

CMS Released FY 2023 IPPS Final Rule

On Monday, August 1st, the Centers for Medicare and Medicaid Services (CMS) released the fiscal year (FY) <u>2023 Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long Term Care Hospital (LTCH) Prospective Payment System</u> Final Rule. Under this payment system, CMS sets base payment rates for inpatient stays based on the patient's diagnosis and severity of illness. Subject to certain adjustments, a hospital receives a single payment for the case based on the payment classification assigned at discharge through Medicare Severity Diagnosis-Related Groups (MS-DRGs). These finalized changes take effect on October 1, 2022.

Finalized Base Payment for FY 2023

CMS finalized a base FY 2023 IPPS payment update of +4.3%. This is based on a market basket update of 4.1 percent and the multifactor productivity (MFP) adjustment, which CMS estimates a 0.3 percent reduction. This also includes a 0.5 percent increase to the standardized amount per section 414 of the MACRA. CMS will also reduce the market basket increase portion of the formula by one-quarter for hospitals that fail to submit quality data; and a three-quarters reduction of the market basket increase portion of the formula for hospitals not considered "meaningful EHR users."

Data Used in Rate Setting

CMS finalized the proposal to use FY 2021 MedPAR claims and FY 2020 cost reports for purposes of FY 2023 rate setting, with certain modifications to account for the anticipated decline in COVID-19 hospitalizations of Medicare beneficiaries at IPPS hospitals and LTCHs as compared to FY 2021.

MS-DRG Documentation and Coding Adjustment

Determined by prior rulemakings, section 631 of the American Taxpayer Relief Act of 2012 (ATRA) amended section 7(b)(1)(B) of Pub. L. 110–90 requires the Secretary to make a recoupment adjustment to the standardized amount of Medicare payments to acute care hospitals to account for changes in MS– DRG documentation and coding that do not reflect real changes in case-mix, totaling \$11 billion by FY 2017. Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) then replaced the single positive adjustment CMS intended to make in FY 2018 once the recoupment required by section 631 of the ATRA was complete with a 0.5 percentage point positive adjustment to the standardized amount of Medicare payments to acute care hospitals for FYs 2018 through 2023. (The FY 2018 adjustment was subsequently adjusted to 0.4588 percentage point by section 15005 of the 21st Century Cures Act.). For FY 2023, CMS finalized the proposal to make an adjustment of +0.5 percentage point to the standardized amount consistent with the MACRA; this is the final adjustment prescribed by section 414.

Market-Based MS-DRG Relative Weight

CMS finalized the proposal to modify the calculation of the FY 2023 MS-DRG relative weights by first calculating two sets of weights, one including, and one excluding COVID-19 claims in the FY 2021 data, and then averaging the two sets of relative weights to determine the FY 2023 MS-DRG relative weight values. The purpose of this is to account for the anticipated decline in COVID-19 hospitalizations of Medicare beneficiaries at IPPS hospitals during FY 2023. CMS also modified its methodologies for

HEADQUARTERS 1891 Preston White Drive Reston, VA 20191 703-648-8900 GOVERNMENT RELATIONS 505 Ninth St. N.W. Suite 910 Washington, DC 20004 202-223-1670 CENTER FOR RESEARCH AND INNOVATION 50 South 16th St., Suite 2800 Philadelphia, PA 19102 215-574-3150 AMERICAN INSTITUTE FOR RADIOLOGIC PATHOLOGY 1100 Wayne Ave., Suite 1020 Silver Spring, MD 20910 703-648-8900 determining the FY 2023 outlier fixed-loss amount by calculating and averaging two fixed-loss amounts (one with COVID-19 claims and one with COVID-19 claims excluded). CMS will also use charge inflation factors and cost-to-charge (CCR) adjustment factors based on data prior to the PHE to provide a more reasonable approximation of the increase in costs that will occur from FY 2021 to FY 2023. CMS also modified the IPPS outlier fixed-loss amount calculation to factor in certain payment increases for COVID-19 cases provided by the CARES Act.

Add-On Payments for New Services and Technologies for FY 2023

In general, CMS extends new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the upcoming fiscal year.

Alternative Inpatient New Technology Add-on Payment Pathway

Beginning with applications for FY 2021, new technology add-on payments a medical device that is part of FDA's Breakthrough Devices Program may qualify for the new technology add-on payment under an alternative pathway. CMS reviews the application based on the information provided by the applicant only under the alternative pathway specified by the applicant at the time of new technology add-on payment application submission. However, to receive approval for the new technology add-on payment under that alternative pathway, the technology must have the applicable FDA designation and meet all other requirements.

FY 2023 Applications for New Technology Add-On Payments (Traditional Pathway)

CMS received 18 applications for the new technology add-on payments (NTAP) under the traditional pathway for FY 2023. Seven applicants withdrew their respective applications for lifileucel, narsoplimab, TERLIVAZ (terlipressin), teclistamab, mosunetuzumab, XENOVIEW, and treosulfan prior to the issuance of FY 2023 IPPS final rule.

Xenoview

Polarean, Inc. and The Institute for Quality Resource Management applied for new technology add-on payments for XENOVIEW for FY 2023. XENOVIEW is a gas blend used in chest magnetic resonance imaging (MRI) that is processed to consist of 89% Helium, 10% Nitrogen, and 1% Xenon. The applicant stated that the 1% Xenon in the gas blend is hyperpolarized (HP) to create Xenon-129 (129Xe) (that is, 80% purity of 129Xe isotope), which allows for high resolution 3-dimensional (3-D) images of the lungs and assessment of the lungs' functional status when inhaled by a patient during a pulmonary MRI scan. Xenoview withdrew their application prior to the release of the FY 2023 IPPS final rule.

FY 2023 Applications for New Technology Add-On Payments (Alternative Pathways)

Beginning with applications for FY 2021, a medical device that is part of FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation may qualify for the new technology add-on payment under an alternative pathway. Under the alternative pathway, a technology will be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS and will not need to meet the requirement that it represents an advance that substantially improves the diagnosis or treatment of Medicare beneficiaries. These technologies must still meet the cost criterion.

Nelli® Seizure Monitoring System

The Nelli® Seizure Monitoring System is software designed to automate the analysis of audio and video data to identify seizure events with a positive motor component as an adjunct to seizure monitoring in a hospital inpatient or home setting for adults and children 6 years of age and older. Per the applicant, the software provides objective summaries of semiological components of identified events (including velocity and acceleration of movements, seizure frequency, seizure duration, heart rate, and respiratory rate) to enable the detection and classification of epileptic events using pretrained artificial intelligence (AI).

The applicant stated that the Nelli® Seizure Monitoring System is not yet commercially available as it is awaiting 510(k) clearance of the device from the FDA for the same indication, which the applicant submitted on August 17, 2021. The Nelli® Seizure Monitoring System did not meet the July 1 deadline for FDA approval or clearance of the technology and, therefore, the technology is not eligible for consideration for new technology add-on payments for FY 2023.

Precision TAVI™ Coronary Obstruction Module

The Precision TAVI Coronary Obstruction Module, which would be an added feature of the Precision TAVI Software System, is intended to provide intelligent decision support powered by artificial intelligence (AI) and machine learning to help physicians accurately predict potential coronary artery obstructions in transcatheter aortic valve replacement (TAVR) procedures.

Precision TAVI withdrew their application prior to the release of the FY 2023 IPPS final rule.

Changes to the Hospital Wage Index for Acute Care Hospitals

To prevent large year-to-year variations in wage index values, CMS will apply a 5 percent cap on any decrease to a hospital's wage index from their prior FY's wage index, regardless of the circumstances causing the decline. A hospital's wage index would not be less than 95% of its final wage index for the prior FY. CMS will apply this wage index cap policy in a budget neutral manner through a national adjustment to the standardized amount.

Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2023

For FY 2023, CMS will distribute roughly \$6.8 billion in uncompensated care payments, a decrease of approximately \$318 million from FY 2022. In response comments that the use of only one year of data would lead to significant variations in year-to-year uncompensated care payments, for FY 2023, CMS will use the two most recent years of audited data on uncompensated care costs from Worksheet S-10 of hospitals' FY 2018 and FY 2019 cost reports to distribute these funds.

Beginning in FY 2023, CMS will discontinue the use of low-income insured days as a proxy for uncompensated care in determining the amount of uncompensated care payments for IHS and Tribal hospitals, and hospitals located in Puerto Rico. CMS is also establishing a new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico beginning in FY 2023.

Payments for Indirect and Direct Graduate Medical Education Costs

Changes to Graduate Medical Education (GME) Payments Based on Litigation

The U.S. District Court for the District of Columbia struck down CMS' method of calculating direct GME payments to teaching hospitals when those hospitals' weighted full-time equivalent (FTE) resident counts

exceed their direct GME FTE cap. In the case, the court ordered CMS to recalculate reimbursement owed, holding that CMS' regulation impermissibly modified the statutory weighting factors.

The modified policy addresses situations for applying the FTE cap when a hospital's weighted FTE count is greater than its FTE cap but would not reduce the weighting factor of residents that are beyond their initial residency period to an amount less than 0.5. Specifically, effective for cost reporting periods beginning on or after October 1, 2022, if the hospital's unweighted number of FTE residents exceeds the FTE cap, and the number of weighted FTE residents also exceeds that FTE cap, the respective primary care and obstetrics and gynecology weighted FTE counts and other weighted FTE counts are adjusted to make the total weighted FTE count equal the FTE cap. If the number of weighted FTE residents does not exceed that FTE cap, then the allowable weighted FTE count for direct GME payment is the actual weighted FTE count.

Additionally, law requires caps on the number of FTE residents that each teaching hospital may include in its indirect medical education (IME) adjustment and direct GME payment formulas. To provide flexibility to teaching hospitals that cross-train residents, CMS allows teaching hospitals to enter into "Medicare GME affiliation agreements" to share and redistribute those cap slots to accommodate the actual rotations of their residents. The law also includes a provision allowing additional cap slots for urban hospitals that establish "rural training tracks" with rural hospitals, now called Rural Training Programs (RTPs). CMS's current regulations do not allow GME affiliation agreements for RTPs. Stakeholders have requested that RTPs be afforded the same flexibility as other teaching hospitals to share their RTP cap slots via special RTP affiliation agreements. With this final rule, CMS will allow an urban and a rural hospital participating in the same RTP to enter into an "RTP Medicare GME affiliation agreement" effective for the academic year beginning July 1, 2023. This should promote workforce development and training in rural areas, where there are known challenges with access to care.