**CMS Released FY 2022 IPPS Proposed Rule**

On Tuesday, April 27th, the Centers for Medicare and Medicaid Services (CMS) released the fiscal year (FY) [2022 Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long Term Care Hospital (LTCH) Prospective Payment System](https://www.federalregister.gov/public-inspection/2021-08888/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the) Proposed Rule. The proposed rule provides updates for Medicare fee-for-service payment rates and policies for inpatient hospitals and long-term care hospitals for FY 2022. CMS pays acute care for inpatient stays under the IPPS. 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). Comments are due to CMS by 5pm EDT on June 28, 2021.

**Proposed Payment for FY 2022**

CMS proposes a base FY 2022 IPPS payment update of +2.3%. This is based on a market basket update of 2.5 percent and the multifactor productivity (MFP) adjustment, which CMS estimates a 0.2 percent reduction. 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 proposes to use the FY 2019 data, for example the FY 2019 MedPAR file, for the FY 2022 ratesetting for circumstances where the FY 2020 data is significantly impacted by the COVID-19 public health emergency (PHE), primarily in that the utilization of inpatient services reflect generally markedly different utilization for certain types of services in FY 2020 than would have been expected in the absence of the PHE. CMS is also considering the use of the same FY 2020 data that it would ordinarily use for purposes of FY 2022 ratesetting. CMS is soliciting comments on alternative approaches or data sources that could be used in Medicare fee-for-service (FFS) ratesetting.

**Proposed MS-DRG Documentation and Coding Adjustment**

The American Taxpayer Relief Act of 2012 (ATRA) amended section 7(b)(1)(B) of Pub. L. 110–90 to require 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 over a 4-year period of FYs 2014, 2015, 2016, and 2017. Prior to the ATRA, this amount could not have been recovered under Pub. L. 110 90. Section 414 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) replaced the single positive adjustment CMS intended to make in FY 2018 with a 0.5 percent 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 percent by section 15005 of the 21st Century Cures Act.) For FY 2022, CMS proposes to make an adjustment of + 0.5 percent to the standardized amount.

**Market-Based MS-DRG Relative Weight--Proposed Policy Changes (§413.20)**

In FY 2021 rulemaking, CMS finalized a provision that required hospitals to report on their Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage payers. CMS proposes to repeal this requirement for cost reporting periods ending on or after January 1, 2021 and the associated methodology it had finalized for incorporating this information into ratesetting. CMS states that it is taking this step out of consideration for the varying contract arrangements used to negotiate MA rates with Medicare Advantage Organizations and, given what it believes is limited utility of the data, because of information provided in response to the Information Collection Requirement (ICR) about the burden this would place on hospitals.

**Proposed FY 2022 Applications for New Technology Add-On Payments**

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. However, CMS proposes a one-year extension of new technology add-on payments for those technologies for which the new technology add-on payment would otherwise be discontinued beginning with FY 2022.

*FY 2022 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. CMS received 17 applications for new technology add-on payments for FY 2022 under the alternative new technology add-on payment pathway. One applicant withdrew its application prior to the issuance of this proposed rule. Of the remaining 16 applications, 13 of the technologies received a Breakthrough Device designation from FDA and three were designated as a Qualified Infectious Disease Product by the FDA.

*FY 2022 Applications for New Technology Add-On Payments (Traditional Pathway*)

CMS received 37 applications for new technology add-on payments for new medical services and technologies for FY 2022. Prior to publication, 5 applications were withdrawn. One of the applications was by Aidoc Medical for Aidoc Briefcase for pulmonary embolism (PE). The applicant stated that the device assists hospitals and radiologists by flagging and communicating suspected positive findings of PE in computed tomography (CT) pulmonary angiography (CTPA) examinations, which prompts the radiologist to assess relevant Digital Imaging and Communications in Medicine (DICOM) imaging files, allowing suspect cases to receive attention sooner than otherwise would have occurred, which in turn improves clinical outcomes. With Briefcase for PE, CTPA images are automatically forwarded to the applicant’s cloud-based engine where they are analyzed by an AI algorithm. The applicant claims that when Briefcase for PE detects a suspected PE, the radiologist is alerted via the user interface of the Aidoc Worklist Application that is installed on the radiologist’s desktop. The applicant asserted that the notification prompts the radiologist to review the CTPA images and communicate with the emergency room team currently caring for the patient so that the appropriate clinical action may be taken sooner than it would otherwise have occurred in the absence of the tool.

In the proposed rule, CMS expresses interest in public comments regarding issues related to determining newness for technologies that use AI, an algorithm, or software. Specifically, CMS is interested in comments on how these technologies, including devices classified as radiological computer aided triage and notification software and radiological computer-assisted diagnostic software, may be considered for the purpose of identifying a unique mechanism of action; how updates to AI, an algorithm, or software would affect an already approved technology or a competing technology; whether software changes for an approved technology could be considered a new mechanism of action, and whether an improved algorithm by competing technologies would represent a unique mechanism of action if the outcome is the same as an approved AI new technology.

**Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2022**

Medicare makes DSH payments to IPPS hospitals that serve more than a threshold percent of low-income patients. In this proposed rule, CMS proposes to:

* To establish a measure suppression policy for the duration of the public health emergency for COVID-19;
* To suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS), Medicare Spending Per Beneficiary (MSPB), and five Healthcare-Associated Infection (HAI) measures, for the FY 2022 Program year;
* To suppress the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia (PN) Hospitalization (MORT-30-PN) measure for the FY 2023 program year.

**Hospital Readmissions Reduction Program: Proposed Updates and Changes (§§ 412.150**

**through 412.154)**

CMS proposes to adopt a policy for the duration of the PHE for COVID-19 that will enable CMS to suppress the use of quality measures via adjustment to the Hospital Readmissions Reduction Program’s scoring methodology if they determine that circumstances caused by the COVID-19 PHE have affected those measures and the associated “excess readmissions” calculations significantly.

CMS requests public comment on possible future stratification of results by race and ethnicity for condition/procedure-specific readmission measures and by expansion of standardized data collection to additional social factors, such as language preference and disability status.

**Payments for Indirect and Direct Graduate Medical Education Costs**

Section 126 of the Consolidated Appropriations Act (CAA), 2021, division CC (Pub. L. 116-260) requires the distribution of an additional 1,000 new Medicare-funded medical residency positions to train physicians. The Consolidated Appropriations Act, 2021 (CAA) contained 3 provisions affecting Medicare direct GME and IME payments to teaching hospitals:

* Section 126: makes available 1,000 new Medicare-funded GME positions (not more than 200 new positions per fiscal year), to be distributed beginning in fiscal year 2023, with priority given to hospitals in 4 statutorily-specified categories.
* Section 127: makes changes relating to the determination of both an urban and rural hospital’s FTE resident limit for direct GME and IME payment purposes with regard to residents training in an accredited rural training track (RTT), and the 3-year rolling average used to calculate payments.
* Section 131: makes changes to the determination of direct GME per resident amounts and direct GME and IME full-time equivalent (FTE) resident limits of hospitals that hosted a small number of residents for a short duration.

CMS proposes to distribute the slots to qualifying hospitals, as specified by the law, including those located in rural areas and those serving areas with a shortage of health care professionals. The 1,000 new slots will be phased in at no more than 200 slots per year beginning in FY 2023. CMS estimates that this additional funding will total approximately $1.8 billion from FY 2023 through FY 2031. CMS proposes to prioritize applications from qualifying hospitals that serve geographic areas and underserved populations with the greatest need.

CMS proposes that the application deadline for the additional positions available for a fiscal year be January 31 of the prior fiscal year. Meaning, for FY 2023, the proposed application deadline would be January 31, 2022. CMS proposes that a hospital would show a demonstrated likelihood of filling the additional positions for which it applies by demonstrating that it does not have sufficient room under its current FTE resident caps to accommodate a planned new program or expansion of an existing program.

**Medicare Shared Savings Program**

CMS proposes changes to policies for the Shared Savings Program that allow eligible ACOs participating in the BASIC track’s glide path the option to elect to forgo automatic advancement along the glide path’s increasing levels of risk and potential reward for performance year 2022. Under this proposal, prior to the automatic advancement for PY 2022, an eligible ACO may elect to remain in the same level of the BASIC track's glide path in which it participated during PY 2021. For PY 2023, an ACO that elects this advancement deferral option would be automatically advanced to the level of the BASIC track's glide path in which it would have participated during PY 2023 if it had advanced automatically to the required level for PY 2022 (unless the ACO elects to advance more quickly before the start of PY 2023).

**Quality Data Reporting Requirements for Specific Providers and Suppliers**

CMS seeks comments on proposed updates to the quality programs regulated under the IPPS, including advancing digital quality measurement (dQM) and the use of Fast Healthcare Interoperability Resources (FHIR) in hospital quality programs. CMS also seeks comment on approaches for closing the health equity gap among the hospital quality programs; and seeks input on the proposed updates to various inpatient hospital quality program measures.

**Request for Information (RFI): Changes Under Consideration to Advance Digital Quality Measurement [dQM]: Actions in Four Areas to Transition to Digital Quality Measures by 2025**

Given the goal of fully transitioning all quality reporting and value-based purchasing programs to digital quality measurement by 2025, CMS is collecting information for planning the changeover of CMS programs to complete digital measurement. To maintain the alignment and harmonization outlined in the 2020 Department of Health and Human Services (HHS) Health Quality Roadmap, CMS is approaching HHS’ priorities with other federal entities, like the Office of the National Coordinator on Health Information Technology (i.e., 21st Century Cures Act), to promote data interoperability and access. The five-part RFI seeks comments on the following:

CMS acknowledges that reporting quality measurement data through electronic health records (EHR) imposes burden on those reporting. Data sources have evolved since the start of CMS quality programs. For instance, sources like administrative systems and electronically submitted clinical assessment data do not provide robust enough data required by emerging quality measures. CMS has shifted its measurement priorities from assessing clinical processes to clinical outcomes and patient-reported outcomes. Therefore, CMS proposes that quality measures should integrate with data sources capable of capturing this level of information.

In this proposed rule, CMS defines dQMs as measures with “sources of health information that are captured and can be transmitted electronically and via interoperable systems.” For instance, in addition to administrative systems and electronically submitted clinical assessment data, dQMs may also source information from case management systems, medical and wearable devices, as well as patient portal applications collecting patient-generated health data, health information exchanges (HIEs), or registries, to name a few. To successfully capture data from various digital sources, dQM elements must be standardized and interoperable among the different data sources. CMS is working with the free open source FHIR Framework (http://hl7.org/fhir) to capture electronic clinical quality measures (eCQMs). As described in the proposed rule, the FHIR Framework, which establishes a common language and process for all health information technology, would inform the dQM structure and data submission for CMS’ quality reporting programs. Given the potential adoption of FHIR and its standardized language, CMS is seeking comment on aligning quality measurement data with interoperability requirements. Comments are also sought on approaches that could support the inclusion of non-standardized data.

To attain CMS’ modernized vision of quality measurement, this RFI seeks input on the potential redesign of CMS programs’ measures. Should the FHIR Framework be adopted into CMS quality programs, quality measures functionality may expand. For instance, CMS is considering defining and developing dQM software that could incorporate end-to-end measure calculation solutions utilizing data from FHIR-based resources (maintained by providers, payers, CMS, etc.) to calculate measure scores and generate reports.

CMS is also considering a pathway to data aggregation as a method of supporting quality measurement. In other words, by implementing dQMs with their associated multiple data sources, data fragmentation would decline. Information stored in different locations would become accessible for meeting the criteria of a particular quality measure, thereby establishing a measurement-focused patient-centered care narrative. As stated in the proposed rule, CMS anticipates expanding and developing policies for third-party data aggregators, like qualified clinical data registries and qualified registries, to maintain the integrity of the measure reporting process.

In concordance with the HHS 2020 Quality Roadmap, CMS is attempting to align quality measure reporting programs across federal and state agencies and private payers by adopting a dQM portfolio that meets programmatic requirements across agencies. Such alignment would leverage existing HHS initiatives, like the CMS Meaningful Measures Framework 2.0.

**Closing the Health Equity Gap in CMS Hospital Quality Programs – Request for Information**

Consistent with the executive order on Advancing Racial Equity and Support for Underserved Communities through the Federal Government, in conjunction with the CMS Quality Strategy and Meaningful Measures Framework, CMS issued an RFI within the proposed rule. Comments sought from stakeholders will inform CMS on achieving health equity for all patients by implementing new health equity-focused policies.

The proposed rule states that "Significant and persistent inequities in health care outcomes exist in the United States." And that "belonging to a racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; living in a rural area, or being near or below the poverty level" is associated with worse health outcomes. Although different factors result in disparate health outcomes, CMS cites that limited access to high-quality care is a significant contributor. Therefore, CMS proposes improving data collection of the elements influencing inequities within their quality programs. CMS perceives that this would present opportunities for providers to receive the resources necessary to improve their care quality.

In the proposed rule, CMS mentions multiple ongoing efforts to close the health equity gap among its programs. These include: transparency of health disparities, supporting providers and others with evidence-informed solutions to address social determinants of health for achieving health equity, and reporting to providers on gaps in the quality of the program in which they participate. In this RFI, CMS seeks feedback on incorporating the CMS Disparity Methods into the Hospital Inpatient Quality Reporting (IQR) program. The methods comprise two types of analyses, the Within-Hospital disparity method, and the Across-Hospital method. Both stratify quality measure data by dual eligibility status (a demonstrated predictor of poor health outcomes) and illustrate variations in outcome rates among patient groups within a provider's patient population. However, each method's analysis renders different results informing how providers may improve their disparity gaps. The Within-Hospital disparity method allows hospitals to make disparity size comparisons against other hospitals.

In contrast, the Across-Hospital Method provides results that provide information on a hospitals' performance when treating patients with certain social risk factors. Until CMS identifies specific factors for delivering the most valuable information to stakeholders, dual eligibility status is the proxy for social risk. CMS proposes applying the methods to multiple IQR program condition/procedure-specific readmission measures with plans to provide hospital-specific confidential reports of disparity results to minimize these gaps. CMS requests comments regarding exploring additional social risk factors, evaluating new sources of social risk factor data (and how to capture it), and examining the feasibility of social risk factors to influence outcome measures.

As part of their goal for achieving health equity across programs, CMS proposes bolstering the CMS Disparity Methods to consist of quality measure results stratified by race and ethnicity and improve demographic data collection to capture sex, sexual orientation, gender identity, language preference, tribal membership, and disability status, all in support of the development of a Hospital Equity Score. By expanding the CMS Disparity Methods to include two social risk factors (dual eligibility and race/ethnicity), CMS perceives that broadening the comprehensiveness of health equity information provided to hospitals would improve the care delivered by providers. CMS requests comments on aggregating equity results of multiple measures that assess numerous social risk factors to calculate a summary score so that it could enhance the usefulness of the confidential equity results.

**Hospital Inpatient Quality Reporting Program**

CMS proposes the inclusion of a new quality measure within the HIQRP. The *Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (Hybrid HWM)*poses minimal impact on Radiology departments and facilities captured within the Program. As proposed, the measure will be collected voluntarily from July 2022 until June 2023. If finalized, the measure will become mandatory for collection beginning in July 2023. CMS implemented condition-specific measures to assess national hospital mortality rates for specific measured conditions and/or procedures during previous rulemaking cycles. Since their implementation, CMS has witnessed a decline in mortality rates regarding the measures' respective conditions and/or procedures. As a result, CMS proposes the addition of the *Hybrid HWM* to measure hospital performance across a broader set of patients and more hospital areas.

**Proposed Updates to the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program**

CMS proposes to remove quality measure PCH-15/NQF #0383 Oncology: Plan of Care for Pain – Medical Oncology and Radiation Oncology from the PCHQR program. According to CMS, the measure is infeasible to collect the data elements because the measure steward reverted specifications to an earlier version of the measure.