Policy Update

CMS Releases CY 2023 Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule

On November 1, 2022, the Centers for Medicare & Medicaid Services (CMS) released the calendar year (CY) 2023 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems Final Rule [CMS-1772-FC], finalizing payment rates and policy changes affecting Medicare services furnished in hospital outpatient and ambulatory surgical center (ASC) settings for CY 2023.

For CY 2023, CMS applied a productivity-adjusted market basket increase of 3.8% under the Hospital Outpatient Prospective Payment System (OPPS) and the ASC Payment System. However, CMS applied several budget neutrality and other adjustments, including a significant 3.09 percentage point reduction to account for changes to its 340B drug purchasing policy. After accounting for these adjustments, the CY 2023 OPPS conversion factor increased by 1.67% over the 2022 value. The ASC conversion factor increased by 3.88%, a different and more favorable adjustment largely because it is not directly impacted by the 340B-specific budget neutrality adjustment. In continuation of the agency's existing policy, hospitals and ASCs that fail to meet their respective quality reporting program requirements will be subject to a 2% reduction.

Based on the finalized policies, CMS estimates that total payments to OPPS and ASC providers (including beneficiary cost-sharing and estimated changes in enrollment, utilization and case-mix) for CY 2023 will be approximately $86.5 billion and $5.3 billion, respectively, for an increase of approximately $6.5 billion and $230 million, respectively, from CY 2022 program payments.

The finalized regulations are available here. The press release and accompanying fact sheet are available here and here, respectively.

Key Takeaways from the CY 2023 OPPS and ASC Payment System Final Rule:

- CMS finalized its proposal to expand the categories of services subject to the prior authorization process to include facet joint interventions. To provide participants additional time to prepare for the addition of facet joint interventions to the prior authorization process, CMS finalized a July 1, 2023, implementation date, rather than the proposed March 1, 2023, implementation date.
- CMS finalized its proposal to return payments for 340B drugs under the CY 2023 OPPS final rule to the full average sales price (ASP) plus 6% rate, reversing the ASP minus 22.5% rate that was established beginning in 2018. The final rule includes a corresponding budget neutrality adjustment applicable to all other items and services paid under the OPPS that decreases payments by 3.09%. Pursuant to a Supreme Court decision, CMS must return payments withheld from the 2018 policy change for the years 2018 through 2022, but CMS has not yet determined how it will do so. CMS indicated that it will make a proposal in a separate rule prior to the release of the CY 2024 OPPS rule.
- CMS did not extend the transitional pass-through payment for the five technologies with pass-through periods expiring at the end of CY 2022.
- CMS finalized certain policy proposals to ensure continued access to mental health services via telehealth following the conclusion of the COVID-19 public health emergency (PHE).
- CMS will exempt rural sole community hospitals from its site-neutral payment policy for the first time.
- CMS finalized conditions of participation, payment policies and the enrollment process for rural emergency hospitals, the new hospital type authorized by legislation enacted in 2020.
- CMS further cemented recent flexibilities allowing certain non-physician practitioners to supervise select diagnostic services.
- CMS finalized its policy to compensate hospitals for the increased cost of acquiring certain personal

protective equipment during the COVID-19 pandemic.

OPPS Major Final Policies

Prior Authorization Process for Certain Services

Key Takeaway: CMS finalized its policy to add facet joint interventions as a new service category subject to the hospital outpatient prior authorization process on or after July 1, 2023.

For CY 2020, CMS finalized a policy whereby hospitals must seek provisional affirmation of coverage before select outpatient services are furnished to beneficiaries and before a claim can be submitted for processing. This prior authorization requirement applied initially to only five categories of services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty and vein ablation.

In the CY 2021 rulemaking cycle, CMS expanded the services subject to prior authorization, adding two new categories of services (cervical fusion with disc removal and implanted spinal neurostimulators) for dates of service on or after July 1, 2021. CMS did not change the list of services subject to prior authorization in CY 2022, holding steady with the previously established seven categories.

For CY 2023, CMS finalized its proposal to add a new service category (facet joint interventions) to the prior authorization process. CMS originally proposed to include this new service category for dates of service on or after March 1, 2023, but instead finalized an implementation date of July 1, 2023, which is consistent with previous July 1 implementation dates for current service categories. The finalized service category will consist of facet joint injections, medial branch blocks and facet joint nerve destruction. See the table below for the full list of services finalized.

2023 Finalized List of Additional Outpatient Department Services that Require Prior Authorization

CPT® Code	Facet Joint Interventions
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
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
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)
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
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
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)
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint

CPT® Code	Facet Joint Interventions
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint

Source: Table 103 of the CMS CY 2023 OPPS and ASC Final Rule [CMS-1772-FC]

CMS cited both an internal analysis and multiple US Department of Health and Human Services (HHS) Office of Inspector General (OIG) reports as the basis for finalizing a new facet joint intervention service category. CMS concluded that the increases in volume for facet joint services are "unnecessary" based on findings that the rate of increase for the utilization in this service category compared to overall outpatient department services was not explained by what was perceived to be legitimate clinical/coding reasons or external possible causes. Various OIG reports found improper Medicare payments and "questionable billing practices," including a 2021 OIG report showing that Medicare improperly paid physicians $9.5 million for selected facet joint denervation procedures.

CMS likely will continue to incorporate additional categories of services in future years as the agency seeks to rein in spending that it perceives to be excessive.

Transitional Pass-Through Payment for Medical Devices

Key Takeaway: CMS did not provide a one-year extension for technologies whose transitional pass-through period is set to expire on December 31, 2022. CMS finalized its policy to post applications online starting on March 1, 2023.

Transitional pass-through payment for new devices is intended to allow for adequate payment of new innovative technology during the interval in which the technology is introduced to the market and CMS collects the data necessary to incorporate the costs for these devices into the accompanying procedure's payment rate. Devices that meet the requisite qualification criteria are eligible to receive transitional pass-through payment. CMS also has established an alternative pathway for devices approved under the US Food and Drug Administration (FDA) Breakthrough Device Program.

In the CY 2021 rulemaking cycle, CMS acknowledged the PHE's impact on utilization and sought stakeholder feedback on whether the agency should use its authority to provide separate payment for an undefined period of time after pass-through status ends for these device categories to account for the period of time that device utilization was reduced. In the CY 2022 rulemaking, CMS exercised its authority to provide an additional four quarters of payment under pass-through for the one device (C1823 Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads) whose transitional payments were set to otherwise expire at the end of CY 2021. For CY 2023, CMS finalized its policy to return to the "regular update process" and did not extend the pass-through period for the five devices whose eligibility is set to expire at the end of December 2022. CMS will continue add-on payments for eight technologies (see Table 52) whose pass-through period does not expire at the end of the current calendar year.

CMS did not finalize any changes to its qualification criteria for transitional pass-through payments for medical devices.

As part of its quarterly review cycle, CMS evaluated eight applications for device pass-through payments—two through the breakthrough pathway and six through the traditional pathway. CMS approved four devices, including the two with breakthrough designation, for transitional pass-through. The remaining four were denied for not meeting either the newness or the substantial clinical improvement

criteria.

Based on feedback from stakeholders and as part of a stated effort to increase transparency, CMS finalized its proposal to publicly post completed applications, key relevant materials and updated application information starting on March 1, 2023, except for any materials not releasable to the public due to copyright. By posting these materials online, CMS seeks to streamline discussion of the applications to highlight any questions or concerns raised as part of the application review.

Revisions to the Inpatient Only List

Key Takeaway: CMS finalized the removal of 11 services and the addition of eight recently created CPT codes to the inpatient only (IPO) list.

CMS has a policy of identifying services that it perceives to be safely provided only in an inpatient setting. Services designated as inpatient only will not be paid by Medicare when furnished on an outpatient basis. In the CY 2021 OPPS/ASC final rule, CMS announced that it would eliminate the IPO list over the course of three years (85 FR 86084-88). In CY 2021, the first year of the transition, CMS removed 298 codes from the IPO list. However, in the CY 2022 OPPS/ASC final rule, the new Biden Administration reversed course, withdrew the planned phased elimination of the IPO list and added back all but a small number of the 298 codes removed in CY 2021.

In this final rule, CMS finalized removal of 11 codes starting in CY 2023 based on its determination that they meet the five longstanding criteria to be safely furnished in outpatient settings and for removal from the IPO list. CMS also added eight codes, newly created by the American Medical Association CPT Editorial Panel, to the IPO list for CY 2023. See table 65 for the impacted codes.

Payment for 340B Drugs

Key Takeaway: CMS finalized its proposal to increase payments for 340B drugs to the full ASP plus 6% rate, reversing the ASP minus 22.5% rate that was in place beginning in 2018.

In the CY 2018 OPPS final rule, CMS implemented a controversial policy that changed reimbursement to hospitals for 340B-acquired drugs and biologicals. CMS changed payment for these drug purchases only from the traditional ASP plus 6% to an adjusted amount of ASP minus 22.5% for certain separately payable drugs or biologicals acquired through the 340B program.

Hospitals led by several national hospital associations immediately sued to invalidate this change, and on June 15, 2022, the Supreme Court of the United States ruled unanimously that HHS may not vary payment rates for drugs and biologicals among groups of hospitals without having conducted a survey of hospitals' acquisition costs. This decision ruled in favor of hospitals opposing the CY 2018 payment adjustment, and against the CMS policy.

As a result of this decision, CMS was compelled to restore payments to the original ASP plus 6%. For CY 2023, CMS will pay for 340B drugs at the full ASP plus 6% rate, reversing the ASP minus 22.5% rate that was in place beginning in 2018. The final rule also includes a corresponding budget neutrality adjustment applicable to all other items and services paid under OPPS that decreases payments by 3.09%. CMS implemented the policy in a budget-neutral fashion. Because payments increased for many hospitals that do not participate in the 340B program, and even to some that do, CMS needed to make a corresponding adjustment to the conversion factor to preserve budget neutrality in the other direction. This payment reduction applies to all hospitals.

Per the Supreme Court decision, CMS also must compensate hospitals that unlawfully had payments reduced for the past years. CMS is evaluating how to apply this ruling to CY 2018–2022. In this final rule, CMS did not address how it will determine 340B payment for CY 2018–2022 or readjust for budget neutrality in those years, but indicated that it will do so in a separate rule prior to the release of the CY 2024 OPPS rule.

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

Key Takeaway: CMS exempted rural sole community hospitals from site-neutral payment policies.

In 2015, Congress enacted legislation requiring that Medicare reconcile payment differences between the hospital OPPS and the Medicare Physician Fee Schedule (PFS) for certain services furnished at off-campus provider-based entities, effectively requiring CMS to cap payments for these services at PFS amounts. Beginning in 2019, CMS extended the payment reduction for clinic visits described by HCPCS code G0463 to off-campus provider-based outpatient departments that previously were excepted or grandfathered from site-neutral payment policies. CMS phased in the payment reduction over two years.

CMS's decision to extend the site-neutral payment policy was controversial and has been the subject of litigation since it was implemented. In September 2019, a federal district court sided with hospital plaintiffs, ruling that CMS lacked statutory authority to implement the change. However, in July 2020, the US Court of Appeals for the District of Columbia Circuit reversed the lower court in favor of CMS, holding that the agency's regulation was a reasonable interpretation of the statutory authority to adopt a method to control for unnecessary increases in the volume of the relevant service. The hospital plaintiffs appealed to the Supreme Court, but the Court announced in June 2021 that it would not take up the case, leaving intact the DC Circuit's ruling upholding CMS's authority.

For CY 2023, CMS will continue the policy of paying the PFS-equivalent rate of 40% of the OPPS payment rate for hospital outpatient clinic visits coded under HCPCS G0463 when delivered by a previously excepted off-campus provider-based department. However, in a welcome development for many rural providers, CMS finalized its policy to exempt services furnished by excepted off-campus provider-based departments of rural sole community hospitals. The agency noted that exempting rural sole community hospitals from the site-neutral payment policy will help maintain access to care in rural areas. Stakeholders urged CMS to extend this exemption to other rural hospitals, but CMS declined to do so at this time.

Supervision by Non-Physician Practitioners

Key Takeaway: CMS further extended supervision authority to non-physician practitioners for select diagnostic services.

In 2020, in response to the COVID-19 pandemic, CMS liberalized its regulations to allow certain non-physician practitioners (nurse practitioners, physician assistants, clinical nurse specialists and certified nurse midwives) to supervise the performance of diagnostic x-ray tests, diagnostic laboratory tests and other diagnostic tests paid under the PFS for the duration of the PHE to the extent they were authorized to do so under their scope of practice and applicable state law. In the CY 2021 PFS final rule, CMS further revised its regulations to make the previous revisions permanent and to add certified registered nurse anesthetists to the list of non-physician practitioners permitted to provide supervision of diagnostic tests to the extent authorized to do so under their scope of practice and applicable state law.

CMS finalized its policy to further revise existing supervision requirements to clarify that nurse practitioners, clinical nurse specialists, physician assistants, certified registered nurse anesthetists and certified nurse midwives may provide general, direct and personal supervision of outpatient diagnostic services to the extent that they are authorized to do so under their scope of practice and applicable state law.

Medicare Payment for Personal Protective Equipment

Key Takeaway: CMS finalized a plan to compensate hospitals for the additional resource costs they face in procuring domestic National Institute for Occupational Safety & Health (NIOSH) approved surgical N95 respirators

In the fiscal year (FY) 2023 Inpatient Prospective Payment System (IPPS) rulemaking, CMS finalized a policy whereby Medicare will make special additional payments under the IPPS and OPPS for wholly domestically made NIOSH-approved surgical N95 respirators. Under this policy, CMS will adjust payment to compensate hospitals for the additional resource costs of acquiring domestically made NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023. CMS

intends to create a new supplemental cost reporting form that will collect the necessary information from hospitals, and subject these reported costs to review by Medicare Administrative Contractors during cost report review processes. CMS will allow hospitals to rely on a written statement from the manufacturer stating that the NIOSH-approved surgical N95 respirator that the hospital purchased is domestic under CMS's definition. CMS estimates that total OPPS spending in 2023 for this policy will be $8.3 million (0.01% of all OPPS spending), which will be implemented in a budget-neutral manner.

Behavioral Health

Key Takeaway: CMS designated mental health services delivered via telehealth by hospital clinical staff to a beneficiary at home as a covered outpatient service.

During the COVID-19 PHE, beneficiaries have had the opportunity to obtain mental health services from a clinical staff member of a hospital or critical access hospital (CAH) using communication technology. This furnishing of care has been possible because of flexibilities that CMS adopted to allow hospitals to furnish care in this manner during the PHE. Absent any changes, this flexibility would have ended at the conclusion of the PHE.

CMS finalized its proposal to designate remote mental health services furnished by clinical staff to a beneficiary's home as a covered outpatient service under OPPS. The clinical staff must be physically located in the hospital when providing the mental health services. Consistent with other related Medicare payment policies, a beneficiary must undergo an in-person visit within six months of starting telehealth visits under OPPS and within 12 months of each mental health visit furnished. Clinical staff must be able to provide two-way, audio/visual services but may use audio-only to accommodate a beneficiary's technological limitations, abilities and preferences. The requirement for an in-person visit is waived for 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.

To implement this policy, CMS established three new codes specific to OPPS to appropriately describe these services.

HCPCS	Long Descriptor
C7900	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 15-29 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7901	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 30-60 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7902	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, each additional 15 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service (List separately in addition to code for primary service)

CMS will crosswalk C7900 and C7901 to the physician payment facility rate for 96159 (Health behavior intervention, individual, face-to-face; each additional 15 minutes (List separately in addition to code for primary service)) and 96158 (Health behavior intervention, individual, face-to-face; initial 30 minutes). The final payment rate for C7900 is $29.68 (proposed at $30.21), and for C7901 it is $75.85 (proposed at $76.98). C7902 will be policy packaged as an add-on code.

Skin Substitutes

Key Takeaway: CMS did not finalize its proposal to change the terminology of skin substitutes. The agency seeks further input from stakeholders and intends to host a town hall in early 2023 to

address nomenclature, coding and payment for these products.

CMS has had a longstanding policy to unconditionally package skin substitutes with their accompanying surgical procedure. In packaging the skin substitutes, CMS established a policy that divides the skin substitutes into a high-cost group and a low-cost group in order to meet the agency's stated goal of ensuring "adequate resource homogeneity among APC assignments for the skin substitute application procedures." For CY 2023, CMS will continue its current policy of assigning skin substitutes to a high- or low-cost group based on the product's geometric mean unit (GMU) cost or per-day cost relative to the GMU or per-day cost thresholds ($47 per cm^2 or $837, respectively) based on claims data. Where pricing is available and claims data is not available, CMS will assign to the low-cost or high-cost category based on ASP + 6% compared to the GMU threshold. Where ASP is not available, CMS will use wholesale acquisition cost (WAC) WAC + 3% or 95% of average wholesale price (if no WAC) to determine cost category assignment. Where no pricing is available, the product will be assigned to the low-cost category.

In the proposed OPPS rule, CMS highlighted a policy proposal put forth in the CY 2023 PFS rulemaking relative to skin substitutes whereby the agency would treat all skin substitute products consistently across healthcare settings as incident-to supplies. While finalized policies in the PFS do not apply to the hospital outpatient setting, CMS considered taking a similar approach in the hospital outpatient setting. CMS's objectives to refine Medicare policies for skin substitutes include the following:

- Ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department setting
- Ensuring that all skin substitute products are assigned an appropriate HCPCS code
- Using a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human- or animal-based material, so that CMS can incorporate payment methodologies that are more consistent
- Maintaining clarity for interested parties on CMS skin substitutes policies and procedures.

CMS intends to take a phased approach over the next one to five years to consider potential changes to policies involving skin substitutes. This timeline will allow CMS sufficient time to consider input from stakeholders on coding and policy changes through CMS's rulemaking process, and to account for FDA's regulation of these products. CMS seeks comments on the payment policy objectives, as well as the phased approach and timeline.

CMS finalized its policy to eliminate HCPCS code C1849, which is the code that providers have been using in the OPPS to report the usage of synthetic skin substitute products. CMS finalized that providers should use product-specific HCPCS codes for synthetic skin substitute products that are currently described by HCPCS code C1849. CMS also finalized a policy to assign any synthetic skin substitute product that is currently described by HCPCS code C1849, would have been described by HCPCS code C1849, or is assigned a code in the HCPCS A2XXX series, to the high-cost skin substitute group. These products will be assigned to the high-cost skin substitute group even if cost and pricing data are not available for any individual product.

CMS believes that the existing terminology of "skin substitutes" is problematic because it is overly broad. Skin substitute products are not a substitute for skin *per se* but rather a wound covering that is used to promote healing. For CY 2023, CMS originally proposed to replace the term "skin substitutes" with the term "wound care management" or "wound care management products." Appreciating the complexity in proposing this change in terminology, CMS sought comments on this proposal and was particularly interested in feedback on how to address the challenges with CPT reference.

Based on feedback, CMS did not finalize a change to the terminology of skin substitutes. The agency believes that additional dialogue will be beneficial before finalizing new terminology. CMS intends to host a town hall in early 2023 to further understand the concerns that interested parties have regarding changes in terminology and payment policies for these products. CMS will address additional changes in future rulemaking.

ASC Major Finalized Policies

ASC Covered Procedures List

Key Takeaway: CMS finalized the addition of four procedures to the ASC covered procedures list (CPL).

CMS maintains a list of procedures eligible for reimbursement in the ASC setting. Each year, CMS reviews the ASC CPL to determine if there are services that should be added or removed. For CY 2023, CMS added four procedures (CPT codes 19307, 37193, 38531 and 43774) to the ASC CPL, concluding that they can be safely performed in an ASC setting for a typical Medicare beneficiary.

CMS also changed the name of the process it finalized last year for submitting procedures to be considered for the ASC CPL from "Nominations" to "Pre-Proposed Rule CPL Recommendation Process." According to agency, this naming change will avoid confusion and/or misinterpretation that the nomination process was the only way for stakeholders to suggest procedures to be added to the ASC CPL. CMS also reiterated that stakeholders can submit recommendations for procedures to be considered for inclusion in the ASC CPL during public comment on the final rule.

Finally, citing internal delays in infrastructure development and Paperwork Reduction Act processes for the implementation of the nomination process, CMS announced that starting on January 1, 2024 (instead of the originally planned date of January 1, 2023), stakeholders can recommend a procedure by March 1 of a calendar year for inclusion in the ASC CPL the following calendar year.

OPPS and ASC Quality Finalized Policies

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

Key Takeaway: CMS made certain quality measures voluntary in response to the COVID-19 pandemic and seeks comment on topics under consideration for the new rural emergency hospital (REH) quality reporting program.

The hospital outpatient quality reporting program is a pay-for-quality data reporting program for Medicare hospital outpatient departments. Hospitals that fail to meet program requirements are subject to a two percentage point reduction in OPPS payments. Similarly, the ASC quality reporting program is the quality program for the ASC setting and requires ASCs to meet program requirements or receive a reduction of two percentage points in their annual fee schedule update.

In response to the COVID-19 pandemic, CMS finalized the policy that the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) and (ASC-11) measures will be voluntarily reported. CMS also finalized the alignment of the hospital outpatient quality reporting program patient encounter quarters for chart-abstracted measures to the calendar year for the annual payment update determinations.

The Consolidated Appropriations Act, 2021, enacted in December 2020, established REHs as a new Medicare provider type. An REH is a rural facility that was previously a CAH or a "subsection (d) hospital" with 50 or fewer beds. The act also required the Secretary to establish quality measurement reporting requirements for these REHs. In the final rule, CMS finalized a requirement that in order for REHs to participate in the REH quality reporting program, they must have an account with the hospital quality reporting secure portal and a designated security official. CMS seeks comment on several measures under consideration for the new REH quality reporting program, and notes that topics of interest for future rulemaking could include rural emergency department services, rural behavioral and mental health, rural maternal health, rural telehealth services and health equity.

Other Finalized Policies

Rural Emergency Hospitals

Key Takeaway: CMS established the conditions of participation (CoPs) and enrollment requirements for REHs. CMS also finalized policies to pay REHs 105% of OPPS payments for services furnished to program beneficiaries and to make a substantial supplemental monthly facility payment.

In July 2022, CMS released proposed regulations necessary to implement portions of the new REH provider type. The proposed CoPs for REHs announced in that rule generally track the CoPs for CAHs and would allow for REHs to be staffed with a registered nurse, clinical nurse specialist or licensed practical nurse when the REH is providing emergency or observation services, with higher-level staffing (*e.g.*, physician or non-physician practitioner) only required to be available to respond when needed. CMS also proposed to allow REHs to provide a wide range of outpatient services, subject to a community needs assessment. Although REHs are prohibited by statute from providing inpatient service, CMS indicated that it would allow for REHs to keep patients for more than 24 hours when needed, as long as the REH does not exceed the annual average 24-hour length of stay requirement. That proposed rule contained only the CoPs and did not address REH payment methodology or quality reporting requirements.

In this final rule, CMS established CoPs that include a full range of health and safety standards specific to governance, services offered, staffing, physical environment and emergency preparedness. Specific requirements include the following:

- REHs must have a clinician on-call at all times and available onsite within 30 or 60 minutes, depending on whether the facility is located in a frontier area.
- The REH emergency department must be staffed 24 hours per day and seven days per week by an individual competent in the skills needed to address emergency medical care.
- REHs must develop, implement and maintain a quality assurance and performance improvement program.
- The annual per-patient average length of stay cannot exceed 24 hours.
- REHs must have an infection prevention and control and antibiotic stewardship program.

Separately, in the OPPS proposed rule, CMS proposed the REH payment methodology and quality reporting requirements. The statute provided CMS with considerable flexibility to define the “other medical and health services” that may be reimbursed as REH services. In this final rule, CMS finalized a broad definition of “REH services” to include all services that are eligible for reimbursement under the OPPS, providing REHs with considerable flexibility to tailor the outpatient services they may offer (provided that the REH CoPs are met).

REHs will be paid for furnishing REH services at 105% of the OPPS payment rate for equivalent covered outpatient department services. Beneficiaries will not be charged coinsurance on the additional 5% payment. REHs are permitted to 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 will not be considered REH services and therefore will be paid under the applicable fee schedule for such services without the additional 5% payment increase. CMS also finalized the monthly facility payment proposal with various methodology modifications. The final monthly REH facility fee is $272,866 for CY 2023.

CMS also finalized its enrollment requirements for REHs. One of the most important REH enrollment provisions provides that a facility may submit a change of application, through Form CMS-855A, rather than requiring an REH to submit an initial enrollment application to convert from a CAH to a REH.

CMS also finalized certain of the proposed revisions to existing exceptions to the physician self-referral

law (commonly known as the Stark Law), to ensure that certain compensation exceptions are available to protect compensation arrangements between an REH and a physician or physician-owned entity. The REH CoPs require REHs to furnish radiology and clinical laboratory services and outpatient prescription drugs, all of which are categorized as designated health services (DHS) under the Stark Law and its implementing regulations. Therefore, a REH is considered to be a DHS entity and will need to consider the applicability of the Stark Law to its financial relationships with physicians and physician-owned entities. CMS did not finalize the proposed exception for ownership or investment interests in an REH. This exception, if it had been finalized, would have permitted physician ownership and/or investment in REHs. Because of concerns regarding the risk of program or patient abuse based on the REH exception as proposed, CMS declined to finalize this exception. REHs will be eligible to rely on the rural provider exception and will not be obligated to comply with the additional requirements applicable to "hospitals" under this exception. An REH may qualify for this exception if the entity furnishes substantially all (not less than 75%) of the DHS it furnishes to residents of rural areas.

Organ Acquisition

Key Takeaway: As a follow-up to the FY 2022 IPPS rulemaking cycle, CMS finalized a methodology for calculating the Medicare share of organ acquisition costs.

Medicare reimburses transplant hospitals and organ procurement organizations (OPOs) for organ acquisition costs under a reasonable cost basis, separate from the inpatient hospital diagnosis-related group payment. It is long-standing policy that Medicare pays for only its share in organ acquisition costs when Medicare beneficiaries are involved. When an organ is furnished to another OPO or transplant hospital, it has been a Medicare policy to assume that most of the unknown transplant recipients are Medicare beneficiaries, and to permit such an organ to be counted as a Medicare usable organ when calculating Medicare's share in organ acquisition costs.

In the FY 2022 IPPS proposed rule, CMS proposed several sweeping proposals to codify longstanding Medicare organ procurement payment policies and reorganize existing organ acquisition payment regulations so that all organ acquisition payment policies are housed together. While CMS finalized several policies in the FY 2022 IPPS final rule as proposed, the agency did not proceed with its proposal to revise the methodology for counting the Medicare share of organ acquisition costs. CMS indicated that it would address the unresolved organ counting policy in subsequent rulemaking.

In the CY 2023 OPPS proposed rule, CMS proposed to require that transplant hospitals and OPOs exclude organs used for research from both the numerator (Medicare usable organs) and the denominator (total usable organs) when determining Medicare's share of organ acquisition costs on the Medicare cost report. CMS defines a "research organ" to be an organ used for research (with the exception of certain pancreata), regardless of whether the organ was intended for research, or intended for transplant and subsequently used for research. Under this proposal, transplant hospitals and OPOs would also be required to deduct the cost incurred in procuring an organ for research from their total organ acquisition costs.

In this final rule, CMS finalized its proposal to exclude research organs from the calculation of Medicare's share of organ acquisition costs. CMS also finalized a policy that when transplant hospitals or OPOs include the costs to procure research organs in the organ acquisition costs, they must account for those costs in one of two ways: by deducting the costs to procure organs for research from the total organ acquisition costs, or by offsetting the costs to procure the organs by the revenue received for furnishing the organs to research organizations. This flexibility in how to account for the costs was established so that transplant hospitals and OPOs can account for research costs in a way most consistent with their current accounting practices.

Software as a Service

Key Takeaway: CMS finalized its policy to separately pay for software-as-a-service (SaaS) technologies, whether performed as stand-alone or at the same time as the associated imaging procedure.

Companies continue to bring innovative and emerging technologies to the healthcare marketplace, and these technologies can have meaningful impact on patient care by reducing costs and improving outcomes. One area of particular growth is solutions that analyze data from a patient's diagnostic image to aid or augment the treatment management decision. As CMS noted, these SaaS technologies "rely on complex algorithms or statistical predictive modeling to aid in the diagnosis or treatment of a patient's condition."

Over the last few rulemaking cycles, CMS has established payment rates for SaaS solutions, such as HeartFlow and IDx-DR, on a case-by-case basis, but has not established a formal payment policy. Concurrently, the American Medical Association has established new pairs of CPT codes, where one code represents the service performed as a stand-alone and the other code represents an add-on service performed contemporaneously with the accompanying imaging service. To date, CMS has established a payment rate for the stand-alone code and bundled the payment for the add-on service with the underlying imaging procedure.

For CY 2023, CMS proposed a policy change for these code pairs. The agency acknowledged that the services reported under the "add-on codes" represent distinct services from the underlying imaging procedure and thus do not meet the conventional definition of an add-on service. Based on this revised perception of these services, CMS proposed to do the following:

- Not recognize the add-on codes in these types of code pairings
- Establish a new C-code to describe the add-on service that would be billed with the associated procedure
- Set the payment rate for these new C codes at the same rate as what would have been paid if the service was furnished without the imaging procedure.

In the final rule, CMS proceeded with its policy to pay for these "add-on" codes separately, not viewing the services as those for which CMS would package payment under 42 CFR 419.2(b)(18). However, CMS did not finalize its proposal to create new C codes for the add-on codes (*e.g.*, 0649T, 0722T and 0724T). CMS decided to not finalize these new codes based on feedback from stakeholders that these HCPCS codes were duplicative to existing CPT codes and would likely create confusion among hospitals.

The list of codes impacted by the policy for CY 2023 are presented below (see also table 69 in the final rule).

CPT code	Descriptor	Proposed Status Indicator	Proposed APC
0648T	Quantitative magnetic resonance for analysis of tissue composition (*e.g.*, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (*e.g.*, organ, gland, tissue, target structure) during the same session	S	1511
0649T	obtained with diagnostic MRI examination of the same anatomy (*e.g.*, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	S	1511

CPT code	Descriptor	Proposed Status Indicator	Proposed APC
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	S	1508
0722T	obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (List separately in addition to code for primary procedure)	S	1508
0723T	Quantitative magnetic resonance Cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (*e.g.*, organ, gland, tissue, target structure) during the same session	S	1511
0724T	obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (*e.g.*, organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	S	1511

In the proposed rule, CMS sought input from stakeholders on a payment approach that would apply more broadly to SaaS procedures, acknowledging the heterogeneity in these types of services. Similar to other requests for information, CMS did not finalize any new policies based on stakeholder feedback but noted that it will consider the feedback in future rulemaking.

Driving Competition in the Healthcare Marketplace

Key Takeaway: CMS is interested in provider consolidation, acquisition, mergers and changes in ownership.

On July 9, 2021, President Biden issued an Executive Order on Promoting Competition in the American Economy (EO 14036). In response to that executive order, CMS sought information from the public on how data collected by CMS can be used to promote competition across the healthcare system, including public comments on the following:

- What additional data reported to the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) would be helpful to release to the public and researchers studying the impacts of provider consolidations, mergers, acquisitions and changes in ownership on the affordability and availability of medical care.
- Whether CMS should release data on mergers, acquisitions, consolidations and changes in ownership that have taken place for healthcare providers. CMS has previously published this information for hospitals and nursing homes.
- What other additional information collected by CMS would be helpful to the public and researchers studying the impacts of mergers, acquisitions, consolidations and changes in ownership.

- Whether data for transactions recorded in PECOS prior to 2016 would be useful for the public or researchers. In 2016 CMS completed its initial round of revalidations for PECOS data and resumed regular revalidation cycles in accordance with 42 CFR 424.515.

CMS received more than 200 comments that will be considered in future rulemaking.

Conclusion

A few topline themes emerge from this rulemaking:

- The COVID-19 pandemic is still complicating the rulemaking process. CMS is seeking to walk the line between policies that address the continuing impact of the pandemic and policies that seek to return to regular processes and expectations.
- CMS continues to pursue the administration's key priorities, including a focus on access to care in rural communities, expansion of prior authorization and maintaining access to behavioral health services following the expiration of the PHE.
- While a 3.8% market basket update would be on the upper end of a payment update in a normal year, that update was downwardly adjusted by changes to the 340B payment policy. As hospitals and ASCs continue to confront the consequences of the pandemic and wrestle with inflation and an escalating healthcare labor shortage, this payment increase will fall short for many hospitals.

For more information, contact Luis Arzaluz Angulo, Haile Dagne, Deborah Godes, Kayla Holgash, Kristen O'Brien, Rachel Hollander, Devin Stone, Katie Waldo, Susan Xu or Eric Zimmerman.