On May 11, 2020 the Centers for Medicare and Medicaid Services (CMS) released the Fiscal Year (FY) 2021 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Acute Care Hospital (LTCH) Proposed Rule (CMS-1735-P). AAOS will be submitting formal comments to CMS, due on July 10, 2020.

Major provisions in the proposed rule include an adjusted total increase of 1.6 percent to IPPS payments; requiring hospitals to report certain payment information on their Medicare cost report to be used in a potential change to the methodology for calculating the MS-DRG relative weights to reflect market-based pricing; increasing the number of quarters for which hospitals are required to report electronic clinical quality measures (eCQM) data; and updating the Food and Drug Administration’s (FDA) Breakthrough Devices program. Below is a detailed summary of key proposals:

Proposed Changes to Payment Rates under IPPS

- Proposed increase of approximately 3.1 percent in operating payment rates for general acute care hospitals paid under the IPPS that successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program and are meaningful electronic health record (EHR) users.
  - Reflects the projected hospital market basket update of 3.0 percent reduced by a 0.4 percentage point productivity adjustment, as well as a proposed +0.5 percentage point adjustment required by legislation
  - CMS projects the rate increase, together with other proposed changes to IPPS payment policies, will increase IPPS operating payments by approximately 2.5 percent.
  - Proposed changes in uncompensated care payments, new technology add-on payments, and capital payments will decrease IPPS payments by approximately 0.4 percent.
  - CMS estimates a total increase in overall IPPS payments of approximately 1.6 percent.
- CMS projects total Medicare spending on inpatient hospital services, including capital, will increase by about $2.07 billion in FY 2021.

Proposed Changes to Payment Rates under LTCH PPS

- CMS expects LTCH PPS payments to decrease by approximately 0.9 percent or $36 million, which reflects the continued statutory implementation of the revised LTCH PPS payment system.
- LTCH PPS payments for FY 2021 for discharges paid using the standard LTCH payment rate are expected to increase by 2.1 percent after accounting for the proposed annual standard Federal rate update for FY 2021 of 2.5 percent, and an estimated decrease in outlier payments and other factors.
- LTCH PPS payments for cases that will complete the statutory transition to the lower payment rates under the dual rate system are expected to decrease by approximately 20 percent.
  - This accounts for the LTCH site-neutral payment rate cases that will no longer be paid a blended payment rate with the end of the statutory transition period, which represent approximately 25 percent of all LTCH cases and 10 percent of all LTCH PPS payments.

CAR T-cell Therapy
• Proposing Medicare Severity-Diagnosis Related Group (MS-DRG) 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy) effective beginning FY 2021
  • AAOS supported NTAP application for this in FY 2020

Price Transparency proposals (pg. 944)
• Proposing to require hospitals to report certain market-based payment rate information on their Medicare cost report for cost reporting periods ending on or after 1/1/2021 to be used in a potential change to the methodology for calculating the IPPS MS-DRG relative weights to reflect relative market-based pricing
• Specifically, hospitals would report on the Medicare cost report the two median payer-specific negotiated charges categorized by MS-DRG
  • For third-party payers that use the same MS-DRG system as Medicare, the payer-specific negotiated charges that the hospital uses to determine the median by MS-DRG would be the payer-specific negotiated charges the hospital negotiated with that third party payer for the MS-DRG to which the patient discharge was classified
  • For third-party payers that do not use the MS-DRG system, the payer-specific negotiated charges would be based on the system used by that third-party payer, including the per diem rates or All Patients Refined Diagnosis Related Group (APR-DRGs)
    • When this is the case, the hospital would determine and report the median payer-specific negotiated charges by MS-DRG using the payer-specific negotiated charges for the same or similar package of services that can be cross-walked to an MS-DRG
• Hospitals would be required to report on the Medicare cost report both the median payer-specific negotiated charge that the hospital has negotiated with all of its Medicare Advantage (MA) organization payers by MS-DRG, and the median payer-specific negotiated charge the hospital has negotiated with all of its third-party payers, including MA organizations by MS-DRG
• These payer-specific negotiated charges used by hospitals to calculate these medians would be the payer-specific negotiated charges for service packages that hospitals are required to make public under the requirements finalized in the Outpatient Prospective Payment System (OPPS) 2020 Hospital Price Transparency Final Rule which can be cross-walked to an MS-DRG
• CMS is seeking comment on a potential change to the IPPS MS-DRG relative weight calculation methodology to incorporate this market-based rate information, beginning in FY 2024 (pg. 952)
• Use of payer-specific negotiated charges would replace the current use of gross charges that are reflected on the hospital’s chargemaster and cost information from Medicare cost reports for the development of the IPPS MS-DRG relative weights
  • Would be calculated using a subset of the payer-specific negotiated charges
• The median payer-specific negotiated charges calculated and submitted by hospitals for each MS-DRG would be limited to charges hospitals have negotiated with MA organizations and third-party payers, including MA organizations
• CMS believes this would decrease Medicare’s reliance on hospital chargemasters and be reflective of the market-based pricing in fee-for-service inpatient reimbursements
• Switch from cost-based to market-based methodology for estimating weights of MS-DRGs
• CMS considering whether this data or another approach reflective of the market-based charges by MS-DRG would provide an appropriate basis for estimating the relative hospital resources used with respect to discharges classified within a single MS-DRG compared to discharges classified within other MS-DRGs

Graduate Medical Education (pg. 923)
• Indirect Medical Education (IME) payment adjustment factor determines amount of additional payment made to hospitals with residents in an approved GME program to reflect the higher indirect patient care costs of teaching hospitals compared to nonteaching hospitals
• For discharges occurring during FY 2021, the multiplier is 1.35
• CMS estimates that this adjustment will result in an increase in IPPS payment of 5.5-percent for every 10-percent increase in the hospital’s resident-to-bed ratio
• Proposing to amend the policy regarding the closing of teaching hospitals and residency programs
  • Temporary funding for affected residents would be linked to the day the closure of a hospital or program was publicly announced instead of the day the program closed
  • Allow funds to be transferred temporarily for residents who are not physically at the closing hospital or program, but had intended to train at or return to it after a rotation
• Receiving hospitals of displaced residents will be required to apply for a temporary increase in the Medicare resident cap by submitting a letter to its Medicare Administrative Contractor within 60 days of beginning the training of displaced residents
  • No longer required to include a resident’s complete social security number on the application, only the last four digits
• The maximum number of FTE resident cap slots that could be transferred to all receiving hospitals is the number of IME and direct GME FTE resident cap slots belonging to the hospital that has the closed program

FDA Breakthrough Devices Program and New Technology Add-On Payment (NTAP) Proposals
• Alternative Pathway for Certain Transformative New Devices (page 276 of 1602)
  o For FY 2021 and subsequent fiscal years, if a medical device is part of FDA’s Breakthrough Devices Program or a product is designated by FDA as a Qualified Infectious Disease Product (QIDP), and received FDA marketing authorization, it 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 represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
  o Technologies must still meet the cost criterion.
  o An applicant cannot combine a marketing authorization for an indication that differs from the technology’s indication under the Breakthrough Device Program, and for which the applicant is seeking to qualify for the new technology add-on payment.
• 15 proposed FY 2021 applications for New Technology Add-On Payments (NTAP) via the traditional pathway, including:
  o SpineJack® System (pg. 547)
"The applicant described the SpineJack® system as an implantable fracture reduction system, which is indicated for use in the reduction of painful osteoporotic vertebral compression fractures (VCFs) and is intended to be used in combination with Stryker VertaPlex and VertaPlex High Viscosity (HV) bone cement."

- Per CMS, there appears to be a lack of data comparing the SpineJack® system to conservative medical therapy, thus they are requesting public comment on whether the SpineJack® system meets the substantial clinical improvement criterion.

- 3 proposed FY 2021 applications for NTAP via the Alternative Pathways for Breakthrough Devices (pg. 617)
  - CMS proposing to approve all three.
- 6 proposed applications for NTAP via Alternative Pathways for Qualified Infectious Disease Products (QIDPs) (pg. 631)
  - CMS proposing to approve all six.

**Hospital Quality Programs**

- Hospital Readmissions Reduction Program: Proposed Updates and Changes (pg. 877)
  - No changes to measures or the definition of “dual eligible”.
  - CMS is proposing to automatically adopt applicable periods (i.e., performance periods for measures used in the Program) beginning with the FY 2023 program year and all subsequent program years.
- Hospital Value-Based Purchasing (VBP) Program: Updates (pg. 888)
  - No changes to performance measures.
  - Newly established performance standards for certain measures for the FY 2023, FY 2024, FY 2025, and FY 2026 program years, including COMP-HIP-KNEE (NQF 1550) (pg. 899-906).
- Hospital-Acquired Condition (HAC) Reduction Program: Proposed Updates and Changes (pg. 911)
  - No changes to measures (no ortho-specific measures).
  - Proposal to automatically adopt applicable periods (i.e., performance periods for measures used in the Program) beginning with the FY 2023 program year and all subsequent program years.
  - CMS proposes several changes to the process for validation of HAC Reduction Program measure data to better align the Hospital IQR Program measure validation process, which happens concurrently.
    - Proposing to only use measure data from the third and fourth quarters of 2020 for the FY 2023 program year. For FY 2024 and subsequent years, they are proposing to use measure data from all of CY 2021 for both the HAC Reduction Program and the Hospital IQR Program.
    - CMS proposes reducing the randomly selected hospital pool from up to 400 hospitals to up to 200 hospitals for validation for the FY 2024 program year and subsequent years.
    - Proposing to require hospitals to submit digital files when submitting medical records for validation of HAC Reduction Program measures, for the FY 2024 program year and subsequent years.
• Hospitals would be required to submit PDF copies of medical records using direct electronic files submission via a CMS-approved secure file transmission process.
  - Hospitals would be reimbursed at $3.00 per chart.

• Hospital Inpatient Quality Reporting (IQR) Program (pg. 1090)
  - No new measures proposed. Summary of previously finalized measures on pages 1093-1096.
  - CMS is “proposing to progressively increase, over a 3-year period, the number of quarters for which hospitals are required to report eCQM data, from the current requirement of one self-selected quarter of data to four quarters of data.”

• Increasing reporting for electronic clinical quality measures (eCQMs) to:
  - 2 self-selected calendar quarters of data (CY 2021)
  - 3 self-selected calendar quarters of data (CY 2022)
  - 4 self-selected calendar quarters of data (CY 2023)

• Proposing an electronic health record (EHR) reporting period of 90-continuous days during calendar year 2022 for new and returning participants.

• Proposing to add EHR Submitter ID as a fifth key element for file identification beginning with the CY 2021 reporting period/FY 2023 payment determination.
  - Validation of Hospital IQR Program Data (pg. 1110)
    - CMS is proposing to: “(1) update the quarters of data required for validation for both chart-abstracted measures and eCQMs; (2) expand targeting criteria to include hospital selection for eCQMs; (3) change the validation pool from 800 hospitals to 400 hospitals; (4) remove the current exclusions for eCQM validation selection, (5) require electronic file submissions for chart-abstracted measure data; (6) align the eCQM and chart-abstracted measure scoring processes; and (7) update the educational review process to address eCQM validation results.”
  - Public reporting on Hospital Compare of eCQM performance data beginning with the CY 2021 reporting period.

• Public Display Requirements (pg. 1133)
  - Proposal to start the public display of eCQM data on the Hospital Compare website (or its successor website) and/or data.medicare.gov, beginning with data reported by hospitals for the CY 2021 reporting period/FY 2023 payment determination and for subsequent years that would be included with the fall 2022 refresh of the website.

The proposed rule (CMS-1735-P) can be downloaded from the Federal Register at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-10122.pdf

The CMS Fact Sheet on the proposed rule can be viewed at: https://www.cms.gov/newsroom/fact-sheets/fiscal-year-fy-2021-medicare-hospital-inpatient-prospective-payment-system-ipps-and-long-term-acute