market basket methodology, for CY 2023, CMS is increasing payment rates under the ASC payment system by 3.8 percent for ASCs that meet the quality reporting requirements.

This increase is based on a hospital market basket percentage increase of 4.1 percent reduced by a productivity adjustment of 0.3 percentage point. Based on this update, CMS estimates that total payments to ASCs (including beneficiary cost-sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2023 will be approximately $5.3 billion, an increase of approximately $230 million compared to estimated CY 2022 Medicare payments.

Changes to the List of ASC Covered Surgical Procedures: (Page 18) (Page 819)

For CY 2023, CMS is finalizing its proposal, with modification, to add four procedures, to the ASC covered procedures list (CPL) based upon existing criteria at § 416.166.

Hospital Outpatient Quality Reporting (OQR) Program: (Page 18) (Page 918)

CMS is finalizing its proposals to: (1) add a data validation targeting criterion to the existing four targeting criteria that reads: "Any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an ECE for one or more quarters," beginning with the CY 2023 reporting period/ CY 2025 payment determination; (2) align patient encounter quarters with the calendar year,

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beginning with the CY 2024 reporting period/ CY 2026 payment determination; and (3) change the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) Measure from Mandatory to Voluntary Beginning with the CY 2027 Payment Determination.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program: (Page 18) (Page 975)

For the ASCQR Program measure set, CMS is finalizing its proposal to change the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (ASC-11) Measure from Mandatory to Voluntary beginning with the CY 2027 payment determination.

Organ Acquisition Payment Policy: (Page 19)

CMS is finalizing its proposal to exclude research organs from the ratio used to calculate Medicare's share of organ acquisition costs and a is modifying the requirement to offset costs by allowing providers to follow their accounting practices of adjusting costs, offsetting revenue or establishing a non-reimbursable cost center, which will maintain or lower the cost of procuring and providing research organs to the research community. Finally, CMS is finalizing its proposal to cover as organ acquisition costs certain hospital services provided to donors whose death is imminent, to promote organ procurement and enhance equity.

Rural Emergency Hospital (REH) Payment Polices: (Page 20)

Section 125 of the **Consolidated Appropriations Act** (CAA) established a new provider type called Rural Emergency Hospitals (REHs), effective January 1, 2023. By statute, covered outpatient department services provided by REHs will receive an additional 5.0 percent payment for each service. Beneficiaries will not be charged a copayment on the additional 5.0 percent payment.

REHs are facilities that convert from either a critical access hospital (CAH) or a rural hospital (or one treated as such under section 1886(d)(8)(E) of the Social Security Act) with less than 50 beds, and that do not provide acute care inpatient services. REHs may provide outpatient services that are not otherwise paid under the OPPS (such as services paid under the Clinical Lab Fee Schedule) as well as post-hospital extended care services furnished in a unit of the facility that is a distinct part of the facility licensed as a skilled nursing facility; however, these services would not be considered REH services and therefore would be paid under the applicable fee schedule and will not receive the additional 5.0 percent payment increase that CMS will apply to REH services.

Rural Emergency Hospitals (REH) and Critical Access Hospital Conditions of Participation (CoP): (Page 19)

CMS is finalizing the Conditions of Participation that REHs must meet in order to participate in the Medicare and Medicaid programs. This rule also finalizes changes to the Critical Access Hospitals (CAH) CoPs for the location and distance requirements, patient's rights requirements, and flexibilities for CAHs that are part of a larger health system.

Rural Emergency Hospitals (REH): Provider Enrollment: (Page 20)

CMS is outlining provider enrollment requirements for REHs. The most important of these are that REHs: (1) must comply with all applicable provider enrollment provisions in 42 CFR Part 424, subpart P in order to enroll in Medicare; and (2) may submit a Form CMS-855A change of information application

continued

(rather than an initial enrollment application) to convert to an REH.

Rural Emergency Hospital Quality Reporting (REHQR) Program: (Page 20)

CMS is finalizing its proposal to require a QualityNet account and Security Official (SO) requirement in line with other quality programs for purposes of data submission and access of facility level reports.

Rural Emergency Hospitals (REH) Physician Self-Referral Law Update: (Page 20)

CMS is finalizing revisions to certain existing exceptions to make them applicable to compensation arrangements to which an REH is a party. CMS is not finalizing its proposed exception for ownership or investment interests in an REH.

COMMENT

For more information on REHs, please refer to CMS' fact sheet on the subject at: https://www.cms.gov/newsroom/fact-sheets/cy-2023-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-1.

Overall Hospital Quality Star Ratings: (Page 20)

CMS is finalizing it proposal to state the use of publicly available measure results on Hospital Compare or its successor websites from a quarter within the previous 12 months (instead of the "previous year").

Addition of a New Service Category for Hospital Outpatient Department Prior Authorization Process: (Page 21)

CMS is adding Facet Joint Interventions as a category of services to the prior authorization process for hospital outpatient departments beginning for dates of service on or after July 1, 2023.

Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes: (Page 22)

For CY 2023, mental health services furnished remotely by hospital staff using communications technology to beneficiaries in their homes will be a covered outpatient department services payable under the OPPS and CMS has created OPPS-specific coding for these services.

CMS is finalizing its proposal to require an in-person service within 6 months prior to the initiation of the remote service and then every 12 months thereafter, that exceptions to the in person visit requirement may be made based on beneficiary circumstances (with the reason documented in the patient's medical record), and that more frequent visits are also allowed as driven by clinical needs on a case-by-case basis.

CMS is clarifying that the requirement that an in-person visit occur within 6 months prior to the initial mental health telehealth service does not apply to beneficiaries who began receiving mental health telehealth services in their homes during the PHE or during the 151-day period after the end of the PHE.

CMS is also finalizing its proposal that audio-only interactive telecommunications systems may be used to furnish these services in instances where the beneficiary is not capable of, or does not consent to, the use of two-way, audio/video technology.

Supervision by Nonphysician Practitioners of Hospital and CAH Diagnostic Services Furnished to Outpatients: (Page 22)

continued

To improve clarity, CMS is finalizing its proposal to replace cross-references at § 410.27(a)(1)(iv)(A) and (B) and§ 410.28(e) to the definitions of general and personal supervision at § 410.32(b)(3)(i) and (iii) with the text of those definitions.

CMS is also finalizing its proposal to revise § 410.28(e) for clarity so that certain nonphysician practitioners (nurse practitioners, physician assistants, clinical nurse specialists and certified nurse midwifes) may supervise the performance of diagnostic tests to the extent they are authorized to do so under their scope of practice and applicable State law.

Exemption of Rural Sole Community Hospitals (SCH) from the Method to Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs): (Page 22)

CMS is finalizing its proposal to exempt rural Sole Community Hospitals (rural SCHs) from the site-specific Medicare Physician Fee Schedule (PFS)-equivalent payment for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier "PO" on claim lines).

Payment Adjustments under the IPPS and OPPS for Domestic NIOSH Approved Surgical N95 Respirators: (Page 23)

CMS is finalizing its proposal to provide payment adjustments to hospitals under the IPPS and OPPS for the additional resource costs they incur to acquire domestic NIOSH-approved surgical N95 respirators. The payment adjustments will commence for cost reporting periods beginning on or after January 1, 2023.

II. UPDATES AFFECTING OPPS PAYMENTS (Page 34)

A. Recalibration of APC Relative Payment Weights (Page 34)

Calculation of Single Procedure APC Criteria-Based Costs

Blood and Blood Products (Page 43) (567)

CMS will continue to establish payment rates for blood and blood products using its blood-specific CCR methodology. Addendum B contains the final CY 2023 payment rates for blood and blood products.

Brachytherapy Sources (Page 45) (Page 869)

CMS will maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2023.

CMS is finalizing its proposal to designate four brachytherapy APCs as Low Volume APCs for CY 2023.

The final CY 2023 payment rates for brachytherapy sources are included in Addendum *B*

Comprehensive APCs (C-APCs) for CY 2023 (Page 49)

A C-APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service.

A list of services excluded from the C-APC policy is included in Addendum J at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices. (Page 51)

Addendum J includes the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). (Page 58)

continued

The rule's Table 1 contains the specific C-APC complexity adjustment code combinations for CY 2023. (Page 59)

The rule's Table 2 lists the final (70) C-APCs for CY 2023. All C-APCs are displayed in Addendum J. (Page 68)

CMS is finalizing, as proposed, C-APC 5372 (Level 2 Urology and Related Services) for CY 2023.
(Page 68)

Calculation of Composite APC Criteria-Based Costs

Mental Health Services Composite APC (Page 71)

CMS says that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services would be paid through composite APC 8010 for CY 2023.

Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) (Page 73)

The rule's Table 3 (Page 76) lists the HCPCS codes that will be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC final geometric mean costs for CY 2023.

B. Conversion Factor (CF) (Page 87)

For CY 2023, CMS is using a conversion factor of $84.177 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the OPD fee schedule increase factor of 3.8 percent for CY 2023, the required wage index budget neutrality adjustment of 0.9998, the adjustment to account for the change in policy for drugs purchased under the 340B Program of 0.9691, and the adjustment of 0.16 percentage point of projected OPPS spending for the difference in pass-through spending that results in a conversion factor for CY 2023 of **$85.585**. The proposed CF was $86.785. The major reduction is due to the 340B drug payment change.

C. Wage Index Changes (Page 95)

The OPPS labor-related share remains at 60 percent of the national OPPS payment.

CMS is finalizing its proposal without modification to use the FY 2023 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2023. (Page 103)

Any policies and adjustments for the FY 2023 IPPS post-reclassified wage index will be reflected in the final CY 2023 OPPS wage index beginning on January 1, 2023, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, the imputed floor wage index adjustment in all-urban states, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), an adjustment to the wage index for certain low wage index hospitals to help address wage index disparities between low and high wage index hospitals, and a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY.

D. Statewide Average Default CCRs (Page 105)

continued

CMS will calculate the default ratios for CY 2023 using the June 2020 HCRIS cost reports.

E. Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) under Section 1833(t)(13)(B) of the Act for CY 2023 (Page 107)

For CY 2023, CMS will continue the current policy of a 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, applied in a budget neutral manner.

F. Payment Adjustment for Certain Cancer Hospitals for CY 2023 (Page 109)

The rule's Table 6 the estimated percentage increase in OPPS payments to each of the 11 eligible cancer hospital for CY 2023.

G. Hospital Outpatient Outlier Payments (Page 114)

CMS sets the projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. CMS estimates that the aggregate outlier payments for CY 2022 will be approximately 1.26 percent of the total CY 2022 OPPS payments.

CMS is setting the outlier threshold that exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus **$8,625.** The current threshold is $6,175. (Page 119)

For CMHCs, the threshold would be 3.40 times the payment rate, and the outlier payment will be calculated as 50 percent of the amount by which the cost exceeds 3.40 times APC 5853.

H. Calculation of an Adjusted Medicare Payment from the National Unadjusted Medicare Payment (Page 121)

The national unadjusted payment rate is the is the payment rate for most APC's before accounting for the wage index adjustment or any applicable adjustments.

The national unadjusted payment rates are contained in Addendum A at: "https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates" and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B is calculated by multiplying the final CY 2023 scaled weight for the APC by the CY 2023 conversion factor.

III. OPPS AMBULATORY PAYMENT CLASSIFICATION (APC) GROUP POLICIES (Page 133)

A. OPPS Treatment of New CPT and Level II HCPCS Codes

CMS recognizes the following codes on OPPS claims:

Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
Category III CPT codes, which describe new and emerging technologies, services, and procedures;
MAAA CPT codes, which describe laboratory multianalyte assays with algorithmic analyses (MAA);
PLA CPT codes, which describe proprietary laboratory analyses (PLA) services; and
Level II HCPCS codes (also known as alpha-numeric codes), which are used

continued

primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

The following reflects CMS' treatment of new codes added during the year.

April 2022 HCPCS Codes

For the April 2022 update, 48 new HCPCS codes were established and made effective on April 1, 2022. These codes and their long descriptors are listed in the rules' Table 7. (Page 135)

July 2022 HCPCS Codes

For the July 2022 update, 63 new codes were established and made effective July 1, 2022. The codes and long descriptors are listed in the rule's Table 8. (Page 139)

October 2022 HCPCS Codes (Page 143)

For CY 2022, CMS is continuing its established policy of assigning comment indicator "NI" in Addendum B to those new HCPCS codes that become effective October 1 to indicate that CMS is assigning them an interim status indicator, which is subject to public comment.

January 2023 HCPCS Codes (Page 143)

CMS is soliciting comments on the new Level II HCPCS codes that will be effective January 1, 2023 in this final rule, thereby allowing CMS to finalize the status indicators and APC assignments for the codes in the CY 2024 OPPS/ASC.

B. OPPS Changes – Variations within APCs (Page 147)

The Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the "2 times rule"). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as low volume items and services.

The rule's Table 10 lists 25 APCs that CMS is excepting from the 2 times rule for CY 2023. (Page 153)

C. New Technology APCs (Page 154)

The procedures assigned to the New Technology APCs are listed below.

- *Retinal Prosthesis Implant Procedure* (Page 160)
- Administration of Subretinal Therapies Requiring Vitrectomy (APC 1562) (Page 161)
- Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy (Page 165)
- Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APCs 1520, 1522 & 1523 (Page 168)
- V-Wave Medical Interatrial Shunt Procedure (APC 1590) (Page 171)
- Corvia Medical Interatrial Shunt Procedure (Page 174)
- Supervised Visits for Esketamine Self-Administration (APC codes 1512 and 1516) (Page 176)
- DARI Motion Procedure (APC 1505) (Page 179)
- Histotripsy Service (APC 1575) (Page 180)
- Liver Multiscan Service (APC 1511) (Page 182)
- Minimally Invasive Glaucoma Surgery (MIGS) (APC 1526) (Page 184)
- Scalp Cooling (APC 1520) (Page 187)

continued

- Optellem Lung Cancer Prediction (LCP) (APC 1508) (Page 189)
- Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP) (APC 1511) (Page 191)
- CardiAMP (APC 1574) (Page 193)

D. Universal Low Volume APC Policy for Clinical and Brachytherapy APCs (Page 195)

In the CY 2022 OPPS/ASC final rule CMS finalized its proposal to designate clinical and brachytherapy APCs as low volume APCs if they have fewer than 100 single claims that can be used for rate-setting purposes in the claims year used for rate-setting for the prospective year.

The rule's Table 31 includes the APC geometric mean cost without the low volume APC designation, that is, if CMS calculated the geometric mean cost based on CY 2021 claims data available for rate-setting; the median, arithmetic mean, and geometric mean cost using up to four years of claims data based on the APCs' designation as a low volume APC; and the statistical methodology CMS is used to determine the APC's cost for rate-setting purposes for CY 2023.

E. OPPS APC-Specific Policies (Page 200)

CMS has identified the following specific APC policies. They are simply listed below. For specifics, please visit the page sections.

- Abdominal Hernia Repair (APCs 5341 and 5361) (Page 200)
- Administration of Lacrimal Ophthalmic Insert into Lacrimal Canaliculus (APC 5503) (Page 211)
- Artificial Iris Insertion Procedures (APC 5495) (Page 219)
- Blood Product Not Otherwise Classified (NOC) (APC 9537) (Page 221)
- Bone Density Tests/Bone Mass Measurement: Biomechanical Computed Tomography (BCT) Analysis and Digital X-ray Radiogrammetry-Bone Mineral Density (DXR-BMD) Analysis (Page 224)
- Calculus Aspiration with Lithotripsy Procedure (APC 5376) (Page 229)
- Cardiac Computed Tomography Angiography (CCTA) (APC 5571) (Page 232)
- *Cardiac Contractility Modulation (CCM) Therapy (APC 5232) (Page 237)*
- Cardiac Magnetic Resonance (CMR) Imaging (APC 5572 and 5573) (Page 238)
- ClariFix Procedure (APC 5165) (Page 239)
- Cleerly Labs (APC 1511) (Page 241)
- Coflex. Interlaminar Implant Procedure (APC 5116) (Page 243)
- Colonic Lavage (APC 5721) (Page 244)
- CoverScan (APC 5523) (Page 246)
- COVID-19 Vaccine and Monoclonal Antibody Administration Services (Page 247)

CMS proposed to continue to pay $40 per dose for the administration of the COVID–19 vaccines provided in the HOPD setting, and an additional $35.50 for the administration of the COVID-19 vaccines when provided under certain circumstances in the patient's home. CMS is finalizing its proposal to use the equitable adjustment authority at section 1833(t)(2)(E) of the Act to maintain the CY 2022 New Technology APC assignments (specifically, New Technology APCs 1503, 1504, 1505, 1506, 1507, or 1509) and corresponding payment rates for each of the COVID-19 monoclonal antibody product administration HCPCS codes.

- Duplex Scan of Extracranial Arteries (APC 5523) (Page 258)
- Endoscopic Submucosal Dissection (ESD) Procedure (APC 5303) (Page 259)

continued

- Endovenous Femoral-Popliteal Arterial Revascularization (APC 5193) (Page 261)
- External Electrocardiographic (ECG) Recording (APC 5732) (Page 262)
- Eye Procedures (APCs 5502 and 5503) (Page 264)
- Eye-Movement Analysis Without Spatial Calibration (APC 5734) (Page 266)
- Fecal Microbiota Procedure (APC 5301) (Page 267)
- Fractional Flow Reserve Derived from Computed Tomography (FFRCT) (APC 5742) (Page 270)
- Gastrointestinal Motility (APC 5722) (Page 275)
- Gastrointestinal Myoelectrical Activity Study (APC 5723) (Page 277)
- Hemodialysis Arteriovenous Fistula Procedures (APC 5194) (Page 279)
- IB-Stim Application Service (APC 5724) (Page 281)
- IDx-DR: Artificial Intelligence System To Detect Diabetic Retinopathy (APC 5733) (Page 284)
- Insertion of Bioprosthetic Valve (APC 5184) (Page 285)
- InSpace Subacromial Tissue Spacer Procedure (APC 5115) (Page 286)
- Intervertebral Disc Allogenic Cellular and/or Tissue-Based Product Percutaneous Injection
- (APC 5115) (Page 287)
- Magnetic Resonance-Guided Focused Ultrasound Surgery (MRgFUS) (APC 5463) (Page 289)
- Medical Physics Dose (APC 5723) (Page 290)
- Minimally Invasive Glaucoma Surgery (MIGS) (APC 5491) (Page 292)
- Musculoskeletal Procedures (APCs 5111 Through 5116) (Page 295)
- Neurostimulator and Related Procedures (APCs 5461 Through 5465) (Page 296)
- Optilume Cystourethroscopy (APC 5374) (Page 300)
- Pathology Services (APC 5672) (Page 302)
- Percutaneous Arthrodesis of the Sacroiliac Joint (APC 5116) (Page 303)
- Placement of Breast Localization Devices (APCs 5071 and 5072) (Page 307)
- ProSense Cryoablation Procedure (APC 5091) (Page 309)
- Pulmonary Rehabilitation Services (APC 5731) (Page 311)
- Remote Physiologic Monitoring Services (Page 313)
- Repair of Nasal Valve Collapse (APC 5165) (Page 314)
- Single-Use Disposable Negative Pressure Wound Therapy (dNPWT) (APC 5052) (Page 316)
- Surfacer® Inside-Out® Access Catheter System (APC 1534) (Page 318)
- Total Ankle Replacement Procedure (APC 5116) (Page 319)
- Transcatheter Implantation of Coronary Sinus Reduction Device (APCs 5193 and 5194) (Page 321)
- Transnasal Esophagogastroduodenoscopy (EGD) Procedure (APC 5301 and 5302) (Page 323)
- Unlisted Dental Procedure/Service (APC 5871) (Page 326)
- Urology and Related Services (APCs 5371 through 5378) (Page 336)
- Waterjet Prostate Ablation (APC 5376) (Page 341)
- ZOLL µCor™ Heart Failure Management System Service (HFSM) Monitoring (Page 342)

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IV. OPPS PAYMENT FOR DEVICES (Page 344)

A. Pass-Through Payment for Devices

The intent of transitional device pass-through payment, as implemented at § 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate.

Expiration of Transitional Pass-Through Payments for Certain Devices (Page 346)

Currently, there are 14 device categories eligible for pass-through payment. These devices are listed in table below where CMS details the expiration dates of pass-through payment status.

HCPCS Codes	Long Descriptor	Effective Date	Pass-Through Expiration Date
1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads	1/1/2019	12/31/2022
C1824	Generator, cardiac contractility modulation (implantable)	1/1/2020	12/31/2022
C1982	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2022
C1839	Iris prosthesis	1/1/2020	12/31/2022
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2022
C2596	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2022
C1748	Endoscope, single-use (that is, disposable), Upper GI, imaging/illumination device (insertable)	7/1/2020	6/30/2023
C1052	Hemostatic agent, gastrointestinal, topical	1/1/2021	12/31/2023
C1062	Intravertebral body fracture augmentation with implant (e.g., metal, polymer)	1/1/2021	12/31/2023
C1825	Generator, neurostimulator (implantable), nonrechargeable with carotid sinus baroreceptor stimulation lead(s)	1/1/2021	12/31/2023
C1761	Catheter, transluminal intravascular lithotripsy, coronary	7/1/2021	6/30/2024
C1831	Personalized, anterior and lateral interbody cage (implantable)	10/1/2021	9/30/2024
C1832	Autograft suspension, including cell processing and application, and all system components	1/1/22	12/31/2024
C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)	1/1/22	12/31/2024

New Device Pass-Through Applications (Page 355)

CMS says it received "eight" complete applications by the March 1, 2022 quarterly deadline. (Page 359)

Two were based on the Alternative Pathway Device Pass-through Applications:
aprevo™ Intervertebral Body Fusion Device (Page 360)

continued

CMS is finalizing *approval* of device pass-through payment status for aprevo™

MicroTransponder® ViviStim® Paired Vagus Nerve Stimulation (VNS) System (Vivistim® System) (Page 370)

CMS states that the Vivistim. System *meets* the requirements for device pass-through payment status

2. Traditional Device Pass-through Applications (Page 384)

CMS received the following traditional device pass-through devices. They are;

The BrainScope TBI (model: Ahead 500) (Page 384)

CMS says the device *does not meet* the eligibility criteria at § 419.66(b)(4).

(2) NavSlim™ and NavPencil (Page 387)

CMS states the device *does not meet* the substantial clinical improvement criterion.

(3) SmartClip™ (Page 409)

CMS *is not approving* the SmartClip™ for transitional pass-through payment status in CY 2023 because the device does not meet the newness or substantial clinical improvement criterion.

(4) Evoke® Spinal Cord Stimulation (SCS) System (Page 438)

CMS is finalizing *approval* for device pass through payment status for the Evoke. SCS System effective beginning January 1, 2023.

(5) Pathfinder® Endoscope Overtube (Page 462)

CMS *is not approving* the Pathfinder® for transitional pass-through payment status in CY 2023 because the technology does not meet the substantial clinical improvement criterion.

(6) The Uretero1 (Page 475)

CMS *is approving* the Uretero1 for transitional pass-through payment status beginning January 1, 2023.

B. Proposal to Publicly Post OPPS Device Pass-through Applications (Page 488)

"To increase transparency, enable increased interested party engagement, and further improve and streamline our evaluation process, we propose to publicly post future applications for OPPS device pass-through payment online. Specifically, beginning with applications submitted on or after January 1, 2023, we propose to post online the completed OPPS device pass-through application forms and related materials (e.g., attachments, supportive materials) we receive from applicants. Additionally, we propose to post online information acquired subsequent to the application submission (e.g., updated application information, additional clinical studies, etc.). We propose that we would publicly post all completed application forms and related materials at the same time that the proposed rule is issued, which would afford interested parties the full public comment period to review the information provided by the applicant in its application in conjunction with the proposed rule. We are not proposing to change our policy that applicants whose applications are not approved through the quarterly review process may elect to withdraw their application from consideration in the next applicable rulemaking cycle."

CMS is adopting its proposal with modifications. CMS is now making the effective of March 1, 2023. Using this alternative effective date, CMS will begin publicly posting all OPPS device pass-through applications summarized with a cross-reference to the publicly posted application, as previously described beginning in the CY 2025 proposed and final rules.

continued

C. Device-Intensive Procedures (Page 502)

CMS will use CY 2021 claims information for determining device offset percentages and assigning device-intensive status. The full listing of the CY 2023 device-intensive procedures can be found in Addendum P.

COMMENTS

This is a long, detailed and complex section extending nearly 180 pages.

One can appreciate the burden and work involved to provide the comprehensive information regarding new device pass through applications. Nonetheless, as with many other sections of this rule, CMS does not provide clear and concise decision-making.

Other rules, such as the recent final Home Health and ESRD CY 2023 updates provide such, making it much more easy to find CMS' final policies.

CMS needs to do the same with the OPPS rule.

V. OPPS PAYMENT CHANGES FOR DRUGS, BIOLOGICALS, AND RADIOPHARMACEUTICALS (Page 517)

A. Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Drugs and Biologicals with Expiring Pass-Through Payment Status in CY 2022 (Page 520)

There are 32 drugs and biologicals for which pass-through payment status expires on December 31, 2022 or for which the equitable adjustment to mimic continued pass-through payment will end on December 31, 2022. These are listed in the rule's Table 57. (Page 522)

The packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B.

2. Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Expiring in CY 2023. (Page 524)

There are 43 drugs and biologicals for which pass-through payment status will expire during CY 2023. They are shown in the rule's Table 58. (Page 526)

3. Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Continuing in CY 2023. (Page 531)

The drugs and biologicals with continuing pass-through payment status expiring after December 31, 2023, are shown in the rule's Table 59. (Page 533)

B. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status (Page 537)

Packaging Threshold (Page 540)

The packaging threshold for CY 2023 will be **$135**, an increase from the current threshold of $130.

Packaging of Payment for HCPCS Codes that Describe Certain Drugs, Certain Biologicals, and Certain Therapeutic Radiopharmaceuticals Under the Cost Threshold ("Threshold-Packaged Drugs" (Page 541)

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B will be based on ASP data from the second quarter of CY 2022. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2022. These payment rates

continued

would then be updated in the January 2023 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2023.

Increased Payment for Biosimilars in the Inflation Reduction Act of 2022 (Page 563)

The ***Inflation Reduction Act of 2022*** (IRA) requires a temporary increase in the add-on payment for qualifying biosimilar biological products from 6 percent to 8 percent of the ASP of the reference biological beginning October 1, 2022. This increase applies for a 5-year period.

For existing qualifying biosimilars for which payment was made using ASP as of September 30, 2022, the 5-year period began on October 1, 2022. For new qualifying biosimilars for which payment is first made using ASP between October 1, 2022, and December 31, 2027, the applicable 5-year period begins on the first day of the calendar quarter during which such payment is made.

Payment for Blood Clotting Factors (Page 567)

The furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting.

CMS will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through applicable program instructions and posting on the CMS website.

CY 2023 OPPS Payment Methodology for 340B Purchased Drugs (Page 569)

Beginning in CY 2018, the Secretary adjusted the 340B drug payment rate to ASP minus 22.5 percent to approximate a minimum average discount for 340B drugs, which was based on findings of the GAO and MedPAC that hospitals were acquiring drugs at a significant discount under the 340B Drug Pricing Program.

This policy has been the subject of significant litigation, recently culminating in the Supreme Court's decision in American Hospital Association v. Becerra, No. 20-1114, 2022 WL 2135490 (June 15, 2022). CMS says that "given the timing of the Supreme Court's decision, we lacked the necessary time to incorporate the adjustments to the proposed payment rates and budget neutrality calculations to account for that decision before issuing this proposed rule." (Page 570)

The payment rates, tables, and addenda in the *proposed* rule reflect a payment rate of ASP minus 22.5 percent for drugs and biologicals acquired through the 340B program for CY 2023.

CMS says "to ensure budget neutrality under the OPPS, after applying this alternative payment methodology for drugs and biologicals, we currently estimate that we would apply an offset of approximately $1.96 billion to decrease the OPPS conversion factor, which would result in a budget neutrality adjustment of 0.9596 to the OPPS conversion factor, for a revised conversion factor of $83.279." (Pages 573) [Note, the final OPPS CF for CY 2023 is $86.785.]

CMS says it is still evaluating how to apply the Supreme Court's decision to calendar years 2018 through 2022. Further, CMS says it plans to issue a separate proposed rule detailing its proposed remedy for CYs 2018 to CY 2022 in advance of the CY 2024 OPPS/ASC proposed rule. (Page 578)

For CY 2023, CMS is maintaining the requirement for 340B hospitals to report the "JG" and "TB" modifiers for informational purposes, but they will have no effect on payment rates. (Page 582)

continued

COMMENT

The material covered in this section is both extremely rambling and duplicative.

High Cost/Low-Cost Threshold for Packaged Skin Substitutes (Page 588)

Skin substitutes assigned to the high-cost group are described by HCPCS codes 15271 through 15278. Skin substitutes assigned to the low-cost group are described by HCPCS codes C5271 through C5278.

The rule's Table 62 includes the final CY 2023 cost category assignment for each skin substitute product covered and by the policies implemented as a result of the retirement of HCPCS Code C1849. (Page 600)

Requirement in the Physician Fee Schedule CY 2023 Proposed and Final Rule for HOPDs and ASCs to Report Discarded Amounts of Certain Single-dose or Single-use Package Drugs (Page 620)

Section 90004 of the ***Infrastructure Investment and Jobs Act*** ("the Infrastructure Act") amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug.

VI. ESTIMATE OF OPPS TRANSITIONAL PASS-THROUGH SPENDING FOR DRUGS, BIOLOGICALS, RADIOPHARMACEUTICALS, AND DEVICES (Page 623)

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payments for drugs, biologicals, radiopharmaceuticals, and categories of devices for a given year to an "applicable percentage," currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year.

CMS estimates for this final rule that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2023 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2023 would be approximately$135.5 million (approximately $82 million for device categories and approximately $53.5 million for drugs and biologicals), which represents only 0.16 percent of total projected OPPS payments for CY 2023 (approximately $86.5 billion). Therefore, CMS estimates that pass-through spending in CY 2023 will not amount to 2.0 percent of total projected OPPS CY 2023 program spending. (Page 633)

VII. OPPS PAYMENT FOR HOSPITAL OUTPATIENT VISITS AND CRITICAL CARE SERVICES (Page 634

CMS will continue to utilize a Physician Fee Schedule (PFS)-equivalent payment rate for hospital outpatient clinic visit services described by HCPCS code G0463 when it is furnished by excepted off-campus provider-based departments. The PFS-equivalent rate for CY 2023 is 40 percent of the OPPS payment (that is, 60 percent less than the OPPS rate).

VIII. PAYMENT FOR PARTIAL HOSPITALIZATION SERVICES (Page 637)

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric

continued

care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders.

CMS says that "for only CY 2023, and not subsequent years, we are applying an equitable adjustment, under the authority of section 1833(t)(2)(E) of the Act, to finalize **$142.70** as the CY 2023 CMHC PHP APC payment rate, which is the same payment rate in effect for the CY 2022 CMHC PHP APC." (Page 642)

The calculated CY 2023 geometric mean per diem cost for all hospital-based PHPs for providing three or more services per day (APC 5863) is $275.83. (Page 659)

The final CY 2023 PHP geometric mean per diem costs are shown in the rule's Table 63 and are used to derive the final CY 2023 PHP APC per diem rates for CMHCs (subject to the equitable adjustment discussed above) and hospital-based PHPs. The final CY 2023 PHP APC per diem rates are included in Addendum A. (Page 659)

CY 2023 PHP APC Geometric Mean Per Diem Costs

CY 2023 APC	Group Title	Final PHP APC Geometric Mean Per Diem Costs
5853	Partial Hospitalization (3 or more services per day) for CMHCs	$135.68
5863	Partial Hospitalization (3 or more services per day) for hospital-based PHPs	$275.83

COMMENT

If one can follow the logic of this section, CMS is applying a payment adjustment to the partial hospitalization rate of three or more services per day for CMHCs using the CY 2022 only amount of $142.70. Therefore, should the above table rate of $135.68 be $142.70?

IX. SERVICES THAT WILL BE PAID ONLY AS INPATIENT SERVICES (Page 674)

In the CY 2021 OPPS/ASC final rule, CMS finalized its proposal to eliminate the IPO list over the course of three years. As part of the first phase of this elimination of the IPO list, CMS removed 298 codes from the list beginning in CY 2021.

The rule's Table 65 contains the changes to the IPO list for CY 2023. The complete list of codes describing services that are designated as inpatient only services beginning in CY 2023 are also included in Addendum E. (Page 688)

X. NONRECURRING POLICY CHANGES (Page 691)

CMS addresses the following non-recurring policy changes as noted below.

- *Payment for Mental Health Services Furnished as Medicare Telehealth Services or by Rural Health Clinics and Federally Qualified Health Centers* (Page 691)
- Hospital Payment for Mental Health Services Furnished Remotely During the PHE for COVID-19 (Page 692)
- Comment Solicitation in the CY 2022 OPPS/ASC Proposed Rule (Page 694)
- Current Crisis in Mental Health and Substance Use Disorder (Page 695)
- CY 2023 OPPS Payment for Mental Health Services Furnished Remotely by Hospital Staff (Page 697)
- Comment Solicitation on Intensive Outpatient Mental Health Treatment, including Substance

continued

- Use Disorder (SUD) Treatment Furnished by Intensive Outpatient Programs (IOPs) (Page 710)
- Direct Supervision of Certain Cardiac and Pulmonary Rehabilitation Services by Interactive Communications Technology (Page 712)
- Use of Claims Data for CY 2023 OPPS and ASC Payment System Rate-setting Due to the PHE (Page 715)
- Supervision by Nonphysician Practitioners of Hospital and CAH Diagnostic Services Furnished to Outpatients (Page 725)
- Coding and Payment for Category B Investigational Device Exemption Clinical Devices and Studies (Page 738)
- OPPS Payment for Software as a Service (Page 739)
- Payment Adjustments under the IPPS and OPPS for Domestic NIOSH-Approved Surgical N95 Respirators (Page 771)
- Exemption of Rural Sole Community Hospitals from the Method to Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs) (Page 785)

XI. CY 2023 OPPS PAYMENT STATUS AND COMMENT INDICATORS (Page 800)

For CY 2023, CMS proposed to revise the definition of status indicator "A" to include unclassified drugs and biologicals that are reportable under HCPCS code C9399. When HCPCS code C9399 appears on a claim, the Outpatient Code Editor (OCE) suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological's average wholesale price (AWP) using the Red Book or an equivalent recognized compendium, and processes the claim for payment.

In addition, CMS proposed to revise the definition of status indicator "F" by removing hepatitis B vaccines. Hepatitis B vaccines should not be subject to deductible and coinsurance similar to other preventive vaccines, but services that are currently listed under the definition of status indicator "F" are subject to deductible and coinsurance. CMS also proposed to revise the definition of status indicator "L" in order to add hepatitis B vaccines to the list of other preventive vaccines that are not subject to deductible and coinsurance.

CMS has adopted these proposals.

The complete list of CY 2023 payment status indicators and their definitions is displayed in Addendum D1.

XII MedPAC recommendations. We have chosen to skip this material. (Page 803)

XIII. UPDATES TO THE AMBULATORY SURGICAL CENTER (ASC) PAYMENT SYSTEM (Page 805)

A. Calculation of the ASC Payment Rates and the ASC Conversion Factor (Page 902)

For CY 2023, CMS adjusts the CY 2022 ASC conversion factor ($49.916) by the ASC wage index budget neutrality factor of 1.0008 in addition to the productivity-adjusted hospital market basket update of 3.8 percent, which results in a CY 2023 ASC conversion factor of **$51.854** for ASCs meeting the quality reporting requirements.

For ASCs not meeting the quality reporting requirements, CMS adjusts the CY 2022 ASC conversion factor ($49.916) by the wage index budget neutrality factor of 1.0008 in addition to the non- reporting/ productivity-adjusted hospital market basket update of 1.8 percent (3.8-2.0),

continued

which results in a CY 2023 ASC conversion factor of **$50.885.** (Page 916)

Addenda AA and BB reflect the full ASC payment updates and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program.

B. ASC Treatment of New and Revised_ Codes (Page 809)

April 2022 HCPCS Codes (Page 811)

For the April 2022 update, there were no new CPT codes but, there were several new Level II HCPCS codes.

The rule's Table 71 lists the new Level II HCPCS codes implemented April 1, 2022, along with their payment indicators for CY 2023.

July 2022 HCPCS Codes (Page 813)

The new HCPCS codes that were recognized as ASC covered ancillary services in July 2022 through the quarterly update CRs, are listed in the rule's Table 72.

October 2022 HCPCS Codes (Page 816)

For CY 2023, consistent with CMS' established policy, CMS proposed that the Level II HCPCS codes that will be effective October 1, 2022, would be flagged with comment indicator "NI" in Addendum BB to indicate that CMS has assigned the codes interim ASC payment indicators for CY 2023.

January 2023 HCPCS Codes (Page 816)

These codes are listed in Addendum AA and Addendum BB with short descriptors only, CMS is listing them again in Addendum O with the long descriptors.

Level II HCPCS codes that will be effective January 1, 2023, are included in this final rule with comment period, and will also be released to the public through in the January 2023 ASC Update CR and the CMS HCPCS website.

C. Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services (Page 819)

CMS is finalizing its proposal, without modification, to permanently designate the 6 procedures in the rule's table 76 as office-based procedures. (Page 824)

The rule's table 78 contains 9 surgical procedures as temporary office-based for CY 2023. (Page 825)

The ASC covered surgical procedures subject to the device-intensive procedure payment methodology for CY 2023, are assigned payment indicator "J8" and are included in Addendum AA and FF. (Page 828)

CMS is assigning the device offset percentage of CPT code 0627T to CPT code 0629T and assigning CPT code 0629T device-intensive status. (Page 834)

Under current ASC policy, all ASC device-intensive covered surgical procedures are subject to the no cost/full credit and partial credit device adjustment policy. Specifically, when a device-intensive procedure is performed to implant or insert a device that is furnished at no cost or with full credit from the manufacturer, the ASC would append the HCPCS "FB" modifier on the line in the claim with the procedure to implant or insert the device.

D. Changes to the List of ASC Covered Surgical Procedures for CY 2023 (Page 842)

CMS proposed to update the ASC Covered

continued

Procedures List (CPL) by adding lymphatic procedure to the list for CY 2023, as shown in the rule's Table 79.

CMS says a few stakeholders expressed disappointment that CMS only proposed to add one code for CY 2023.

Further, CMS notes that multiple commenters recommended specific codes that they believed met the criteria to be added to the ASC CPL, including cardiovascular and cardiac ablation codes, thyroid-related procedures, and electroconvulsive therapy. Several orthopedic providers requested that total shoulder arthroplasty, total ankle arthroplasty and lumbar spine fusion procedures be added to the CPL, based on claims of safe and routine performance in ASCs, low infection rates, and financial savings.

CMS received 64 procedure recommendations in total, listed in the rule's Table 80. Some of these recommendations were accompanied by supporting literature or evidence, while other comments only provided anecdotal evidence and simply stated general support for these procedures. (Page 843)

CMS says it believes that four procedures (CPT codes 19307, 37193, 38531, and 43774) out of the 64 procedure recommendations can be safely performed for the typical beneficiary in the ASC setting and meet the general standards and exclusion criteria for the ASC CPL as set forth in 42 CFR 416.166(b) and (c), respectively.(Page 848)

D. ASC Special Payment Policy for OPPS Complexity-Adjusted C-APCs (Page 861)

CMS is finalizing the ASC special payment policy for OPPS complexity-adjusted C-APCs, as proposed. CMS is creating C codes that represent code combinations. The final C codes for CY 2023 can be found in ASC addendum AA. (Page 868)

E. ASC Payment System Policy for Non-Opioid Pain Management Drugs and Biologicals that Function as Surgical Supplies (Page 877)

The rule's table 83 lists the four drugs that met CMS' finalized criteria established in CY 2022 and received separate payment under the ASC payment system.

CMS is finalizing **§ 416.174(a)(3), which states that non-opioid pain management drugs or biologicals that function** as a supply in a surgical procedure are eligible for separate payment if the drug or biological does not have transitional pass-through payment status under § 419.64. In the case where a drug or biological otherwise meets the requirements under § 416.174 and has transitional pass-through payment status that will expire during the calendar year, the drug or biological would qualify for separate payment under § 416.174 during such calendar year on the first day of the next calendar year quarter after its pass-through status expires. Second, CMS is finalizing § 416.174(a)(4), which states that the drug or biological must not already be separately payable in the OPPS or ASC payment system under a policy other than the one specified in § 416.174. (Page 885) The rule's table 84 lists the five drugs that CMS is finalizing as eligible to receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2023. *(Page 893)*

F. New Technology Intraocular Lenses (NTIOLs) (Page 898)

CMS did not receive any request for review to establish a new NTIOL class for CY 2023. CMS did not propose to revise the payment adjustment amount for CY 2023.

The current payment adjustment for a five-year period from the implementation date of a new NTIOL class is $50 per lens. This amount has not changed since 1999.

continued

XIV REQUIREMENTS FOR THE HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM (Page 918)

Modifications to Previously Adopted Measures (Page 921)

CMS is changing the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) Measure from mandatory to voluntary beginning with the CY 2027 payment determination. (Page 926)

Previously Finalized and Proposed Hospital OQR Program Measure Sets (Page 927)

Table 85 below summarizes the previously finalized Hospital OQR Program measure set for the CY 2024 payment determination. (Page 927)

Table 85 Hospital OQR Program Measure Set for the CY 2024 Payment Determination

NQF #	Measure Name
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention
0514	OP-8: MRI Lumbar Spine for Low Back Pain
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-38: COVID-19 Vaccination Coverage Among Health Care Personnel
None	OP-39: Breast Cancer Screening Recall Rates

Table 86 below summarizes the Hospital OQR Program measure set including for the CY 2025 payment determination: (Page 927)

continued

Table 86 Hospital OQR Program Measure Set for the CY 2025 Payment Determination

NQF #	Measure Name
0514	OP-8: MRI Lumbar Spine for Low Back Pain
None	OP-10: Abdomen CT – Use of Contrast Material
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients
0499	OP-22: Left Without Being Seen
0661	OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
1536	OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery
2539	OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
None	OP-35: Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	OP-36: Hospital Visits after Hospital Outpatient Surgery
None	OP-37a: Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery Survey (OAS CAHPS) – About Facilities and Staff
None	OP-37b: OAS CAHPS – Communication About Procedure
None	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery
None	OP-37d: OAS CAHPS – Overall Rating of Facility
None	OP-37e: OAS CAHPS – Recommendation of Facility
None	OP-38: COVID-19 Vaccination Coverage Among Health Care Personnel
None	OP-39: Breast Cancer Screening Recall Rates
None	OP-40: ST-Segment Elevation Myocardial Infraction (STEMI) electronic clinical quality measure (eCQM)

Alignment of Hospital OQR Program Patient Encounter Quarters for Chart-abstracted Measures to the Calendar Year Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination (Page 955)

CMS is finalizing its proposal to align the patient and encounter quarters for chart-abstracted measures with the calendar year beginning with the CY 2024 for reporting/ CY 2026 payment determination. (Page 958)

XV. REQUIREMENTS FOR THE AMBULATORY SURGICAL CENTER QUALITY REPORTING (ASCQR) PROGRAM (Page 975)

Modifications to Previously Adopted Measures (Page 983)

CMS is finalizing its proposal to change ASC–11 from mandatory to voluntary beginning with the CY 2025 reporting period/ CY 2027 payment determination.

ASCQR Program Quality Measure Set (Page 983)

The rule's table 94 summarizes the previously finalized ASCQR Program measure set for the CY 2023 reporting period/ CY 2025 payment determination and the CY 2024 reporting period/ CY 2026 payment determination.

continued

Table 94 ASCQR Program Measure Set for the CY 2023 Reporting Period/ CY 2025 Payment Determination and the CY 2024 Reporting Period/CY 2026 Payment Determination

ASC #	NQF #	Measure Name
ASC-1	0263	Patient Burn
ASC-2	0266	Patient Fall
ASC-3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265	All-Cause Hospital Transfer/Admission
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel

The rule's table 95 summarizes the previously finalized ASCQR Program measure set for the CY 2025 reporting period/ CY 2027 payment determination and as modified by the finalized proposal in this CY 2023 OPPS/ASC final rule. (Page 984)

Finalized ASCQR Program Measure Set for the CY 2025 Reporting Period/ CY 2027 Payment Determination

ASC #	NQF #	Measure Name
ASC-1	0263	Patient Burn
ASC-2	0266	Patient Fall
ASC-3	0267	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265	All-Cause Hospital Transfer/Admission
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11*	1536	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-15a	None	OAS CAHPS – About Facilities and Staff
ASC-15b	None	OAS CAHPS – Communication About Procedure
ASC-15c	None	OAS CAHPS – Preparation for Discharge and Recovery
ASC-15d	None	OAS CAHPS – Overall Rating of Facility
ASC-15e	None	OAS CAHPS – Recommendation of Facility
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel*

* The ASC-11 measure was previously finalized as mandatory for the CY 2025 program year as set forth in the CY 2022 OPPS/ASC final rule with comment period and is being finalized as voluntary in this final rule.

continued

The OQR and ASCQR sections contain much more information than the material presented here. Items addressed include potential future additions; the form, manner and timing of data submissions; and, extraordinary exceptions.

FINAL THOUGHTS

As previously noted, this analysis does not include all material expressed in the rulemaking.

This has been one of CMS' more difficult rules to comprehend. Indeed, some sections are concise and understandable while others are not. As stated before, the logic to the partial hospitalization material rambles as does the material for 340B changes.

Trying to follow CMS' logic of numbering within its rules is complicated and extremely time consuming. CMS needs to more completely cite full sections within the body of the rule. Telling one this "a" and it follows with "b" may not very helpful. CMS needs to add the Section, for example "II." This needs to be followed with the major sub-section head, for example Section II "A."

The OPPS and ASC payment systems rely on extensive coding. The amount of coding changes are both extensive and impact final payments.

CMS' continued historical information and time frames maybe helpful to some, but to most, it is simply overkill and a distraction. It adds significant unneeded verbiage. We believe most would like to see updates that simply focus on what is the current policy and to what is changing for the following year(s). Prior development is totally unnecessary.

These unneeded history citations are like an automaker explaining all the changes that have been made for the last 20 or more years to its latest models. Buyers do not care about such. They just want to know the improvements in the latest models.

These rules should not be a continuing historical learning tool inasmuch as much prior information is no longer relevant and has been superseded.

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