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Policy Update

CMS Releases FY 2021 IPPS Proposed Rule

Summary

Yesterday, the Centers for Medicare and Medicaid Services (CMS) released proposed updates to the Inpatient Prospective Payment System (IPPS) for fiscal year (FY) 2021, including updates to Medicare payment policies and payment rates for most acute care hospitals. Of particular note, is the agency's discussion of a potential new market-based methodology for establishing relative weights for Medicare Severity Diagnosis Related Groups (MS-DRGs).

In the proposed rule, CMS indicates that it does not expect to release the FY 2021 IPPS final rule by August 1 or August 2. Current statute requires the IPPS final rule to be published at least 60 days prior to its effective date (August 1). However, the Congressional Review Act (CRA) allows the agency to not meet the 60-day requirement under certain circumstances. CMS is planning on providing the final rule 30 days prior to its effective date (September 1), citing the COVID-19 public health emergency as grounds for not meeting the 60-day requirement.

A CMS factsheet on the proposed rule is available here. Comments are due on July 10, 2020.

Key Takeaways

1. CMS estimates that provisions in the proposed rule would result in an estimated $1.98 billion increase in FY 2021 payments to IPPS hospitals. Increases are primarily driven by the proposed increase to IPPS rates, but are also impacted by other proposed changes.

2. The proposed FY 2021 standardized amount for hospitals that successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program and that are meaningful electronic health record (EHR) users is $5,979.74 — an increase of 3.08 percent over the FY 2020 standardized amount.

3. CMS requests public comment on a potential market-based MS-DRG relative weight methodology that would begin in FY 2024 and that would utilize the market-based data collected on hospital cost reports.

4. CMS proposes additional changes to the NTAP process to facilitate add-on payments for certain antimicrobial products, including accelerating access to add-on payments by allowing conditional approval for products not FDA-authorized by July 1.

5. CMS proposes to maintain the low wage index policy first implemented for FY 2020. Hospitals with wage index values below 0.8420 would benefit in FY 2021.

6. CMS declines to propose updates to the Overall Hospital Quality Star Rating on Hospital Compare despite previous indications it would.

FY 2021 Standardized Amount

The proposed FY 2021 standardized amount for hospitals that successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program and that are meaningful electronic health record (EHR) users is $5,979.74. This would result in an increase of 3.08 percent over the FY 2020 standardized amount ($5,801.13) for these hospitals. The proposed update reflects an increase of 3.0 percent for the market basket increase, less a 0.4 percent productivity adjustment, plus a 0.5 percent positive adjustment for documentation and coding mandated by Section 414 of MACRA for fiscal years 2018 through 2023, as well as budget neutrality adjustments discussed in the proposed rule.

The standardized amount varies based on an individual hospital's participation in the Hospital IQR Program and meaningful use of EHR. Hospitals that fail to submit quality data are subject to a -0.75 percent adjustment and hospitals that fail to be a meaningful EHR user are subject to a -2.25 percent adjustment.

Proposed FY 2021 standardized amounts are shown below. Amounts shown are the sum of the labor-related and non-labor related shares without adjustment for geographic factors.

	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
FY 2021 Standardized Amount	$5,979.74	$5,848.61	$5,936.03	$5,804.89
FY 2020 Standardized Amount	$5,801.13	$5,673.91	$5,758.73	$5,631.51
Percent Change	3.08%	3.08%	3.08%	3.08%

Market-Based MS-DRG Relative Weight Methodology and Data Collection

POTENTIAL CHANGE IN METHODOLOGY FOR CALCULATING MS-DRG RELATIVE WEIGHTS

Key Takeaway: CMS is seeking public comment on a potential market-based MS-DRG relative weight methodology beginning in FY 2024 that would utilize market-based data collected from hospital cost reports.

CMS calculates payment for a specific case under the IPPS by multiplying an individual hospital's geographically adjusted standardized amount per case by the relative weight for the MS-DRG to which the case is assigned. Each MS-DRG relative weight represents the average resources required to care for cases in that particular MS-DRG, relative to the average resources required to care for cases across all MS-DRGs. MS-DRG classifications and relative weights are required to be adjusted at least annually to account for changes in resource consumption.

Currently, DRG relative weights are calculated using a cost-based methodology that primarily utilizes hospital charges from the MedPAR claims data and hospital cost report data from the Healthcare Cost Report Information System (HCRIS). CMS has in recent years sought to reduce the Medicare program's reliance on hospital charge data, believing that charge-master (gross) rates may not reflect true market costs.

CMS evaluated existing research comparing Medicare fee-for-service (FFS) rates, Medicare Advantage (MA) rates, and rates of other commercial payers and concluded that payer-specific charges negotiated between hospitals and MA organizations are generally well-correlated with Medicare IPPS payment rates, and payer-specific charges negotiated between hospitals and other commercial payers are generally not as well-correlated with Medicare IPPS payment rates. As a result, CMS is considering a more market-based methodology for estimating MS-DRG relative weights using the median payer-specific negotiated charge for each MS-DRG for payers that are MA organizations.

The specific methodology being considered includes the following steps:

Step	Description	Method
1	Standardize the Median MA Organizations Payer-Specific Negotiated Charges	Remove the effects of differences in area wage levels, and cost-of living adjustments for hospital claims from Alaska and Hawaii
2	Create a Single Weighted Average Standardized Median MA Organization Payer-Specific Negotiated Charge by MS-DRG Across Hospitals	Weight the standardized payer-specific negotiated charge for each MS-DRG for each hospital using that hospital's Medicare transfer-adjusted case count for that MS-DRG
3	Create a Single National Weighted Average Standardized Payer-Specific Negotiated Charge Across all MS-DRGs	Weight based on the national Medicare transfer adjusted case counts by MS-DRG
4	Calculate the Market-based Relative Weights	Calculate as the ratio of the single weighted average standardized median MA organization payer-specific negotiated charge for that MS-DRG across hospitals from Step Two to the single national weighted average standardized median MA organization payer-specific negotiated charge across all MS-DRGs from Step 3.
5	Normalize the Market-based Relative Weights	Normalize by an adjustment factor so that the average case weight after recalibration would be equal to the average case weight before recalibration.

CMS seeks comments on this potential methodology, which the agency says would be implemented beginning in FY 2024, and which CMS may adopt in the FY 2021 IPPS/LTCH PPS Final Rule. CMS suggests implementing in FY 2024 to allow time to collect and evaluate the median payer-specific negotiated charge data submitted on hospital cost reports and provide the public with information regarding the analysis in future rulemaking.

MARKET-BASED RATE DATA COLLECTION

Key Takeaway: CMS proposes to collect market-based rate information on the Medicare cost report for cost reporting periods ending on or after January 1, 2021.

CMS proposes that hospitals would be required to report certain market-based payment rate information on their Medicare cost report for cost reporting periods ending on or after January 1, 2021. This information would be used in the new methodology for calculating MS-DRG relative weights.

Hospitals would report on the Medicare cost report two median payer-specific negotiated charges "by MS-DRG." For a third-party payer that uses the same MS-DRG patient classification system used by Medicare, the payer-specific negotiated charges that the hospital uses to calculate 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. Because not all third-party payers use the MS-DRG patient classification system, for those third-party payers that do not, the payer-specific negotiated charges they negotiate with hospitals would be based on the system used by that third-party payer, such as per diem rates or APR-DRGs. In that case, the hospital would determine and report the median payer-specific negotiated charges by MS-DRG using its payer-specific negotiated charges for the same or similar package of services that can be crosswalked to an MS-DRG.

CMS proposes that hospitals would report on the Medicare cost report the following data elements: (1) the median payer-specific negotiated charge by MS-DRG that the hospital has negotiated with all of its MA payers; and (2) the median payer-specific negotiated charge by MS-DRG that the hospital has negotiated with all of its third-party payers, which would include MA organizations. The data would be become publicly accessible in the HCRIS dataset in a de-identified manner.

CMS believes that because hospitals are already required to publicly report payer-specific negotiated charges, in accordance with the Hospital Price Transparency Final Rule, that the additional calculation and reporting of the median payer-specific negotiated charge will be less burdensome for hospitals.

New Technology Add-on Payments

EXPANDED ALTERNATIVE PATHWAY AND CONDITIONAL APPROVAL FOR CERTAIN ANTIMICROBIAL PRODUCTS

Key Takeaway: CMS proposes additional changes to the NTAP process to facilitate add-on payments for certain antimicrobial products, including accelerating access to add-on payments by allowing conditional approval for products not FDA-authorized by July 1.

Under the new technology add-on payment (NTAP) program, CMS provides additional payment for new medical services or technologies ("new technologies") in the inpatient hospital setting. Services and technologies defined as new and that meet specific cost thresholds and demonstrate substantial clinical improvement over existing services or technologies qualify for an add-on payment under this program.

With the intent to support and improve beneficiary access to new technology, the FY 2021 IPPS proposed rule includes a number of policies streamlining and facilitating access to add-on payments for certain antimicrobial products.

- **Proposed Expansion of Alternative Pathway for Certain Anti-Microbial Products:** For FY 2021, CMS created an alternative pathway to qualify for NTAP for products designated by US Food and Drug Administration (FDA) as Qualified Infectious Disease Products (QIDPs). Under the established alternative pathway, FDA-approved QIDPs only need to meet the cost criterion to receive the add-on payment (and not the newness or the substantial clinical improvement criteria). For FY 2022, CMS proposes to expand this alternative pathway to include medical products that (a) are approved through the US Food and Drug Administration (FDA) Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway) and (b) have received FDA marketing authorization for the indication covered under LPAD. If finalized, LPADs would also only need to meet the cost criterion to receive the add-on payment. This proposed change would begin with NTAP applications received for FY 2022.

- **Proposed Conditional NTAP Approval:** Currently, CMS requires a product or technology to receive FDA marketing authorization by July 1 prior to the fiscal year for which the applicant applied for NTAP in order to be considered in the final rule for NTAP approval (*e.g.,* by July 1, 2020, for FY 2021 implementation). CMS proposes to give conditional NTAP approval to QIDP and LPAD designated products that do not receive FDA marketing authorization by July 1, if the products otherwise meet the applicable add-on payment criteria. Under this proposal, QIDP and LPAD products must receive FDA marketing authorization or approval by July 1 of the fiscal year for which the applicant applied for add-on payments (*e.g.,* by July 2022 for FY 2022 implementation). For products receiving conditional NTAP approval, add-on payments would begin with discharges in the quarter following FDA market authorization of approval.

- **Proposed Calculation of NTAP:** Currently, NTAP payments are set equal to 65 percent of the estimated costs of the inpatient case in excess of the full diagnosis-related group payment, up to a maximum of 65 percent of the costs of the technology. For antimicrobial products approved for NTAP through the alternative pathway, the NTAP payment percentage is 75 percent. This payment percentage would also apply to LPADs, if the alternative pathway is expanded. CMS is not proposing any further changes to the add-on payment for FY 2021.

NTAP APPLICATIONS FOR FY 2021

In this proposed rule, CMS presents 23 FY 2021 NTAP applications. Of these, 14 new applications are through the traditional pathway and 9 applications are through established alternative pathways (3 devices with break-through status and 6 products designed as QIDP). CMS also proposes to continue for FY 2021 add-on payments for 10 of the 18 technologies currently eligible (the remaining eight technologies no longer qualify as new).

MS-DRG Changes

NEW MS-DRG FOR CAR-T CELL THERAPY

Key Takeaway: CMS proposes new MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy).

In response to multiple stakeholder requests for a new MS-DRG for procedures involving chimeric antigen receptor T-cell immunotherapies (CAR-T) and given the additional claims data now available on these procedures, CMS proposes to create the MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy). Any cases reporting the existing CAR-T ICD-10-PCS procedure codes (XW033C3 or XW043C3) would be assigned to this MS-DRG. If CMS approves and finalizes additional procedure codes describing CAR-T cell therapies, CMS will use its established process to assign these procedure codes to the most appropriate MS-DRG. As these CAR-T cases would no longer be assigned to MS-DRG 016, CMS proposes to revise the title for MS-DRG 016 from “Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy” to “Autologous Bone Marrow Transplant with CC/MCC”.

CMS is proposing to discontinue the NTAPs for two CAR-T products – Yescarta and Kymriah.

MS-DRG RECLASSIFICATION REQUEST SUBMISSION DEADLINE

Key Takeaway: CMS changes the deadline for submitting MS-DRG reclassification requests to October 20 of each year.

When deciding to make modifications to the MS-DRGs, CMS considers whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS-DRG.

CMS is changing the deadline to request changes to the MS-DRGs from November 1st of each year to October 20th of each year to allow additional time for the review and consideration of any proposed updates. Interested parties should submit any comments and suggestions for FY 2022 by October 20, 2020 via the CMS MS-DRG Classification Change Request Mailbox located at: MSDRGClassificationChange@cms.hhs.gov.

MAJOR COMPLICATION OR COMORBIDITY (MCC) OR COMPLICATION OR COMORBIDITY (CC) SUBGROUPS

Key Takeaway: CMS applies the criteria for creating a subgroup under a base MS-DRG to the non-complication or comorbidity (NonCC) subgroup.

MS-DRGs contain base DRGs that are subdivided into one, two, or three severity of illness levels. To determine if the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS-DRG is warranted, CMS evaluates the following criteria:

- A reduction in variance of costs of at least 3 percent;
- At least 5 percent of the patients in the MS-DRG fall within the CC or MCC subgroup;
- At least 500 cases are in the CC or MCC subgroup;
- There is at least a 20 percent difference in average costs between subgroups; and
- There is a $2,000 difference in average costs between subgroups.

In order to warrant creation of a CC or MCC subgroup within a base MS-DRG, the subgroup must meet all five of the criteria.

For FY2021, CMS is proposing to expand the previously listed criteria to also include the NonCC subgroup. CMS believes that applying these criteria to the NonCC subgroup would better reflect resource stratification and also promote stability in the relative weights by avoiding low volume counts for the NonCC level MS-DRGs.

The table below illustrates how the five criteria are applied to each CC subgroup, including their application to the NonCC subgroup beginning with this FY 2021 proposed rule (the order in which the criteria are displayed has been revised for illustrative purposes):

CMS first evaluates whether the creation of a new CC subgroup within a base MS-DRG is warranted by determining if all the criteria are satisfied for a three way split. If the criteria fail, the next step is to determine if the criteria are satisfied for a two way split. If the criteria for both of the two way splits fail, then a split (or CC subgroup) would generally not be warranted for that base MS-DRG.

Criteria Number	Three-Way Split 123 (MCC vs CC vs NonCC)	Two-Way Split 1_23 MCC vs (CC+NonCC)	Two-Way Split 12_3 (MCC+CC) vs NonCC
1. At least 500 cases in the MCC/CC/NonCC group	500+ cases for MCC group; **and** 500+ cases for CC group; and 500+ cases for NonCC group	500+ cases for MCC group; **and** 500+ cases for (CC+NonCC) group	500+ cases for (MCC+CC) group; **and** 500+ cases for NonCC group
2. At least 5% of the patients are in the MCC/CC/NonCC Group	5%+ cases for MCC group; and 5%+ cases for CC group; **and** 5%+ cases for NonCC group	5%+ cases for MCC group; **and** 5%+ cases for (CC+NonCC) group	5%+ cases for (MCC+CC) group; **and** 5%+ cases for NonCC group
3. There is at least a 20% difference in average cost between subgroups	20%+ difference in average cost between MCC group and CC group; **and** 20%+ difference in average cost between CC group and NonCC group	20%+ difference in average cost between MCC group and (CC+NonCC) group	20%+ difference in average cost between (MCC+ CC) group and NonCC group
4. There is at least a $2,000 difference in average cost between subgroups	$2,000+ difference in average cost between MCC group and CC group; **and** $2,000+ difference in average cost between CC group and NonCC group	$2,000+ difference in average cost between MCC group and (CC+ NonCC) group	$2,000+ difference in average cost between (MCC+ CC) group and NonCC group
5. The R^2 of the split groups is greater than or equal to 3	$R^2 > 3.0$ for the three way split within the base MS-DRG	$R^2 > 3.0$ for the two way 1_23 split within the base MS-DRG	$R^2 > 3.0$ for the two way 12_3 split within the base MS-DRG

Wage Index

LOW WAGE INDEX HOSPITAL POLICY

Key Takeaway: CMS proposes to maintain the low wage index support policy first implemented for FY 2020. Hospitals with wage index values below 0.8420 would benefit in FY 2021.

For FY 2020, CMS implemented a policy that increased the wage index for hospitals with a wage index value below the 25th percentile. Impacted hospitals had their wage index value increased by half the difference between the otherwise applicable wage index value for that hospital and the 25th percentile wage index value across all hospitals. CMS achieved budget neutrality for this change y adjusting the standardized amount that is applied across all IPPS hospitals and indicated that this policy would be effective for at least 4 years.

For FY 2021, CMS proposes to maintain this policy. Hospitals with a wage index value below the 25th percentile will have their wage index value increased by half the difference between the final wage index for

that hospital and the 25th percentile across all hospitals. The 25th percentile for FY 2021 is estimated to be 0.8420. CMS proposes to continue to achieve budget neutrality by adjusting the standardized amount.

Hospital Inpatient Quality Programs and Initiatives

HOSPITAL STAR RATINGS

Key Takeaway: CMS declines to propose updates to the Overall Hospital Quality Star Rating on Hospital Compare despite previous indications it would.

The Hospital Star Rating system compares hospitals on a range of measures which are published on the Hospital Compare website. Stakeholders have expressed concerns about the agency's methodology, and asked the agency to suspend publication until methodological issues are resolved. CMS previously indicated that it would propose revisions to the Overall Hospital Quality Star Rating methodology based on feedback received from stakeholders and results from a technical expert panel, but CMS did not do so in this rulemaking, saying instead that the agency limited this year's rulemaking to essential policies given focus on coronavirus-related activities. CMS intends to address this area in a future rulemaking according to an agency statement accompanying release of the proposed rule.

OTHER HOSPITAL INPATIENT PROGRAMS AND INITIATIVES

CMS is presenting a limited set of proposals for the IPPS quality programs, which are summarized below.

Program	Brief Description	Proposal(s)
Hospital Readmissions Reduction Program	The Hospital Readmission Reduction Program (HRRP) reduces payments to hospitals with excess readmissions. A hospital's performance is based on six unplanned readmission measures. The annual payment reduction is capped at 3% (i.e., payment adjustment factor of 0.97).	**FY 2023 applicable period**: CMS uses a three-year data collection period referred to as an "applicable period" for HRRP measures. For FY 2023, CMS is proposing an applicable period from July 1, 2018 through June 30, 2021. To streamline this policy, CMS proposes to automatically update the applicable period annually by 1 year for all subsequent years, unless otherwise specified by the Secretary.
Hospital Value-Based Purchasing Program	The Hospital Value-Based Purchasing (VBP) Program withholds participating hospitals' Medicare payments by two percent and uses these reductions to fund incentive payments based on a hospital's performance on a set of outcome measures.	**Performance standards**: CMS assesses each hospital's performance under this program by comparing its Achievement and Improvement scores for each applicable measure. CMS uses a threshold and a benchmark to establish performance standards that are used in scoring a hospital's performance. In this rule, CMS is providing estimated and newly established performance standards for certain measures for the FY 2023 - FY 2026 program years.

Program	Brief Description	Proposal(s)
Hospital-Acquired Condition Reduction Program	Under the Hospital-Acquired Condition (HAC) Program, hospital report on a set of measures on hospital-acquired conditions. Hospitals with scores in the worst performing quartile will be subject to a 1 percent payment reduction.	**FY 2023 applicable period**: CMS uses a 24-month data collection period referred to as an "applicable period" for the HAC program. CMS proposes that for FY 2023, the applicable period for two HAC measures (*CMS PSI 90 and CDC NHSN HAI*) will be the 24-month period beginning 1 year advanced from the previous program year's start of the applicable period. To streamline this policy, CMS proposes an automatic advance of this this 24-month period by 1 year for all subsequent years, unless otherwise specified by the Secretary. **Validation of HAC Reduction Program Measure Data**: CMS is proposing a number of technical changes to the validation process for the HAC Reduction Program to better align it with the Hospital Inpatient Quality Reporting (IQR) Program. **Digital Submissions for Medical Records Requests**: CMS is 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.
Hospital IQR Program	Under the Hospital IQR Program, hospitals are required to report data on measures in order to receive the full annual percentage increase for IPPS services that would otherwise apply.	**Data submission**: CMS is proposing to require the use of electronic file submissions via a CMS-approved secure file transmission process and will no longer allow the submission of paper copies of medical records or copies on digital portable media (e.g. flashdrive) **Electronic Clinical Quality Measures (ECQMs)**: CMS is proposing a number of technical changes related to the validation, analysis, scoring, validation and educational reviews of ECQMs.

Program	Brief Description	Proposal(s)
Medicare And Medicaid Promoting Interoperability Programs	The Medicare and Medicaid EHR Incentive Programs (now known as the Promoting Interoperability Programs) were established in 2011.	CMS includes a number of policies related to these programs in the 2021 proposed rule. The more significant policies include: • an EHR reporting period of a minimum of any continuous 90-day period in CY 2022 for new and returning participants (eligible hospitals and CAHs); • maintaining the Electronic Prescribing Objective's Query of PDMP measure as optional and worth 5 bonus points in CY 2021; • progressively increasing the number of quarters for which hospitals are required to report eCQM data, from the current requirement of one self-selected calendar quarter of data, to four calendar quarters of data, over a 3-year period; and • begin publicly reporting eCQM performance data beginning with the eCQM data reported by eligible hospitals and critical access hospitals for the reporting period in CY 2021 on the *Hospital Compare* and/or data.medicare.gov websites or successor websites
PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program	The PCHQR is a quality reporting program for PPS-exempt cancer hospitals.	**Measure refinement**: CMS is proposing to refine two existing program measures: Catheter-associated Urinary Tract infection (CAUTI) (NQF #0138) and Central Line-associated Bloodstream Infection (CLABSI) (NQF #0139). CMS is also proposing to publicly display the refined versions of the measures beginning in the fall of CY 2022.