American Hospital Association™
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Regulatory Advisory

August 1, 2022

Hospital Outpatient, Ambulatory Surgical Center Proposed Rule for CY 2023

The Centers for Medicare & Medicaid Services (CMS) July 15 released its calendar year (CY) 2023 outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) proposed rule that would increase OPPS rates by a net 2.7% in CY 2023 compared to CY 2022. The rule also includes proposals related to the 340B Drug Pricing Program, Rural Emergency Hospital (REH) model, and site-neutral clinic visit payment policy, among other items. The final rule will be published on or around Nov. 1 and take effect Jan. 1, 2023. CMS will accept comments on the proposed rule through Sept. 13.

KEY HIGHLIGHTS

CMS' proposed rule would:

- Increase Medicare hospital OPPS rates by a net 2.7% in CY 2023 compared to CY 2022.
- Anticipate paying 340B hospitals at average sales price (ASP) plus 6% in 2023 given the unanimous Supreme Court decision that ruled the agency's prior payment policy as unlawful.
- Establish payment and enrollment policies, as well as foundational quality reporting requirements for the REH model.
- Exempt rural sole community hospitals (SCHs) from the site-neutral clinic visit cuts and instead pay for clinic visits furnished in grandfathered (excepted) off-campus provider-based departments (PBDs) of these hospitals at the full OPPS rate.
- Continue payment for remote behavioral health services beyond the end of the public health emergency (PHE).
- Require prior authorization for an additional service category — facet joint injections and nerve destruction.
- Revise the inpatient-only (IPO) list to remove 10 services and add eight services.
- Add one procedure, a lymph node biopsy or excision, to the ASC covered procedures list (CPL).
- Update certain organ acquisition payment policies and solicit information on methodologies to determine Medicare's share of organ acquisition costs.
- Make payment adjustment for the additional cost that hospitals face in procuring domestic NIOSH-approved surgical N95 respirators.
- Request information about outpatient mental health services and the use of CMS data to drive competition in health care.

AHA TAKE

The AHA is deeply concerned about CMS' proposed payment update of only 2.7% given the extraordinary inflationary environment and continued labor and supply cost pressures hospitals and health systems face. Hospitals and health systems — and their caregivers — have been on the front lines of the COVID-19 pandemic for over two years now. While we have made great progress in the fight against this virus, our members continue to face a range of challenges that threaten their ability to continue caring for patients and providing essential services for their communities. A much higher update is warranted, and we will be closely analyzing CMS' proposed market basket, as well as its proposed productivity offset.

We appreciate CMS' decision to end their unlawful policy to significantly cut payments to 340B hospitals for 2023 following the Supreme Court's recent unanimous ruling in our favor. The end of this harmful policy will help ensure that 340B hospitals can provide comprehensive health care services to the patients and communities they serve. Given that CMS has recognized that its policy was unlawful, we will urge the Administration to promptly reimburse those hospitals affected by these cuts for all years that the policy was in place. At the same time, no hospital should be penalized for the agency's implementation of an unlawful policy. The AHA will continue to push the agency to *not* attempt to recoup funds from the rest of the hospital field, especially as hospitals and health systems continue to deal with rising inflation and skyrocketing costs for supplies, equipment, drugs and labor.

Finally, we look forward to reviewing the proposals for payments under the REH model and further engaging with the agency to establish the new provider type. The REH model will help rural hospitals continue to serve as an access point to care in their communities, which is especially critical given the many challenges they have faced during the pandemic. See the AHA statement on the OPPS proposed rule.

WHAT YOU CAN DO

- **Participate in an AHA members-only webinar on Aug 23 at 3:00 p.m. ET** to share your questions about and feedback on this regulation for AHA's comment letter to CMS. To register for this 90-minute webinar, visit here.
- **Share this advisory with your senior management team,** and ask your chief financial officer to examine the impact of the proposed payment changes on your Medicare revenue for CY 2023.
- **Share this advisory with your billing, medical records, quality improvement and compliance departments, as well as your clinical leadership team** to apprise them of the proposals around the ambulatory payment classifications (APCs), REH and quality measurement requirements.
- **Submit comments to CMS with your specific concerns by Sept. 13 at www.regulations.gov.**

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OPPS PROPOSED RULE CHANGES

OPPS UPDATE AND LINKAGE TO HOSPITAL QUALITY DATA REPORTING

The CY 2022 OPPS conversion factor is $84.177. To calculate the proposed conversion factor for CY 2023, the agency adjusted the 2022 conversion factor by the fee schedule increase factor and made further adjustments for various budget-neutrality factors. The fee schedule increase factor equals the proposed hospital market-basket increase factor of 3.1%, reduced by a statutorily-required productivity adjustment of 0.4 percentage points. Thus, CMS applies the resulting fee schedule increase factor of 2.7% for the CY 2023 OPPS proposed rule. Hospitals that do not meet outpatient quality reporting (OQR) program requirements are subject to a further reduction of 2.0 percentage points, resulting in a proposed fee schedule increase factor of 0.7%. Thus, the proposed CY 2023 OPPS conversion factor is $86.785 for hospitals meeting OQR requirements and $85.093 for hospitals that do not meet OQR requirements.

These payment adjustments, in addition to other proposed changes[1] in the rule, are estimated to result in a net increase in total OPPS payment to hospitals of approximately 3.0%, or $1.8 billion, in CY 2023 compared to CY 2022, which includes beneficiary cost-sharing but not the estimated changes in enrollment, utilization and case-mix. The table below details the impact of proposed policies.

All Hospitals	**3.0%**
Urban Hospitals	2.9%
Large Urban	2.9%
Other Urban	3.0%
Rural	3.2%
Sole Community	3.4%
Other Rural	2.7%

DATA PROPOSED FOR USE IN CY 2023 OPPS AND ASC RATESETTING

CMS proposes to use CY 2021 claims data to set CY 2023 OPPS and ASC rates. While it would typically use the CY 2020 cost report data as well, the agency believes that this year is not the best overall approximation of expected outpatient hospital services due to the PHE. Thus, CMS proposes to use cost report data from the June 2020 extract from the Healthcare Cost Report Information System, which includes cost report data from prior to the PHE. This is the same cost report extract CMS used to set OPPS rates for CY 2022.

[1] This includes the additional adjustments to the conversion factor resulting from a change in the pass-through estimate, the difference from 2022 outlier payments, and proposed changes to rural SCH off-campus policy and N95 mask adjustment.

PROPOSED SITE-NEUTRAL PAYMENT POLICIES FOR OFF-CAMPUS PROVIDER-BASED DEPARTMENTS (PBDs)

CY 2023 Site-neutral Payment in Non-grandfathered (Non-excepted) Off-campus PBDs. Section 603 of the Bipartisan Budget Act of 2015 (BiBA) requires that services, with the exception of dedicated emergency department (ED) services, furnished in off-campus PBDs that began billing under the OPPS on or after Nov. 2, 2015, or that cannot meet the 21st Century Cures "mid-build" exception, will no longer be paid under the OPPS, but under another applicable Part B payment system.

For 2023, the agency continues to identify the Physician Fee Schedule (PFS) as the applicable payment system for most of these non-grandfathered (non-excepted) services and sets payment for most non-grandfathered (non-excepted) services at 40% of the OPPS rate.

Proposed Exemption of Rural SCHs from Site-Neutral Payment Reductions for Outpatient Clinic Visits in Grandfathered (Excepted) Off-campus PBDs. In the CY 2023 proposed rule, the agency indicates that it has continued to assess how the site-neutral policy has been implemented, and how it affects both the Medicare program itself and the beneficiaries it serves. CMS notes that there are a number of special payment provisions designed to maintain access to care in rural SCHs. These include the 7.1% increase in payment for all services and procedures to compensate them for their higher costs relative to other OPPS hospitals and their exemption from CMS' policy to reduce payment for 340B program drugs from ASP+6% to ASP-22.5%.

Further, CMS indicates that many rural providers, and rural SCHs in particular, are often the only source of care in their communities, which means beneficiaries and providers are not choosing between a higher paying off-campus PBD of a hospital and a lower paying physicians' office setting. The closure of inpatient departments of hospitals and the shortage of primary care providers in rural areas further drives utilization to off-campus PBDs in areas where rural SCHs are located.

For these and other reasons, CMS believes that exempting rural SCHs from being paid a PFS-equivalent rate for a clinic visit in an off-campus PBD would help to maintain access to care in rural areas. **Therefore, for CY 2023, CMS proposes to pay the full OPPS payment rate, rather than 40% of the OPPS rate, when a clinic visit is furnished in a grandfathered (excepted) off-campus PBD of a rural SCH.** CMS estimates that this exemption would increase OPPS spending by approximately $75 million in CY 2023, compared to spending in the absence of this proposed policy.

CMS also is requesting comments on whether it would be appropriate to exempt other rural hospitals, such as those with fewer than 100 beds, from this site-neutral payment policy.

PROPOSED 340B DRUG PAYMENT POLICY, INCLUDING IN OFF-CAMPUS PBDs

CMS announced that the agency "fully anticipate(s) applying" a payment rate of ASP plus 6% to 340B-acquired drugs and biologicals in 2023 in light of the Supreme Court's recent decision in *American Hospital Association v. Becerra*. The payment rate of ASP plus 6% also would apply to such drugs and biologicals when furnished in non-excepted off-campus provider-based departments (PBDs) paid under the Medicare PFS. Because of the timing of the court's decision in mid-June, the agency did not have sufficient time to formally propose this policy in the rule. As such, CMS continues to propose the current payment rate of ASP minus 22.5%, which it notes will be restored in the CY 2023 final rule to ASP plus 6% with the requisite changes to the proposed conversion factor.

In restoring the payment rate to ASP plus 6%, CMS stated it needs to make a corresponding decrease to the OPPS conversion factor in order to ensure that the increase in payment from ASP minus 22.5% to ASP plus 6% remains budget neutral. Based on CMS' calculations, the increase in payment would result in approximately $1.96 billion that would need to be offset by a decrease in the OPPS conversion factor through a budget neutrality adjustment of 0.9596. Should CMS finalize paying ASP plus 6% for 340B-acquired drugs, this adjustment would result in lowering the OPPS conversion factor from $86.785 to $83.279. The AHA has long raised concerns that CMS's budget neutrality adjustment to the conversion factor is not accurate and results in underpayments to hospitals. We continue to have concerns that CMS' calculations of the budget neutrality adjustment as outlined in the proposed rule may result in further underpayment of hospitals in CY 2023.

While CMS is clear in its intent to restore the payment rate to ASP plus 6% in the final rule for 2023, it remains unclear whether the agency will continue to require 340B hospitals to report claims using either the "JG" or "TB" modifiers to identify 340B drugs. These and other related 340B policies, such as application of the ASP plus 6% payment policy to drugs with no average sale prices (e.g., wholesale acquisition cost (WAC) or Average Wholesale Price (AWP) priced drugs) are expected to be addressed in the final rule.

The agency also notes it is evaluating the impact of the Supreme Court's decision on its 340B payment policy for CYs 2018 through 2022. CMS notes that the court did not address a remedy to repay affected hospitals in its ruling. As a result, CMS is calling for public comment on ways to craft potential remedies for affected hospitals for CYs 2018 through 2022. The agency also notes in the proposed rule that it conducted a survey of 340B acquisition costs in CY 2020 as a potential remedy in response to the District Court's initial decision to overturn CMS' policy. This survey resulted in a net payment rate calculated by the agency to be ASP minus 28.7%. However, CMS indicates that it did *not* rely on that survey to set payment rates in CYs 2021 and 2022 based on feedback received from commenters and to maintain consistency in payments for hospitals. In this year's proposed rule, the agency once again does not indicate it will use the results of the survey to set payment rates for 340B drugs for CY 2023.

According to CMS' calculations in prior rules, it estimated that 340B hospitals affected by the payment policy found unlawful by the Supreme Court experienced annual payment reductions of approximately $1.6 billion. However, the AHA believes this number underestimates the true value of reduced payments to 340B hospitals. Regardless, any remedy will require repayment of all money taken away from 340B hospitals. The AHA will continue to push the agency for prompt repayment in a manner that does not penalize the rest of the hospital field for the consequences of CMS' decision to implement an unlawful policy. The AHA will provide further guidance on this issue in the coming weeks.

OTHER PROPOSED PAYMENT CHANGES FOR DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS

Packaging Policy for "Threshold-packaged" and "Policy-packaged" Drugs, Biologicals and Radiopharmaceuticals. CMS proposes payment rates for drugs, biologicals and radiopharmaceuticals without pass-through status based on fourth quarter of 2021 ASP data. Updates to the ASP-based rates will be published quarterly and posted on CMS' website through CY 2023.

CMS pays for drugs, biologicals and radiopharmaceuticals that do not have pass-through status in one of two ways: packaged payment or separate payment (individual (APCs). For CY 2023, CMS proposes to increase the packaging threshold for "threshold-packaged" drugs, including nonimplantable biologicals and therapeutic radiopharmaceuticals to $135 per day, $5 more than the CY 2021 threshold. Specifically, drugs, biologicals and radiopharmaceuticals with a per day cost of $135 or less would have their cost packaged in the procedure with which they are billed, such as an outpatient clinic visit. Drugs, biologicals and radiopharmaceuticals costing more than $135 would be paid separately through their own APC.

There are exceptions to this threshold-based packaging policy for certain "policy-packaged" drugs, biologicals and radiopharmaceuticals. Consistent with current CMS packaging policy, the agency proposes to continue to package the costs of all anesthesia drugs; intraoperative items and services; drugs, biologicals and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure (e.g., skin substitutes), regardless of whether they meet the $135 per day threshold. The proposed packaged or separately payable status of each of these drugs or biologicals is listed in Addendum B to the proposed rule.

Proposed Payment for Drugs without Pass-through Status that are not Packaged

Separately Payable Drugs and Biologicals. For CY 2023, CMS proposes to continue its current policy and pay for separately payable drugs and biologicals at the "statutory default rate" of ASP plus 6%. CMS notes that this payment requires no further

adjustment and represents the combined acquisition and pharmacy overhead payment for drugs and biologicals.

Payment for New Drugs Before ASP Data are Available. CMS proposes to continue to pay for new nonpass-through Part B drugs and biologicals during an initial sales period (two quarters) for which ASP pricing data are not yet available at a rate of WAC plus 3%. Other drugs and biologicals where ASP data are not available will continue to be paid at WAC plus 6%. If ASP and WAC data are unavailable, Medicare will pay 95% of AWP.

PROPOSED RECALIBRATION AND SCALING OF APC RELATIVE WEIGHTS

For 2023, CMS proposes to recalibrate the APC relative weights using hospital claims for services furnished during CY 2021. However, as noted above, CMS is continuing to use cost reports that precede the COVID-19 PHE for cost-to-charge ratios (CCR) that are used to adjust charges on claims to cost. As in previous years, the agency standardizes all of the relative payment weights to the APC 5012 (Level 2 Examinations and Related Services) because that is the APC to which Healthcare Common Procedure Coding System (HCPCS) code G0463 (hospital outpatient clinic visit for assessment and management of a patient) is assigned. G0463 is the most frequently billed OPPS service. That is, CMS calculates an "unscaled" – i.e., not adjusted for budget neutrality – relative payment weight by comparing the geometric mean cost of each APC to the geometric mean cost of the APC 5012.

Although CMS has reduced payment for clinic visits furnished in excepted off-campus PBDs, it continues to use visits in these settings in determining the relative weight scalar. The agency notes that while the volume associated with these visits is included in the impact model, and thus used in calculating the weight scalar, the policy has a negligible effect on the scalar. That is, the PFS-equivalent adjuster is applied to the clinic visit payment, not the relative weight, and CMS's clinic visit payment policy is not budget neutral while changes to the weights are budget neutral.

To comply with budget-neutrality requirements, CMS compares the estimated unscaled relative payment weights in CY 2023 to the estimated total relative payment weights in CY 2022 using the service volume in the CY 2021 claims data. Based on this comparison, the CY 2023 unscaled APC payment weights are adjusted by a weight scalar of 1.4152. The effect of the adjustment is to increase the unscaled relative weights by about 41.52% in order to ensure that the CY 2023 relative payment weights are budget neutral.

AREA WAGE INDEX

The area wage index adjusts payments to reflect differences in labor costs across geographic areas. For CY 2023, CMS proposes to continue its policy of applying a 60% labor-related share to determine hospital outpatient payments.

As it has done in previous years, CMS proposes to adopt the final fiscal year inpatient PPS post-reclassified wage index as the calendar year wage index for the OPPS. Thus, any policies or adjustments finalized in the FY 2023 IPPS final rule would be reflected in the final CY 2023 OPPS wage index. These may include policies to:

- Implement a permanent policy to cap any decrease in a hospital's final wage index at 5%;
- Implement an imputed floor wage index adjustment for hospitals in all-urban states;
- Continue its policy to increase the wage index value for low-wage hospitals; and
- Continue to exclude the wage data of urban hospitals that reclassify to rural areas when calculating the wage index for the rural floor.

For hospitals paid under the OPPS but not the IPPS, CMS proposes to continue its longstanding policy to assign the wage index that would be applicable if the hospital were paid under the IPPS, based on its geographic location and any applicable wage index adjustments.

For more information on proposed wage index policies for 2023, see the AHA FY 2023 inpatient PPS proposed rule Regulatory Advisory.

RURAL SCH ADJUSTMENT

CMS proposes to continue increasing payments to rural SCHs, including essential access community hospitals, by 7.1% for all services paid under the OPPS, with the exception of drugs, biologicals, services paid under the pass-through policy, and items paid at charges reduced to costs. The adjustment is budget neutral to the OPPS and applied before calculating outliers and coinsurance.

CANCER HOSPITAL ADJUSTMENT

CMS proposes to continue to provide additional OPPS payments to each of the 11 "exempt" cancer hospitals so that each cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average "target" PCR for other OPPS hospitals. Any change in these additional payments from year to year is required to be budget neutral.

CMS proposes to continue to use the same target PCR it used for 2021 and 2022. Under the proposed policy for 2023, the target PCR would remain at 0.89. This proposed PCR includes a 1.0 percentage point reduction required by a provision in the 21st Century Cures Act.

Therefore, for 2023, CMS would make additional payments to ensure each cancer hospital had a PCR equal to 0.89. Table 4 in the proposed rule shows the estimated hospital-specific payment adjustment for each of the 11 cancer hospitals. The cancer

hospital adjustment is applied at cost report settlement rather than on a claim-by-claim basis.

COMPREHENSIVE APCs

There are currently 69 comprehensive APCs (C-APCs) that package together an expanded number of related items and services contained on the same claim into a single payment for a comprehensive primary service under the OPPS. For CY 2023, CMS proposes to add one new C-APCs in 2023: C-APC 5372 (Level 2 Urology and Related Services). The complete list of CY 2023 C-APCs is in Table 1 of the proposed rule.

For 2023, CMS also proposes a new policy to exclude HCPCS Code C9399 (Unclassified drugs or biologicals) from the C-APC policy. This code allows for pricing of the product at 95% of AWP before a specific HCPCS code is assigned to a new drug or biological. Since the implementation of the C-APC policy in 2015, payment for drugs and biologicals described by this code has been included in the C-APC payment when these products appear on a claim with a primary C-APC service. CMS believes that excluding HCPCS code C9399 from the C-APC policy will ensure that drugs that do not yet have a specific HCPCS code will be priced at 95% of AWP.

PROPOSED CHANGES TO THE IPO LIST

The IPO list specifies those procedures and services for which the hospital will be paid only when the procedures are provided in the inpatient setting because of the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. As part of its annual update process, CMS historically collaborates with applicable stakeholders and interested parties to evaluate the IPO list and to determine whether services should be added to or removed from the list. It uses five criteria to assess procedures for removal from the IPO list:

- Most outpatient departments are equipped to provide the services to the Medicare population.
- The simplest procedure described by the code may be furnished in most outpatient departments.
- The procedure is related to codes that have already removed from the IPO list.
- A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis.
- A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by CMS for addition to the ASC list.

For CY 2023, CMS proposes to remove 10 procedures from the IPO list. Eight of these 10 procedures involve maxillofacial reconstruction services which had been removed from the IPO list in CY 2021 as part of the phased-in elimination of the IPO list, but were

then added back to the IPO list in CY 2022. CMS requests comment regarding the proposal to remove these eight procedures from the IPO list and assign them to APC 5165 – Level 5 ENT Procedures with a status indictor “J1”.

- CPT code 21141 (Reconstruction midface, lefort i; single piece, segment movement in any direction (e.g., for long face syndrome), without bone graft)
- CPT code 21142 (Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft).
- CPT code 21143 (Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft).
- CPT code 21194 (Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; with bone graft (includes obtaining graft))
- CPT code 21196 (Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation)).
- CPT code 21347 (Open treatment of nasomaxillary complex fracture (lefort ii type)); requiring multiple open approaches).
- CPT code 21366 (Open treatment of complicated (e.g., comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft))
- CPT code 21422 (Open treatment of palatal or maxillary fracture (lefort i type))

The remaining two procedures proposed for removal from the IPO list, which involve escharotomy and arthrodesis, are both add-on codes that are billed with the primary procedure CPT codes. CMS requests comment regarding the proposal to remove these procedures from the IPO list and assign them a status indictor “N:”

- CPT code 16036 Escharotomy; each additional incision (list separately in addition to code for primary procedure)
- CPT code 22632 Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)

In addition, CMS proposes to add eight services to the IPO list. These services involve hernia repair, total disc arthroplasty and mesh implantation for delayed closer defects. These procedure codes were newly created by the AMA CPT Editorial Panel for CY 2023 and were deemed to require hospital inpatient admission based on CMS’s clinical review:

- CPT Code 157X1 Implantation of absorbable mesh or other prosthesis for delayed closure of defect(s) (i.e., external genitalia, perineum, abdominal wall) due to soft tissue infection or trauma
- CPT Code 228XX Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)

- CPT Code 49X06 Repair of anterior abdominal hernia(s) (i.e., epigastric, incisional, ventral, umbilical, spigelian), any approach (i.e., open, laparoscopic, robotic), initial, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, incarcerated or strangulated
- CPT Code 49X10 Repair of anterior abdominal hernia(s) (i.e., epigastric, incisional, ventral, umbilical, spigelian), any approach (i.e., open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); 3 cm to 10 cm, incarcerated or strangulated
- CPT Code 49X11 Repair of anterior abdominal hernia(s) (i.e., epigastric, incisional, ventral, umbilical, spigelian), any approach (i.e., open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, reducible
- CPT Code 49X12 Repair of anterior abdominal hernia(s) (i.e., epigastric, incisional, ventral, umbilical, spigelian), any approach (i.e,, open, laparoscopic, robotic), recurrent, including placement of mesh or other prosthesis when performed, total length of defect(s); greater than 10 cm, Cincarcerated or strangulated
- CPT Code 49X13 Repair of parastomal hernia, any approach (ie, open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; reducible
- CPT Code 49X14 Repair of parastomal hernia, any approach (i.e., open, laparoscopic, robotic), initial or recurrent, including placement of mesh or other prosthesis, when performed; incarcerated or strangulated

PROPOSED ADDITION TO THE PRIOR AUTHORIZATION PROGRAM

Citing its statutory authority to control “unnecessary increases in the volume of covered OPD services,” CMS in the CY 2020 OPPS final rule established a prior authorization process as a condition of payment for certain hospital-based services. Table 80 in the proposed rule lists all the service categories and services to which prior authorization currently applies.

In the proposed rule, CMS proposes to add one new service category, Facet Joint Interventions, to the prior authorization list, effective for dates of services on or after March 1, 2023. The Facet Joint Interventions service category would consist of facet joint injections, medial branch nerve blocks, and facet joint nerve destruction. The CPT codes that CMS proposes for inclusion in the Facet Joint Interventions service category are:

- CPT 64490: Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
- CPT 64491: Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level

- CPT 64492: Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s)
- CPT 64493: Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
- CPT 64494: Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level
- CPT 64495: Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s)
- CPT 64633: Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
- CPT 64634: Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint
- CPT 64635: Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
- CPT 64636: Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint

While previous year's additions of services to the prior authorization program were given an effective date of July 1,' CMS notes that it proposes March 1, 2023 as the effective date because the Medicare Administrative Contractors, CMS, and HOPDs already have experience with the prior authorization process. In addition, CMS notes this new service category can be performed by some of the same provider types who furnish other services currently subject to the HOPD prior authorization process.

In its rationale for adding the Facet Joint Interventions service category to the prior authorization program, CMS concludes that both the facet joint injections/medial branch block CPT codes and nerve destruction CPT codes, with 2.5% and 7% annual increases, respectively, demonstrated higher average annual increases in claim submissions between 2012 and 2021 than the 0.6% annual increase for all outpatient department services over the same time period.

In addition, the agency notes that the Department of Health and Human Services Office of the Inspector General has published multiple reports indicating questionable billing practices, improper Medicare payments, and questionable utilization of facet joint interventions. In March 2022, the Department of Justice

reported a $250 million fraud scheme involving physicians allegedly subjecting their patients to medically unnecessary facet joint injections in order to obtain illegal prescriptions for opioids. CMS also reviewed clinical and industry-related literature and did not find any indication that justifies the increases. CMS concludes that increases are due to financial motives.

HOSPITAL OUTPATIENT OUTLIER PAYMENTS

Outlier payments are added to the APC amount to mitigate hospital losses when treating high-cost cases. CMS again proposes to establish separate thresholds for hospitals and community mental health centers (CMHCs). For CY 2023, CMS proposes to set the projected target for outlier payments at 1% of total OPPS payments. The agency proposes to allocate 0.01% of outlier payments to CMHCs for partial hospitalization program (PHP) services.

CMS continues to include both a fixed-dollar and a percentage outlier threshold. In CY 2023, CMS proposes to increase the fixed-dollar threshold for outliers to $8,350 (compared to $6,175 in CY 2022) to ensure that outlier spending does not exceed the outlier target.

Thus, to be eligible for an outlier payment in CY 2023, the cost of a hospital outpatient service would have to exceed 1.75 times the APC payment amount (the percentage threshold), *and be* at least $8,350 more than the APC payment amount. When the cost of a hospital outpatient service exceeds these applicable thresholds, Medicare would make an outlier payment that is 50% of the amount by which the cost of furnishing the service exceeds 1.75 times the APC payment rate.

TRANSITIONAL PASS-THROUGH PAYMENTS

Congress created temporary additional, or “transitional pass-through payments,” for certain innovative medical devices, drugs, and biologicals to ensure that Medicare beneficiaries have access to new technologies in outpatient care. For CY 2023, CMS projects that pass-through payments will be 1.24% of total OPPS payments, or $1.02 billion. This includes $552.3 million in pass-through payments for devices and $472.4 million for drugs and biologicals. These payments are implemented in a budget-neutral manner.

PHP PAYMENT AND POLICY UPDATE

Update to PHP Per Diem Rates. CMS proposes to use its established policies to calculate the PHP APC per diem payment rates for CMHCs and hospital-based PHP providers based on geometric mean per diem costs using the most recent claims and cost data for each provider type, with some modifications. For CY 2023 rate setting, CMS proposes to use CY 2021 claims data and cost information from prior to the COVID-19 PHE; that is, the cost information that was available for the CY 2021 OPPS/ASC rulemaking.

The agency further proposes to maintain the existing rate structure, with a single PHP APC for each provider type with three or more services per day. The agency proposes to follow its existing methodology to calculate the hospital-based and CMHC PHP geometric mean per diem costs for CY 2023. As described in the table below, this results in a proposed CY 2023 PHP per diem cost for hospital-based PHP of $264.06 for APC 5863 and a proposed CY 2023 PHP per diem geometric mean cost for CMHCs of $131.71 for APC 5853. These would be increases for both provider types compared to CY 2022.

Proposed CY 2023 PHP APC Geometric Mean Per Diem Costs

CY 2023 APC	Group Title	Proposed PHP APC Geometric Mean Per Diem Costs	Proposed Payment Rates
5853	Partial Hospitalization (three or more services per day) for CMHCs	$131.71	$130.54
5863	Partial Hospitalization (three or more services per day) for hospital-based PHPs	$264.06	$261.73

BENEFICIARY COINSURANCE

Medicare law provides that the minimum coinsurance is 20% of the OPPS payment amount. The statute also limits a beneficiary's actual cost-sharing amount for a service to the inpatient hospital deductible for the applicable year, which is $1,556 in 2022. CMS estimates that the aggregate beneficiary coinsurance percentage would be 17.8% for all services paid under the OPPS in CY 2023.

OUTPATIENT QUALITY REPORTING PROGRAM (OQR)

CMS does not propose to adopt or remove any quality measures from the OQR. The agency proposes to modify one previously adopted measure and update certain operational aspects of the OQR, and solicits feedback on a few topics. The table below summarizes the OQR Measure Set for the CY 2024-CY 2026 payment determinations if proposals in this rule are finalized, including each measure's National Quality Forum (NQF) identifier (if the measure has been endorsed by NQF). An "X" denotes whether the measure is included in the set for that reporting period; asterisks denote whether reporting of the measure is voluntary.

OQR Measures by Payment Determination Year

Measure Name	NQF #	CY 2024	CY 2025	CY 2026
OP-2: Fibrinolytic Therapy Received within 30 Minutes of ED Arrival	0288	X		

OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	0290	X		
OP-8: MRI Lumbar Spine for Low Back Pain	Endorsement Removed	X	X	X
OP-10: Abdomen CT – Use of Contrast Material	None	X	X	X
OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery	0669	X	X	X
OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients	0496	X	X	X
OP-22: Left Without Being Seen	Endorsement Removed	X	X	X
OP-23: Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Heat CT or MRI Scan Interpretation within 45 Minutes of ED Arrival	0661	X	X	X
OP-29: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	0658	X	X	X
OP-31: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	1536	X*	X*	X*
OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy	2539	X	X	X
OP-35: Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	None	X	X	X
OP-36: Hospital Visits after Outpatient Surgery	2687	X	X	X
OP-37: OAS CAHPS a-e (five individual measures)	None		X*	X
OP-38: COVID-19 Vaccination Coverage Among Health Care Personnel	None	X	X	X
OP-39: Breast Cancer Screening Recall Rates	None	X	X	X
OP-40: ST-Segment Elevation Myocardial Infarction (STEMI) eCQM	None		X*	X

Proposal to Change Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31/ASC-11) from Mandatory to Voluntary. CMS proposes to allow for voluntary rather than mandatory reporting of this measure beginning with the CY 2027 payment determination (CY 2025 reporting period). The measure was adopted in the CY 2014 OPPS/ASC final rule, but implementation was delayed (and the measure ultimately excluded from the measure set) due to concerns

regarding the reporting burden of collecting pre- and post-operative surveys as well as the inconsistency of survey instruments used. In the CY 2022 OPPS/ASC proposed rule, CMS proposed to require reporting of the measure beginning CY 2023; however, the agency finalized a delay in mandatory reporting of the measure until CY 2025 due to comments suggesting the continued reporting burden of the measure (especially considering strains due to the PHE).

In this rule, CMS notes that it has heard ongoing concerns about the reporting burden of this measure in light of national staffing and medical supply shortages as well as changes in patient case volumes, and the existing delay of mandatory reporting is no longer sufficient. Accordingly, the agency proposes to no long require mandatory reporting for this measure in the OQR and ASCQR beginning with CY 2025. CMS notes that it plans to continue to evaluate this policy moving forward and consider mandatory reporting after the end of the PHE, but until further notice a hospital would not be subject to a payment reduction for failing to report this measure.

Proposal to Align Timeline for Chart-abstracted Measures to the Calendar Year. CMS proposes to shift the quarters of data on which OQR payment determinations are based. Currently, the timeframe for these data begins with patient encounter Quarter 2 of two years prior to the payment determination and ends with patient encounter Quarter 1 of the year prior to the payment determination, as opposed to the calendar year (for example: patient encounters that inform the CY 2028 payment determination are assessed from April 1, 2026 through March 31, 2027 rather than January 1 through December 31, 2026). Other CMS quality reporting programs (including the Inpatient Quality Reporting Program) align patient encounter timelines to the calendar year. To mitigate confusion, CMS proposes to align the patient encounter quarters for chart-abstracted measures in the OQR with the calendar year two years prior to the payment determination year beginning with the CY 2024 reporting period.

To implement this process, CMS would transition to the newly proposed timeframe for the CY 2026 payment determination (and subsequent years) by using only three quarters (Q2-Q4 of CY 2023) of data for chart-abstracted measures for the CY 2025 payment determination. Data submission deadlines would not change.

Proposed Addition of Validation Targeting Criterion. In previous rulemaking, CMS established criteria for selecting hospitals for measure data validation. The agency selects a random sample of 450 hospitals for validation, and identifies an additional 50 hospitals for validation using “targeting” criteria, selecting hospitals that:

- Have failed validation requirements in the previous year;
- Have an outlier value for a measure;
- Have not been randomly selected for validation in the past three years; or
- Passed validation in the previous year but had a two-tailed confidence interval that included 75%.

In this rule, CMS proposes to also target hospitals with less than four quarters of data subject to validation receiving an extraordinary circumstances exception for one or more quarters and with a two-tailed confidence interval that is less than 75%. CMS proposes this criterion because such a hospital would have less than four quarters of data available for validation, which would make its validation results considered inconclusive for a payment determination.

Request for Comment: Reimplementation of Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP-26 and ASC-7). CMS seeks comment on whether it should consider adopting a measure assessing procedure volume for the OQR and ASCQR. The agency explains that surgical procedures are increasingly moving into the outpatient space, and thus believes it is important to track the volume of outpatient procedures.

The OQR and ASCQR used to include one volume measure (OP-26 and ASC-7), but this measure was removed in the CY 2018 OPPS/ASC final rule as "there is a lack of evidence to support this specific measure's link to improved clinical quality." In addition, the measure was adopted in the CY 2012 OPPS/ASC final rule and was not reviewed or endorsed by NQF's Measure Applications Partnership (which first began statutorily required pre-rulemaking review of quality measures in February 2012). To be proposed for inclusion in the OQR/ASCQR, the measure would need to undergo this review.

CMS acknowledges in this rule that "quality measurement efforts moved away from procedure volume as it was considered simply a proxy for quality rather than directly measuring outcomes" and that while larger facility surgical volume may be associated with better outcomes, these are likely due to other characteristics that improve care (effective care teams or surveillance, for example) rather than the volumes alone. However, the agency reasons, in an unrelated analysis regarding the development of a pain management measure, CMS found that pain management procedures were the third most common procedure in ASCs, so a pain management measure would provide consumers with important information; "Thus, a volume measure in the Hospital OQR/ASCQR Program's measure set would provide information to Medicare beneficiaries and other interested parties on numbers and proportions of procedures by category performed by individual facilities."

CMS seeks comment on whether it should include a volume measure in the OQR/ASCQR, either by re-adopting OP-26/ASC-7 or developing another volume indicator. The agency requests feedback on the usefulness of such a volume indicator, the mechanism of volume data collection, and other considerations for the design of a volume indicator.

OVERALL HOSPITAL QUALITY STAR RATING

CMS first introduced and reported on its Hospital Compare website the Overall Hospital Quality Star Rating ("star rating") in 2016; the most current refresh of the data and ratings occurred in July 2022. In this rule, CMS provides information on the previously

finalized policy to include Veteran's Health Administration (VHA) hospitals in the program, proposes a slight revision of regulatory language, and note that CMS may apply its measure suppression policy for the 2023 star rating refresh.

Proposed Change to Data Periods Used for Refresh. In the CY 2021 OPPS final rule, CMS stated that it would use publicly available measure results on its Care Compare website "from a quarter within the prior year" to refresh the star ratings. CMS proposes to amend regulatory language to clarify that this phrase refers to any time within the previous 12 months, not just the calendar year.

Potential Future Measure Suppression. CMS notes that almost all measures included in both star ratings refreshes (in 2021 and 2022) are based on pre-COVID data; CMS exempted data reporting requirements for the first two quarters of 2020 due to the pandemic. In consideration for the 2023 refresh, CMS notes that if a measure is considered valid and reliable enough to be reported on Care Compare, then it can also be included in the star ratings even if the measure was "suppressed" in certain programs—for example, for the use of calculated penalties in the Hospital Acquired Conditions program. However, the agency reminds readers that it adopted a policy in the CY 2021 OPPS rule that would allow it to suppress the star rating for extenuating circumstances (such as an error by CMS or a PHE) affecting numerous hospitals.

CMS does not propose any changes to its policies in this rule, and states that it intends to refresh the star rating in 2023; however, the agency also notes that it may exercise its authority to suppress the star rating "should the COVID-19 PHE substantially affect the underlying measure data."

VHA Hospitals. In the CY 2021 OPPS/ASC final rule, CMS adopted a policy to include VHA hospitals' quality measure data to calculate star ratings beginning with the 2023 refresh. In this rule, CMS shares the statistical impact of this policy using the same measures from the April 2021 refresh. Findings include:

- 119 out of 171 VHA hospitals met the requirements to receive a star rating, increasing the number of hospitals receiving a star rating from 3,355 to 3,474;
- The distribution of star ratings was nearly identical for VHA and non-VHA hospitals.
- 93% (3,119) non-VHA hospitals maintained the same number of stars after adding VHA hospitals to the 2021 star ratings. Of the 236 with a different rating, 23 gained a star and 213 lost of star.

ASC PROPOSED RULE CHANGES

ASC PAYMENT UPDATE

For CYs 2019 through 2023, CMS adopted a policy to update the ASC payment system using the hospital market-basket update. As such, for CY 2023, the agency proposes to increase payment rates under the ASC payment system by 2.7% for ASCs that meet

the quality reporting requirements under the ASC quality reporting (ASCQR) program. This proposed increase is based on a proposed hospital market-basket increase of 3.1% minus a proposed productivity adjustment of 0.4 percentage points. CMS would continue its policy of reducing the update by 2.0 percentage points for ASCs not meeting the quality reporting requirements, yielding an update of 0.7% for such ASCs. CMS estimates that payments to ASCs would increase by $130 million in CY 2023 compared to CY 2022.

The resulting 2023 ASC conversion factor proposed by CMS is $51.315 for ASCs reporting quality data, and $50.315 for those that do not[2].

PROPOSED CHANGES TO ASC COVERED PROCEDURES LIST

Proposed Changes to the ASC CPL. CMS evaluates the ASC CPL each year to determine whether procedures should be added to or removed from the list. For CY 2023, CMS proposes to add one procedure, a lymph node biopsy or excision, to the ASC CPL, based upon CMS' review of the clinical characteristics of this procedure, as well as consultation with stakeholders and multiple clinical advisors.

CMS states that it expects to gradually expand the ASC CPL as medical practice, and technology continue to evolve and advance. The agency encourages stakeholders to submit recommendations for procedures be add to the ASC CPL, particularly if there is evidence that these procedures meet criteria and can be safely performed on the typical Medicare beneficiary in the ASC setting.

Proposed Name Change and Delayed Start Date of ASC-CPL Nominations Process. In the CY 2022 final rule, CMS finalized a nominations process for adding surgical procedures to the ASC CPL which was titled "Nominations."

In the CY 2023 proposed rule, CMS notes that this process is not the only way to make recommendations to CMS for adding surgical procedures to the ASC CPL. The agency reminds stakeholders that they can continue to suggest surgical procedures that they believe should be added to the ASC CPL during the public comment period following the proposed rule.

CMS acknowledges that the use of the term "Nominations" in the CY 2022 final rule may have led to confusion, indicating that this process is the primary or only pathway to suggest procedures for addition to the ASC CPL. As a result, CMS proposes to change the name of the process finalized in 2022 from "Nominations" to the "Pre-Proposed Rule CPL Recommendation Process."

In addition, CMS is working to develop the technological infrastructure and Paperwork Reduction Act package for the recommendation process. CMS notes that it was unable

[2] By comparison, the proposed CY 2023 OPPS conversion factor is $86.7850 for hospitals meeting OQR requirements and $85.0930 for hospitals that do not meet OQR requirements.

to complete these processes in time to allow commenters to recommend additional procedures be added to the ASC CPL in advance of the publication of the CY 2023 proposed rule. Therefore, CMS proposes to revise the start date of the recommendation process from Jan. 1, 2023, to Jan. 1, 2024, but reiterates that the agency welcomes all procedure submissions through the public comment process, as they have in previous years.

PROPOSED PACKAGING POLICY FOR NON-OPIOID PAIN MANAGEMENT DRUGS UNDER THE ASC PAYMENT SYSTEM

Under a policy adopted in 2019, non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting are unpackaged and paid separately at ASP + 6%. The goal of the policy is to ensure that there are not financial incentives to use opioids instead of non-opioid alternatives.

For 2022, CMS determined that four such products were eligible for separate payment in the ASC setting. Also, it modified the current non-opioid pain management payment policy in ASCs to require that evidence-based non-opioid alternatives for pain management must:

- be approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act;
- be approved under an abbreviated new drug application under section 505(j); or
- in the case of a biological product, be licensed under section 351 of the Public Health Service Act.

Furthermore, in the CY 2022 rule, CMS established a requirement that that in order for a drug or biological to qualify for separate payment in the ASC setting, it must have an FDA-approved indication for pain management or analgesia and have a per-day cost in excess of the OPPS drug-packaging threshold. For 2023, the OPPS drug packaging threshold is proposed to be $135.

In the CY 2023 proposed rule, CMS re-evaluated the four non-opioid pain management drugs and biologicals that received separate payment in the ASC setting for 2022 to determine whether they continue to qualify for separate payment in 2023. Based on its evaluation CMS proposes that the drugs described by HCPCS codes C9290 (Exparel), J1097 (Omidria), and C9089 (Xaracoll) continue to meet the required criteria and should receive separate payment in the ASC setting. It proposes that the drug described by HCPCS code C9088 (Zynrelef) would not receive separate payment in the ASC setting under this policy.

In its evaluation of whether other drugs or biologicals may be newly eligible in CY 2023 for separate payment in the ASC setting, CMS proposes that one additional drug, described by HCPCS code J1096 (Dextenza), qualifies and should receive separate payment in the ASC setting as a non-opioid pain management drug that functions as a surgical supply for 2023.

ASC QUALITY REPORTING PROGRAM (ASCQR) PROPOSALS

CMS does not propose to adopt or remove any measures from the ASCQR. However, as in its proposal for the OQR, it proposes to modify one previously adopted measure and requests comments on whether it should re-implement a measure assessing facility surgical volume. CMS also seeks feedback on additional issues specific to ASCs. The table below summarizes the OQR Measure Set for the CY 2023 to 2025 reporting periods/CY 2025 to 2027 payment determinations if proposals in this rule are finalized, including its NQF identifier (if the measure has been endorsed by NQF); asterisks denote whether reporting of the measure is voluntary.

ASCQR Measures for CY 2023-CY 2025 Reporting Period/CY 2025 - CY 2027 Payment Determination

ASCQR Identifier	NQF #	Measure Name
ASC-1	Endorsement Removed	Patient Burn
ASC-2	Endorsement Removed	Patient Fall
ASC-3	Endorsement Removed	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	Endorsement Removed	All-Cause Hospital Transfer/Admission
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	Endorsement Removed	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-e	None	OAS CAHPS (five individual measures)**
ASC-17	3470	Hospital Visits after Orthopedic ASC Procedures
ASC-18	3366	Hospital Visits after Urology ASC Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at ASCs
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel

*Voluntary
**Voluntary for CY 2023 and CY 2024

Request for Comment: Potential Future Specialty-Centered Approach for ASCQR. Recognizing the clinician and clinician-group centered, specialized nature of care delivered in ASCs, CMS seeks comment on a potential future direction of quality reporting for the ASCQR that would allow quality-related data for ASCs to be reported

on a customizable measure set that more accurately reflects the care delivered by individual facilities. For example, there could be a set of measures related to different specialties from which an ASC could choose an individualized combination of measures. Another example is the creation of specialized tracks that would standardized quality measures within a specialty area. As a model, CMS cites the Merit-based Incentive Payment System (MIPS), which adjusts physician payments based on the clinician's performance in four categories. Under this program, clinicians may select measures and activities from CMS-created inventories.

CMS requests feedback on whether this concept—quality reporting by specialty—is feasible and desirable, as well as what more broadly applicable measures should be included regardless of specialty (e.g. advance care planning, patient-centered surgical risk assessment and communication, surgical site infection). The agency also asks for input on fundamental aspects of a specialized quality reporting program, such as the number of measures that should be required, the process of measure selection by participants, and other requirements.

Request for Comment: Interoperability in ASCs. CMS wants to explore how ASCs are implementing tools in their facilities toward the goal of interoperability. The agency explains that it is considering a future shift in reporting from QualityNet to electronic clinical quality measures (eCQMs), which are automatically informed using data from facility EHRs. To influence this thinking, CMS would like to learn more about ASCs' capabilities for reporting such measures as well as barriers to interoperability in the ASC setting. CMS proffers a list of example measures in the voluntary MIPS Promoting Interoperability measure set, which assesses clinician performance on activities like e-prescribing, providing patients electronic access to their health information, and conducting security risk analysis, and welcomes comment on whether these specific measure examples would be appropriate and feasible for use in ASCs.

RURAL EMERGENCY HOSPITAL PROPOSALS

Under the Consolidated Appropriations Act of 2021, Congress established a new rural Medicare provider type, the REH, which would allow facilities to provide emergency hospital services for Medicare payment without the need to furnish acute care inpatient services. After soliciting a request for information (RFI) in last year's proposed OPPS rule (see AHA comments on the REH RFI), CMS proposes a number of policies in this rule to help establish the REH model.

Additionally, the agency issued a separate conditions of participation (CoP) proposed rule for REHs, with comments due Aug. 29 (see AHA's Special Bulletin). CMS states that all of the final policies from both the CoP and this OPPS rule will be published in the CY 2023 OPPS final rule with comment period.

Under statute, REHs must be paid 105% of the OPPS rate for covered outpatient services, plus an additional facility payment. The agency proposes a monthly facility payment of $268,294 for CY 2023 – approximately $3.2M annually – and is

soliciting comments on the methodology used to determine the facility payment for CY 2023. For CY 2024 and beyond, the additional annual facility payment would be increased by the hospital market basket percentage.

CMS also proposes to broadly consider all covered outpatient department services as "REH services" and would pay at the applicable OPPS payment rate plus 5%. The agency solicits comments on whether it should adopt a narrower definition of REH services. Items and services that are not "REH services" would be paid under the payment system applicable to that item or service. For example, CMS proposes that an entity that is owned and operated by an REH that provides ambulance services will receive payment under the ambulance fee schedule. Similarly, skilled nursing facility (SNF) services would receive payment under the SNF PPS. Additionally, the agency proposes that items and services furnished by off-campus PBDs that otherwise meet the definition of "REH services" will receive the OPPS rate plus 5%.

CMS also proposes that for the enrollment process, a conversion to an REH can be accomplished via a change of information application. Additionally, the agency proposes certain updates for the physician self-referral law to allow for a "REH exception" to the law's prohibitions. The agency is soliciting comments on these proposals, as well as quality measures for the REH.

REH QUALITY REPORTING PROGRAM (REHQR)

The Consolidated Appropriations Act of 2021 established requirements for a new type of provider, the REH, for payment beginning Jan. 1, 2023. As part of this program, an REH must submit quality measure data. In this rule, CMS does not propose to adopt any specific quality measures; rather, the agency reviews its considerations for the selection of REHQR Program quality measures and establishes overarching programmatic requirements.

Many subsection (d) hospitals and critical access hospitals (CAHs) that are eligible for REH conversion are currently reporting outpatient quality data under the OQR and have publicly available data; participation in quality reporting programs is voluntary for CAHs. In addition, the Medicare Beneficiary Quality Improvement Project (MBQIP) under the Medicare Rural Hospital Flexibility program of the Health Resources and Services Administration uses outpatient quality data voluntary reported by CAHs through the OQR; in 2020, 1,353 CAHs (about 87% of eligible facilities) reported data for at least one OQR measure.

Quality Reporting Requirements. CMS proposes that participating REHs must have a QualityNet account to submit data to the Hospital Quality Reporting (HQR) secure portal. If the REH already has an account, it can update its existing account with its new REH CMS Certification Number. CMS also proposes to require the REH to designate a Security Official (SO), who must establish user accounts to submit quality measure data, review and correct data submissions and preview measure information prior to

public reporting. CMS notes that while an SO is initially required to enable the REH's QualityNet account, it is not required to maintain a SO.

Considerations for REHQR Measures. CMS seeks to adopt a concise set of important, impactful, reliable, accurate and clinically relevant measures for REHs that would inform consumer decision-making and promote quality improvement efforts. To inform this work, CMS considers the following issues:

- Endorsement of the measure by NQF, which may limit how many measures are available;
- Balancing burden with benefit by using claims-based or digital quality measures in place of chart-abstraction;
- Relevance to rural populations by reflecting the types of services delivered most frequently;
- Low service and patient volume that may make data unreliable; and
- Measuring disparities in care delivery and outcomes through data stratification by social drivers of health.

Request for Comment on Potential Measures for the REHQR. CMS requests comment on a selection of measures recommended by the National Advisory Committee on Rural Health and Human Services. CMS seeks feedback on whether these measures would be appropriate for the REHQR program. The measures include:

- OP-2: Fibrinolytic Therapy Received within 30 Minutes of ED Arrival. This chart-abstracted process measure calculates the percentage of ED acute myocardial infarction (AMI) patients with ST-segment elevation on the electrocardiogram closest to arrival time who receive fibrinolytic therapy during the ED stay within 30 minutes of their arrival in the ED. In 2020, about 71% of CAHs reported at least one case for this measure through the MBQIP.
- OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention/ST-Segment Elevation Myocardial Infarction (STEMI) eCQM. OP-3, and the measure CMS is replacing it with (STEMI eCQM) assess the timeliness and appropriateness of STEMI care. About 70% of CAHs reported at least one case for this measure.
- OP-4: Aspirin at Arrival. This chart-abstracted process measure documents the percentage of ED AMI patients or chest pain patients without aspirin contraindications who received aspirin within 24 hours before ED arrival or prior to transfer. The measure was removed from the OQR program due to nationwide performance being sufficiently high with little variation, but CMS believes this measure could be useful for smaller providers.
- OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients. This chart-abstracted measure evaluates ED throughput time. The measure is calculated separately for psychiatric/mental health patients.
- OP-20: Door to diagnostic Evaluation by a Qualified Medical Professional. This chart-abstracted measure assesses the mean time between patient presentation to the ED and the first moment the patient is seen by a qualified medical professional for patient evaluation and management.

- OP-22: Left Without Being Seen. This structural measure calculates the percentage of patients regardless of payer who left the ED before being evaluated by a physician, advanced practice nurse, or physician assistant.
- Emergency Department Transfer Communications (EDTC). This core MBQIP measure assesses how well key patient information is communicated from an ED to any health care facilities.

CMS also seeks comment on other potential measures and topics for consideration in the REHQR, including:

- OP-10: Abdomen Computed Tomography (CT) – Use of Contrast Material. This claims-based diagnostic imaging measure calculates the percentage of CT abdomen studies performed with and without contrast to determine appropriate exposure to radiation.
- OP-32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. This claims-based outcome measure estimates a facility-level rate of risk-standardized, all-cause unplanned hospital visits within 7 days of an outpatient colonoscopy among Medicare fee-for-service patients aged 65 years and older.
- Potential future measure topics:
    - Telehealth
    - Maternal Health
    - Mental Health
    - ED Services
    - Equity

REMOTE OUTPATIENT MENTAL HEALTH SERVICES

As established in the April 30, 2020 interim final rule on regulatory revisions in response to the PHE, CMS will allow hospital and CMHC staff to furnish certain outpatient therapy, counseling, and educational services (including partial hospitalization, or PHP, services) to beneficiaries in remote locations, including the beneficiary's home, for the duration of the PHE. In this rule, CMS establishes permanent payment for these services.

Payment for Outpatient Mental Health Services. CMS proposes to designate certain mental health services performed remotely by clinical hospital staff using telecommunications technology to beneficiaries in their homes as "covered OPD services" for which payment is made under the OPPS. To pay for these services, CMS would create three new HCPCS codes for diagnosis, evaluation, or treatment of a mental health or substance use disorder (one code describing the initial 15-29 minutes, one describing the initial 30-60 minutes, and an add-on code for each additional 15 minutes); these codes would specify that the beneficiary must be in their home and that there is no associated professional services billed under the PFS. Hospital clinical staff would be required to be physically located in the hospital when furnishing remote services.

The agency believes that the costs associated with these remote services more closely resemble those under the PFS rather than the OPPS because the hospital is not accruing all the costs associated with in-person services. Thus, CMS proposes to assign the new HCPCS codes to APCs based on the PFS facility payment rates for similar CPT codes; payment for the add-on code would be packaged. The table below summarizes these proposals.

Proposed Remote Mental Health Service Codes and Pricing

HCPCS Code	Description	CPT Comparison	PFS Facility Rate	Proposed APC	APC Rate
CXX78	Remote mental health service, initial 15-29 minutes	96159	$19.52	5821	$30.48
CXX79	Remote mental health service, initial 30-60 minutes	95158	$56.56	5822	$77.67
CXX80	Remote mental health service, each additional 15 minutes	N/A			

In-Person Service Requirements. CMS proposes to require the beneficiary to receive an in-person service within six months prior to the first remote mental health service and within 12 months after each remote mental health service. These requirements were initially established in the Consolidated Appropriations Act of 2021 and implemented in the CY 2022 PFS rule for physician, RHC, and FQHC services. CMS would also adopt the same exceptions policy as established in the CY 2022 PFS rule: the agency would permit exceptions to the in-person requirements if the clinical staff and beneficiary agree—and the staff document in the medical record—that the risks and burdens of an in-person service outweigh its benefits. Hospitals would also have to document that the patient has a regular source of general medical care and the ability to obtain any needed point-of-care testing. As with the requirements for the PFS, RHCs and FQHCs, these in-person requirements would not apply until the 152nd day after the end of the PHE for COVID-19.

Audio-Only. CMS proposes to allow hospital clinical staff to use audio-only communications technology if an individual patient is not capable of or does not wish to use two-way audio/video technology. Staff must maintain the capability of furnishing two-way audio/video services.

Outpatient Non-PHP Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in their Homes after the COVID-19 PHE. As discussed above, CMS proposes to cover and pay under the OPPS certain behavioral health therapy services furnished remotely by hospital staff using communications technology to beneficiaries in their homes. CMS clarifies that it is not proposing to recognize these proposed OPPS remote services as PHP services. However, the agency notes that none of the PHP

regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital if the proposal is finalized. Specifically, CMS clarifies that under its proposal, a hospital could bill for non-PHP outpatient services furnished to a PHP patient, including remote therapy services furnished by a HOPD. Hospitals would be permitted to bill for these remote non-PHP behavioral health services but would need to continue to comply with documentation requirements that apply to PHP patients.

CMS clarifies that CMHCs may not bill Medicare for any remote mental health services furnished by clinical staff of the CMHC in an individual's home. However, CMS states that if its proposal is finalized, a PHP patient who typically receives PHP services at a CMHC could receive non-PHP remote mental health services from a HOPD. CMS notes that it expects a physician caring for a patient receiving both PHP and non-PHP remote mental health services from a HOPD would update the patient's medical documentation to support the patient's eligibility for participation in a PHP.

OTHER ISSUES

RFI ON OUTPATIENT MENTAL HEALTH SERVICES

In consideration of the mental health crisis exacerbated by the COVID-19 pandemic, the ongoing opioid PHE (originally declared in late 2017 and most recently renewed on July 20, 2022), and shortages in behavioral health professionals, CMS issues requests for comments on outpatient mental health programs to accompany its proposals related to telehealth.

Intensive Outpatient Mental Health Treatment. In some cases, people who do not meet the standards for PHP services still require intensive outpatient services including primary treatment, step-down care from an inpatient setting, withdrawal management, or step-up care from group outpatient treatment. Intensive outpatient programs (IOPs) include a prearranged schedule of core services for a minimum of nine hours per week for adults or six hours per week for adolescents. CMS is seeking comment on whether these services are adequately described by existing CPT codes paid under the OPPS, as well as on additional details about IOPs. For example, the agency is interested in what settings of care furnish these services, the range of services typically offered, the types of practitioners who furnish the services, and any other relevant information.

Remote PHP Services. CMS wants to better understand the use of remote mental health services for PHP patients during the PHE and the potential need for such services in the future. Specifically, the agency requests feedback on how CMHCs and HOPDs have incorporated remote PHP services during the PHE, what patients benefit most from these flexibilities, and what barriers to access the agency could address.

RFI ON USE OF CMS DATA TO DRIVE COMPETITION IN HEALTH CARE MARKETPLACES

CMS requests information on the potential use of CMS data to drive competition in health care marketplaces. The agency notes that President Biden's Executive Order on Promoting Competition in the American Economy (EO 14036) called for a "whole-of-government approach" to address excessive concentration, abuses of market power, unfair competition, and the effects of monopoly and monopsony. It explains that a Fact Sheet accompanying EO 14036 identified hospital consolidation as a particular concern, and it noted that CMS's past efforts at publicizing data and requiring price and cost transparency can be used to increase marketplace competition.

Consistent with the President's Executive Order, the agency now seeks information about how "the data CMS collects could be used to promote competition across the health care system or protect the public from the harmful effects of consolidation within healthcare." Among other things, the agency seeks comments about what "additional information collected by CMS would be useful for the public or researchers who are studying the impacts of mergers, acquisitions, consolidations, or changes in ownership."

PFS PROPOSAL TO REQUIRE HOPDS AND ASCS TO REPORT DISCARDED AMOUNTS OF CERTAIN SINGLE-DOSE OR SINGLE-USE PACKAGE DRUGS

Effective Jan. 1, 2023, the Infrastructure Investment and Jobs Act requires drug manufacturers to provide a refund to CMS for certain discarded amounts from a single-dose container or single-use package drug (excluding radiopharmaceutical or imaging agents, drugs requiring filtration and new drugs). The refund amount is the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10% of total charges for the drug in a calendar quarter. CMS is implementing this provision through the 2023 PFS rulemaking.

CMS' proposal will require that HOPDs and ASCs report the JW modifier or any successor modifier to identify discarded amounts of refundable single-dose container or single-use package drugs or biologicals that are separately payable under the OPPS or ASC payment system. In addition, CMS proposes to require hospitals and ASCs to use a separate modifier, JZ, in cases where no billing units of single use container were discarded. CMS also proposes to conduct periodic review of Part B medication claims to ensure appropriate billing of the required modifiers and discarded drug amounts.

The 2023 OPPS/ASC proposed rule advises interested parties to direct their comments on this issue to the 2023 PFS proposed rule. More information on this proposal can be found in the AHA's CY 2023 PFS Regulatory Advisory [xx hyperlink].

ORGAN ACQUISITION PAYMENT POLICIES

In the FY 2022 IPPS proposed rule, CMS proposed a number of policies to change, clarify and codify Medicare's organ acquisition payment. Due to the nature and volume of comments received, however, the agency did not finalize any policies related to the count of Medicare usable organs as only organs transplanted into Medicare beneficiaries and the count of organs procured for research when calculating Medicare's share of organ acquisition costs.

In this year's OPPS proposed rule, CMS proposes additional revisions, clarification and codifications related to Medicare's organ acquisition payment policies. Specifically, the agency proposes to change how organs procured for research are counted for the purposes of calculating Medicare's share (i.e., requiring transplant hospitals and organ procurement organizations to exclude organs used for research) and clarify that organ acquisition costs include certain hospital costs incurred for services provided to deceased donors.

Additionally, CMS solicits a request of information (RFI) on an alternative methodology for counting organs used in the calculation of Medicare's share of organ acquisition costs.

DIRECT SUPERVISION OF CARDIAC AND PULMONARY REHABILITATION SERVICES BY INTERACTIVE COMMUNICATIONS TECHNOLOGY

In 2020 and 2021 rulemaking, CMS revised regulations to provide that, until the end of the calendar year in which a PHE ends, a physician may provide the required direct supervision for pulmonary rehabilitation (PR), cardiac rehabilitation (CR), and intensive cardiac rehabilitation (ICR) services via virtual presence through audio/video real-time communications technology (excluding audio-only).

In the CY 2022 PFS final rule, CMS added several CR, ICR and PR-related CPT codes to the Medicare telehealth services list. These services will not be able to be furnished as Medicare telehealth services to beneficiaries in their homes after the PHE ends because of the statutory restrictions on eligible originating sites. However, the inclusion of these codes on the Medicare telehealth services list will enable payment for these services when furnished in full using two-way, audio/video communications technology when the beneficiary is in a medical setting that can serve as a telehealth originating site and meet the geographic requirements. These services will remain on the Medicare telehealth services list through the end of CY 2023.

Under current OPPS policy, CR, ICR and PR may be provided in the hospital with the physician direct supervision being provided to a patient via a virtual presence. The virtual supervision policy will end with the conclusion the COVID-19 PHE. After that time, the physician must be immediately available for the direct supervision requirement to be met for the hospital to be paid for CR, ICR and PR. CMS is requesting comments on whether to allow for virtual direct supervision for the physician through the end of 2023, comparable to the PFS.

The agency is also seeking comment on whether there are safety and/or quality of care concerns regarding adopting this policy beyond the PHE and what policies CMS could adopt to address those concerns if the policy were extended post-PHE.

SUPERVISION BY NON-PHYSICIAN PRACTITIONERS OF HOSPITAL AND CAH DIAGNOSTIC SERVICES FURNISHED TO OUTPATIENTS

Prior to 2020, Medicare only allowed physicians to supervise diagnostic tests as a condition of payment in the HOPD of both hospitals and CAHs. In a COVID-19 related interim final rule in May 2020, CMS allowed diagnostic tests furnished in HOPDs to also be supervised by non-physician practitioners (NPPs), to the extent they are authorized under their scope of practice and applicable state law. This interim final rule only provided for a temporary change to the supervision rules but the CY 2021 PFS final rule made the changes permanent.

For CY 2023, CMS proposes to modify the HOP regulations to include NPPs as supervising practitioners, in addition to physicians, for diagnostic and therapeutic services furnished under personal or direct supervision to the extent that they are authorized to do so under their scope of practice and applicable state law.

PROPOSED IPPS AND OPPS PAYMENT ADJUSTMENTS FOR DOMESTIC NIOSH-APPROVED SURGICAL N95 RESPIRATORS

CMS proposes to make payment adjustments under the OPPS (as well as the IPPS in the FY 2023 IPPS proposed rule) for the additional cost that hospitals face in procuring domestic NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after Jan. 1, 2023. Specifically, the agency proposes to base the payment adjustment on the estimated difference in the reasonable costs of a hospital to purchase domestic NIOSH-approved surgical N95 respirators compared to non-domestic respirators, provided as a biweekly interim lump-sum payment. CMS proposes that a hospital would need to separately report on its cost report the aggregate cost and total quantity of domestic and non-domestic respirators. The agency proposed to not make the payment adjustment budget neutral under the IPPS, but would make it budget neutral under the OPPS. CMS states that it may revisit in future rulemaking the budget neutrality approach for OPPS payments, as well as consider expanding this policy to include other forms of personal protective equipment.

PROPOSED CODING AND PAYMENT FOR CATEGORY B INVESTIGATIONAL DEVICE EXEMPTION (IDE) CLINICAL STUDIES AND DEVICES

Medicare may make payment for routine care items and services furnished in FDA-approved studies if CMS determines that the Medicare coverage criteria are met. Medicare may make payment for a Category B IDE device, which refers to a device where initial questions of safety and effectiveness have been resolved, or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type.

In the past, CMS has responded to concerns about coding of Category B IDE devices that could unblind the participant receiving the experimental item relative to those receiving a placebo and thus compromise the studies' scientific validity. To address these concerns, CMS created a temporary HCPCS code to describe a device in both the experimental group and the control group.

For 2023, CMS proposes to establish a new HCPCS code (or revise an existing HCPCS code) and make a single blended payment for devices and services in Category B IDE studies when the Medicare coverage IDE study criteria are met and where CMS determines, that a new or revised code and/or payment rate is necessary to preserve the scientific validity of such a study. The proposal is intended to preserve the scientific validity by avoiding differences in Medicare payment methods that would otherwise reveal the group (treatment or control) to which a patient has been assigned.

The single blended payment rate for the HCPCS code would be dependent on the specific trial protocol and would account for the frequency with which the investigational device is used compared to placebo. It would include payment for the investigational device, placebo control, and routine care items and services of a Category B IDE study.

OPPS PAYMENT FOR SOFTWARE AS A SERVICE

New clinical software — which includes clinical decision support software, clinical risk modeling, and computer aided detection — is becoming increasingly available to providers. These technologies rely on complex algorithms or statistical predictive modeling to aid in the diagnosis or treatment of a patient's condition. CMS refers to these algorithm-driven services that providers pay for, either on a subscription or per-use basis, as Software as a Service (SaaS).

The AMA has established new CPT codes that describe SaaS procedures using two codes: a primary code that describes the standalone clinical software service and an add-on code that describes a clinical software service that is related to and billed concurrent with a diagnostic imaging service. The standalone code is billed when no additional imaging is required because raw images from a prior scan are available for the software to analyze, while the add-on code is billed with an imaging service when a prior imaging scan is unavailable, or the prior images are insufficient. If a patient needs a SaaS procedure and has no existing diagnostic images, the patient would undergo the diagnostic imaging (i.e., CT or MRI), and the SaaS procedure. In this scenario, the provider would report the diagnostic imaging service code and the SaaS add-on code on the same day of service. In contrast, if a patient has pre-existing diagnostic images, the provider would only need to perform the SaaS procedure and would only report the standalone SaaS code.

2023 Proposal for SaaS Add-on Codes. Stakeholders have urged CMS to pay separately for the services described by the SaaS add-on because the technologies are new and associated with significant costs. However, the proposed rule states that the SaaS add-on codes created by the AMA CPT Editorial Panel are not consistent with

CMS' definition of add-on services as the costs of the add-on services exceed the costs of the imaging service with which they would be billed. Rather, CMS believes they are separate and distinct services that should be paid separately.

For 2023, CMS proposes not to recognize the CPT add-on codes that describe SaaS procedures under the OPPS and instead establish C-codes to describe the add-on codes as standalone services. The new C-codes would be billed with the associated imaging service and be paid the same rate as the initial CPT code that provides data analysis using an existing image as both codes use the same technology. CMS lists the new C-codes and their descriptors in the proposed rule.

Comment Solicitation on Payment Policy for SaaS Procedures. The proposed rule describes SaaS procedures as a heterogenous group of services that are challenging to compare to existing medical services for purposes of determining clinical and resource similarity to make an APC assignment. To assist CMS with developing OPPS payment policy, CMS requests public comment on:

- How to identify services that should be separately recognized as an analysis distinct from both the underlying imaging test or the professional service paid under the PFS;
- How to identify costs associated with these kinds of services;
- How these services might be available and paid for in other settings (physician offices, for example); and
- How to consider payment strategies for these services across settings of care.

CMS suggests several alternatives for determining payment for SaaS-type technology services:

- Packaged Payment under a Single Code (G-code): Under this approach, the OPPS would not recognize either the standalone or the add-on codes describing SaaS procedures. Instead, all associated imaging and the SaaS would be described by a single HCPCS code, which could be assigned to a relevant clinical APC.
- Composite APCs: Providing a single payment for groups of services that are performed together, including the diagnostic imaging and SaaS procedure, during a single clinical encounter to result in the provision of a complete service.
- New Technology APCs: Use a HCPCS code (i.e., G- or C- codes) to describe both the diagnostic imaging and the SaaS procedure, and then assign the code that describes the combined services to New Technology APCs that would pay for both services.

CMS also is concerned about the potential for bias in algorithms and predictive modeling, and is requesting comments on how it could encourage software developers to prevent or mitigate the possibility of bias in new applications of this technology.

NEXT STEPS

The AHA will host a 90-minute, members-only webinar on Tue. Aug. 23 at 3 p.m. ET. Please register for this event at this **link.** Related materials and a recording of this webinar will be available on the AHA's OPPS webpage.

We encourage members to model the impact of the APC changes on expected CY 2023 Medicare revenue. Spreadsheets comparing the changes in APC payment rates and weights from 2021 will soon be available on the AHA's OPPS webpage. To access these, you must be logged on to the website.

Submitting Comments. The AHA urges hospitals and health systems to submit comments to CMS. Comments are due by Sept. 13, and may be submitted electronically at www.regulations.gov. Follow the instructions for "Comment or Submission" and enter the file code "CMS-1772-P."

FURTHER QUESTIONS

Please contact Roslyne Schulman, AHA director of policy, at rschulman@aha.org if you have further questions.