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An Analysis and Commentary on Federal Health Care Issues
by Larry Goldberg

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Final FY 2021 Medicare IPPS and LTCH PPS Update Released

The Centers for Medicare and Medicaid Services (CMS) have released a final rule to update both the Hospital Inpatient Prospective Payment System (IPPS) and the Long-Term Care Hospital (LTCH) Prospective Payment System for fiscal year (FY) 2021.

CMS acknowledges this rule is late. It is normally due about August 1, but because of the COVID-19 pandemic CMS is waiving the normal 60-day publication date before implementation this year to 28 days. The rule will still be effective October 1, 2020.

CMS is finalizing numerous items including the following; (a) Market-Based MS-DRG Relative Weight Data Collection and Change in Methodology for Calculating MS-DRG Relative Weights (the reporting of negotiated rates); (b) MS-DRG Documentation and Coding Adjustment; (c) Changes to the New Technology Add-On Payment Policy; (d) Continuation of the Low Wage Index Hospital Policy; (e) DSH Payment Adjustment and Additional Payment for Uncompensated Care; (f) Reduction of Hospital Payments for Excess Readmissions; (g) Hospital Value-Based Purchasing (VBP) Program; (h) Hospital Inpatient Quality Reporting (IQR) Program; (i) Hospital-Acquired Condition (HAC) Reduction Program; (j) PPS-exempt Cancer Hospital Quality Reporting Program; and (k) Medicare and Medicaid Promoting Interoperability Programs.

The 2,160-page document is currently on public display at the ***Federal Register*** office and is scheduled for publication September 18. A display version is available at: https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-19637.pdf.

The IPPS tables for this FY 2021 final rule are available through the Internet on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html. Click on the link on the left side of the screen titled, "FY 2021 IPPS Final rule Home Page" or "Acute Inpatient—Files for Download."

The LTCH PPS tables are also available on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html under the list item for Regulation Number CMS-1735-F.

Comment

The Office of Management and Budget (OMB) says it received the final IPPS rule for its approval on August 3rd. OMB completed its review on September 1st.

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CMS projects this rule will apply to approximately 3,300 acute care hospitals and to approximately 363 LTCH facilities for discharges occurring on and after October 1, 2020.

CMS says the changes in this rule will result in an estimated $3.528 billion increase in FY 2021 payments. The estimated change is primarily driven by a combined $3.022 billion increase in FY 2021 operating payments, an estimated change in capital payments of approximately $0.027 billion, and an estimated increase in new technology add-on payments of $0.479 billion. (3.022+$.027+$0.479=$3,528] (Pages 2,024 and 2,144)

CMS expects LTCHs to experience a decrease in payments of approximately $40 million in FY 2021 relative to FY 2020 primarily due to the end of the statutory transition period for site neutral payment rate cases. (Page 2,145)

More and more PPS and other CMS rules are being issued without a Table of Contents. This rule does contain a table of contents. Nonetheless, the table is incomplete in that subparagraph heads have been omitted. Also, there are a number of missing/ or skipped subparagraph sections in the rule itself.

Again, there is no page numbering. When CMS refers the reader to another section, finding that section is not only difficult, but time consuming, especially when referring to an item from a prior ***Federal Register*** issue.

The following item presented below has been extremely controversial since being proposed in the FY 2021 IPPS rulemaking. CMS has made profound and major changes to the requirement in this final rule.

Market Based MS-DRG Relative Weight Methodology—The Proposed and Final Reporting of Negotiated Charges (Page 1,362)

With respect to hospitals having to report their negotiated charges, CMS is modifying its proposal significantly. CMS says; (Page 1,407)

> "After consideration of the comments received, we are finalizing our proposed market-based data collection requirement with a modification. Specifically, we are finalizing that hospitals would report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MA organization payers, by MS-DRG, for cost reporting periods ending on or after January 1, 2021.
>
> "We are **not finalizing** the proposed requirement that hospitals report on the Medicare cost report the median payer-specific negotiated charge the hospital has negotiated with all of its third-party payers, by MS-DRG.
>
> "We are also **not finalizing** the collection of the alternative data collection measure, the median negotiated reimbursement amount, as discussed in the (IPPS) proposed rule. To determine the median payer-specific negotiated charge for MA organizations for a given MS-DRG, a hospital would follow the process as outlined in the proposed rule (85 FR 32794)."

Note: For many payment issues, the rule's Addendum (beginning on page 1,877) contains much concise and extremely useful payment information. Also, the rule's regulatory impact analysis section has additional helpful information. (Page 2,022)

Finally, the first section of this analysis is based mainly on CMS' fact sheet of the rule. It provides a summary of selected items. The details in the fact sheet have not been verified.

The second section contains details from the rule, itself.

Please note that not all subjects have been discussed.

Fact Sheet Summary Information

Changes to Payment Rates under IPPS

The increase in operating payment rates for general acute care hospitals that successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program and are meaningful electronic health record (EHR) users is approximately 2.9 percent. The proposed increase was 3.1 percent. This reflects a projected hospital market basket update of 2.4 percent, down from a proposed 3.0 percent increase, reduced by a 0.0 percentage point productivity adjustment. This also reflects a + 0.5 percentage point adjustment required by legislation (for prior coding and documentation items).

Hospitals may be subject to other payment adjustments under the IPPS, including:

- Penalties for excess readmissions, which reflect an adjustment to a hospital's performance relative to other hospitals with a similar proportion of patients who are dually eligible for Medicare and full-benefit Medicaid
- Penalty (1.0 percent) for worst-performing quartile under the Hospital-Acquired Condition Reduction Program
- Upward and downward adjustments under the Hospital Value-Based Purchasing Program.

Medicare Uncompensated Care Payments

CMS distributes a prospectively determined amount of uncompensated care payments to "Medicare disproportionate share hospitals" based on their relative share of uncompensated care nationally. As required under law, this amount is equal to an estimate of 75 percent of what otherwise would have been paid as Medicare disproportionate share hospital payments, adjusted for the change in the rate of uninsured people. CMS will distribute roughly $8.3 billion in uncompensated care payments for FY 2021, a decrease of approximately $60 million from FY 2020. This estimate of total uncompensated care payments reflects CMS' Office of the Actuary's projections that incorporate the estimated impact of the COVID-19 pandemic.

For FY 2021, CMS will use a single year of data on uncompensated care costs from Worksheet S-10 of hospitals' FY 2017 cost reports to distribute these funds because CMS says it has conducted many audits of this data.

In addition, for all subsequent years, CMS is adopting a policy under which the most recent available single year of audited Worksheet S-10 data will be used to distribute uncompensated care payments for all eligible hospitals, except Puerto Rico hospitals and Indian Health Service and Tribal hospitals. CMS says it expects the Worksheet S-10 data for an increasing number of hospitals will be audited in future cost reporting years. As a result, CMS says it has confidence that the best available data in future years will be the Worksheet S-10 data for the most recent cost reporting year for which audits have been conducted.

"Fostering Innovation"

CMS has approved 14 technologies that applied for new technology add-on payments for FY 2021. This includes 2 technologies under the alternative pathway for new medical devices that are part of the FDA Breakthrough Devices Program and 5 technologies approved under the alternative pathway for products that received FDA Qualified Infectious Disease Product (QIDP) designation. Additionally, CMS has conditionally approved 1 technology designated as a QIDP that otherwise meets the alternative pathway criteria but has not yet received FDA approval.

CMS also approved 6 technologies submitted under the traditional new technology add-on payment pathway criteria.

Additionally, CMS is continuing the new technology add-on payments for 10 of the 18 technologies currently receiving add-on payments. Eight (8) technologies will no longer be within their newness period in FY 2021, which includes the Chimeric Antigen Receptor (CAR) T-cell therapies approved for the new technology add-on payment in FY 2019.

In total, 24 technologies are eligible to receive add-on payments for FY 2021.

New Technology Add-On Payment Pathway for Certain Antimicrobial Products

In light of recent information that continues to highlight the significant concerns and impacts related to antimicrobial resistance and emphasizes the continued importance this issue represents both for Medicare beneficiaries and public health overall, CMS is adopting some changes regarding new technology add-on payments for certain antimicrobials for FY 2021.

New MS-DRG for Chimeric Antigen Receptor (CAR) T-cell Therapy

CMS has created a new MS-DRG specifically for cases involving CAR T-cell therapies.

Graduate Medical Education Policy

CMS is making policy changes related to closing teaching hospitals and closing residency programs to address the needs of residents attempting to find alternative hospitals in which to complete their training and to foster seamless Medicare indirect medical education and direct graduate medical education funding.

These policy changes expand the existing definition of who is considered a displaced resident (beyond residents who are physically present at the hospital training on the day prior to or the day of hospital or program closure). CMS says these policies will provide greater flexibility for the residents to transfer while the hospital operations or residency programs were winding down, and will allow funding to be transferred for certain residents who are not physically at the closing hospital/closing program. (Page 1,311)

Hospital-Acquired Condition (HAC) Reduction Program

The HAC Reduction Program creates an incentive for hospitals to reduce the incidence of hospital-acquired conditions by requiring the Secretary to reduce payment by 1.0 percent for applicable hospitals, which are subsection (d) hospitals that rank in the worst performing quartile on select measures of hospital-acquired conditions.

CMS is finalizing 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 and update the definition of applicable period at 42 CFR 412.170.

- Refine the validation procedures for healthcare-associated infection (HAI) data beginning with the FY 2024 program year to align with the Hospital Inpatient Quality Reporting (IQR) Program. This includes 1) align the submission quarters with the Hospital IQR Program's submission quarters; 2) reduce the number of hospitals selected for validation from "up to 600" to "up to 400" beginning with the FY 2024 program year (for data beginning with calendar year 2021); and 3) require hospitals to submit electronic copies of records to the Clinical Data Abstraction Center beginning with validation for the FY 2024 program year (that is, beginning with Q1 2021 data). CMs says approximately 70 percent of hospitals already submit records electronically.

Hospital Readmissions Reduction Program (HRRP)

The Hospital Readmissions Reduction Program (HRRP) reduces payments to hospitals with excess readmissions. The program includes 6 claims-based outcomes measures. The ***21st Century Cures Act*** directs CMS to assess payment reductions based on a hospital's performance relative to other hospitals with a similar proportion of patients dually eligible for Medicare and full-benefit Medicaid. CMS is;

- Automatically adopting applicable periods (i.e., performance periods for measures used in the Program) beginning with the FY 2023 program year and all subsequent program years, and update the definition of applicable period at 42 CFR 412.152 to align with the automatic adoption requirement.

Hospital Inpatient Quality Reporting (IQR) Program

The Hospital IQR Program reduces payments to hospitals that fail to meet program requirements. CMS is finalizing proposals related to reporting and public reporting of electronic clinical quality measures (eCQMs) and the validation process. Specifically, the rule finalizes the following proposals to:

- Make changes to the hospital reporting of eCQMs, [in alignment with the Promoting Interoperability (PI) program] including:
    - Progressively increasing the number of quarters of eCQM data reported, from 1 self-selected quarter of data to 4 quarters of data over a 3-year period, by requiring hospitals to report 2 quarters of data for the CY 2021 reporting period/FY 2023 payment determination, 3 quarters of data for the CY 2022 reporting period/FY 2024 payment determination, and 4 quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination and for subsequent years.
    - Adding EHR Submitter ID as the fifth key element for file identification beginning with the CY 2021 reporting period/FY 2023 payment determination.
    - Beginning the public display of eCQM data on the Hospital Compare website (or its successor website) and/or https://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. CMS is clarifying that it plans to initially publish CY 2021 reporting period/FY 2023 payment determination eCQM data, of which there will be two quarters of data per its finalized policy on https://data.medicare.gov, or its successor website, before publishing it on Hospital Compare, or its successor website, sometime in the future.

- Make changes to the Hospital IQR Program validation process including:
    - For chart abstracted measure validation, requiring the use of electronic file submissions via a CMS-approved secure file transmission process and no longer allowing the submission of paper copies of medical records or copies on digital portable media such as CD, DVD, or flash drive.
    - Reducing the number of hospitals selected for validation from "up to 800 to up to 400 hospitals."
    - Combining the validation processes for chart-abstracted measures and eCQMs by aligning: (a) data submission quarters; (b) hospital selection; and (c) scoring processes by providing one combined validation score for the validation of chart-abstracted measures and eCQMs with the eCQM portion of the combined score weighted at zero.
    - Removing the current exclusions for eCQM validation selection.
    - Formalizing the process for conducting educational reviews for eCQM validation in alignment with current processes for providing feedback for chart-abstracted validation results.

Hospital Value-Based Purchasing (VBP) Program

The Hospital VBP Program adjusts payments to hospitals under the IPPS for inpatient services based on their performance. CMS is providing newly established performance standards for certain measures for the FY 2023, FY 2024, FY 2025, and FY 2026 program years.

PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

The PCHQR Program collects and publishes data on an announced set of quality measures. CMS is finalizing proposals to:

- Refine 2 existing National Healthcare Safety Network (NHSN) measures, Catheter-Associated Urinary Tract Infection (CAUTI) and Central Line-Associated Bloodstream Infection (CLABSI), to incorporate an updated methodology developed by the Centers for Disease Control and Prevention that uses updated HAI baseline data that is risk-adjusted to stratify results by patient location.
- Begin to publicly report the updated versions of the CLABSI and CAUTI measures in fall CY 2022.

Medicare and Medicaid Promoting Interoperability Programs

In 2011, the Medicare and Medicaid EHR Incentive Programs (now known as the Promoting Interoperability Programs) were established to encourage eligible professionals, eligible hospitals, and critical access hospitals (CAHs) to adopt, implement, upgrade, and demonstrate meaningful use of certified EHR technology (CEHRT).

CMS is finalizing changes to establish 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) attesting to CMS for the Medicare Promoting Interoperability Program. CMS is finalizing its proposal to continue the Query of Prescription Drug Monitoring Program (PDMP) measure as optional and worth 5 bonus points in CY 2021. CMS is finalizing a change to rename the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. The finalized name will read: Support Electronic Referral Loops by Receiving and Reconciling Health Information measure. Additionally, the FY 2021 IPPS/LTCH PPS final rule finalizes the following proposals to:

- Adopt the following in alignment with the Hospital IQR Program:
    - Progressively increase the number of quarters hospitals are required to report eCQM data (CY 2021 – 2 quarters of data; CY 2022 – 3 quarters of data; and CY 2023 and each subsequent year – 4 quarters of data).
    - Publicly report eCQM performance data for the first time, beginning with data reported by eligible hospitals and CAHs for the CY 2021 reporting period, on Hospital Compare and/or https://data.medicare.gov, or any successor websites.
    - Correct inadvertent technical errors in the regulation text, specifying transition factors for the incentive payments to Puerto Rico eligible hospitals.

Changes to Payment Rates under LTCH PPS

Overall, for FY 2021, CMS expects LTCH-PPS payments to decrease by approximately 1.1 percent or $40 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 2.2 percent primarily due to the annual standard Federal rate update for FY 2021 of 2.3 percent.

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 24 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.

The material that follows is a section-by-section analysis of major components from the final rule. It does not follow the organization contained in the rulemaking. Not all items are presented.

To assist readers because CMS does not provide page numbers, we have added select page numbers in red. These numbers are from the PDF version of the display copy file as posted on September 2, 2020. Items may be addressed in several different locations throughout the rule. Not all page sections are identified.

I. CHANGES TO PAYMENT RATES UNDER IPPS (Addendum Page 1,877)

Rate Update

The increase for general acute care hospitals that successfully participate in the Hospital Inpatient Quality Reporting (IQR) Program and are meaningful electronic health record (EHR) users would be 2.4 percent. This reflects a projected hospital market basket update of 2.4 percent reduced by a 0.0 percentage point multi-factor productivity (MFP) adjustment for a net increase of 2.4 percent.

Also included is a 0.5 percentage point adjustment required by Section 414 of the ***Medicare Access and CHIP Reauthorization Act of 2015*** (MARCA) for prior documentation and coding payment reductions. The 2.4 and 0.5 amounts result in an increase of 2.9 percent.

CMS displays four applicable percentage increases to the standardized amounts for FY 2021, as specified in the following table. The market basket rate of increase below does NOT include the 0.5 percent documentation and coding adjustment. (Page 1,880)

Final FY 2021 Applicable Percentage Increases for the IPPS				
	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
Market Basket Rate-of-Increase	2.4	2.4	2.4	2.4
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.6	-0.6
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-1.8	0	-1.8
MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	0.0	0.0	0.0	0.0
Applicable Percentage Increase Applied to Standardized Amount	**2.4**	**0.6**	**1.8**	**0.0**

Standardized Payment Rates

The current FY 2020 standardized payment amounts, as corrected in the October 8, 2019 ***Federal Register***, are as follows:

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 2.6 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = -0.35 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.85 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.4 Percent)	
Wage Index Greater Than 1.0000							
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,959.10	$1,837.53	$3,872.28	$1,797.23	$3,930.16	$1824.10	$3,843.34	$1,783.80
Wage Index Equal to or Less Than 1.0000							
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,593.91	$2,202.72	$3,515.10	$2,154.41	$3,567.64	$2,186.62	$3,488.83	$2,138.31

The current (FY 2020) large urban labor rate is $3,959.10 and the non-labor rate is $1,837.53 for a total of $5,796.63. The other area labor rate is $3,593.91 and the non-labor component is $2,202.72 for a total of $5,796.63.

The following table (Page 1,944) illustrates the changes from the FY 2020 national standardized amount to the final FY 2021 national standardized amount. The total FY 2020 rates for both the urban and other areas (large and other) is $5,796.63. These amounts are adjusted by the outlier, geographic and the rural demonstration reclassification factors, etc. as shown below. CMS says the result is a total labor/ non-labor amount of $6,219.54. The $6,219.54 amount is then adjusted for FY 2021 by the items listed below.

Changes from FY 2020 Standardized Amounts to the Final FY 2021 Standardized Amounts

	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 Base Rate after removing: 1. FY 2020 Geographic Reclassification Budget Neutrality (0.985447) 2. FY 2020 Operating Outlier Offset (0.949) 3. FY 2020 Rural Demonstration Budget Neutrality Factor (0.999771) 4. FY 2020 Lowest Quartile Budget Neutrality Factor ***(0.997984)**** 5. FY 2020 Transition Budget Neutrality Factor (0.998835)	If Wage Index is Greater Than 1.0000: Labor (68.3%) $4,247.95 Nonlabor (31.7%) $1,971.59 *(Combined labor and nonlabor = $6,219.54)*	If Wage Index is Greater Than 1.0000: Labor (68.3%) $4,247.95 Nonlabor (31.7%) *(Combined labor and nonlabor = $6,219.54)*	If Wage Index is Greater Than 1.0000: Labor (68.3%) $4,247.95 Nonlabor (31.7%) $1,971.59 *(Combined labor and nonlabor = $6,219.54)*	If Wage Index is Greater Than 1.0000: Labor (68.3%) $4,247.95 Nonlabor (31.7%) $1,971.59 *(Combined labor and nonlabor = $6,219.54)*
	If Wage Index is less Than or Equal to 1.0000: **Labor (62%)** **$3,856.11** **Nonlabor (38%)** **$2,363.43** *(Combined labor and nonlabor = $6,219.54)*	**If Wage Index is less Than or Equal to 1.0000:** **Labor (62%)** **$3,856.11** **Nonlabor (38%)** **$2,363.43** *(Combined labor and nonlabor = $6,219.54)*	**If Wage Index is less Than or Equal to 1.0000:** **Labor (62%)** **$3,856.11** **Nonlabor (38%)** **$2,363.43** *(Combined labor and nonlabor = $6,219.54)*	**If Wage Index is less Than or Equal to 1.0000:** **Labor (62%)** **$3,856.11** **Nonlabor (38%)** **$2,363.43** *(Combined labor and nonlabor = $6,219.54)*
FY 2021 Update Factor	**1.024**	**1.006**	**1.0180**	**1.0000**
FY 2021 MS-DRG Recalibration Budget Neutrality Factor	0.997980	0.997980	0.997980	0.997980
FY 2021 Wage Index Budget Neutrality Factor	1.000426	1.000426	1.000426	1.000426
FY 2021 Reclassification Budget Neutrality Factor	0.986583	0.986583	0.986583	0.986583
FY 2021 Rural Demonstration Budget Neutrality Factor	0.999626	0.999626	0.999626	0.999626
FY 2021 Stem Cell Acquisition Budget Neutrality Factor	0.999848	0.999848	0.999848	0.999848
FY 2021 Low Wage Index Hospital Policy Budget Neutrality Factor	0.998835	0.998835	0.998835	0.998835
FY 2021 Transition Budget Neutrality Factor	0.998015	0.998015	0.998015	0.998015
FY 2021 Operating Outlier Factor	0.949	0.949	0.949	0.949
Adjustment for FY 2021 Required under Section 414 of Pub. L. 114-10 (MACRA)	**1.005**	**1.005**	**1.005**	**1.005**
Totals	**$5,961.19**	**$5,856.40**	**$5,926.26**	**$5,821.47**

	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
National Standardized Amount for FY 2021 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (68.3/31.7)	**Labor: $4,071.49 Nonlabor: $1,889.70**	**Labor: $3,999.92 Nonlabor: $1,856.48**	**Labor: $4,047.63 Nonlabor: $1,878.63**	**Labor: $3,976.06 Nonlabor: $1,845.41**
National Standardized Amount for FY 2021 if Wage Index is Less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38)	**Labor: $3,695.94 Nonlabor: $2,265.25****	**Labor: $3,630.97 Nonlabor: $2,225.43**	**Labor: $3,674.28 Nonlabor: $2,251.98**	**Labor: $3,609.31 Nonlabor: $2,212.16**

*This amount should be 0.997984 (as published October 8, 2019 for the math to calculate. In both the proposed IPPS rule and this final rule CMS says the amount is 0.997894).
** In the above table CMS lists the full update nonlabor amount for hospitals with a wage index less than or equal to 1.0000 as $2,264.25. The correct amount should be $2,265.25.

The change between the final FY 2020 full market basket rate of increase amount of $5,796.63 and the FY 2021 amount of $5,961.19 is $164.56, or a net increase of approximately 2.8 percent.

These amounts are before other adjustments such as the hospital value-based purchasing program, the readmission program, and the hospital acquired conditions program.

Labor-Share

The labor-related portion for areas with wage indexes greater than 1.0000 would continue at 68.3 percent. Areas with wage index values equal to or less than 1.000 would remain at 62.0. (Page 1,884)

Comment (Page 2,033)

CMS says that 153 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2021 because they are identified as *not meaningful* EHR users *but do submit* quality information.

CMS says that 37 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2020 because they failed the quality data submission process or did not choose to participate, but *are meaningful* EHR users.

CMS says 30 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2021 because they are identified as *not meaningful* EHR users that *do not submit* quality data under section.

Outlier Payments (Page 1,938)

CMS is finalizing an outlier fixed-loss cost threshold for FY 2021 equal to the prospective payment rate for the MS-DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus **$29,051**. The proposed amount was $30,006. The current dollar threshold is $26,552.

Comment (Page 1,338)

In the proposed IPPS rule CMS said "our current estimate, using available FY 2019 claims data, is that actual outlier payments for FY 2019 were approximately 5.38 percent of actual total MS-DRG payments."

CMS now says, "Our current estimate, using available FY 2019 claims data, is that actual outlier payments for FY 2019 were approximately 5.43 percent of actual total MS-DRG payments. Therefore, the data indicate that, for FY 2019, the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2019."

If outlier payments are increasing, the CMS dollar threshold should increase and not decrease.

Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2021 (Page 1,965)

CMS is finalizing a FY 2021 capital rate **$466.22** for FY 2021. The proposed amount was $468.36. The current amount is $462.33 (as corrected October 8, 2019).

Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2021 (Page 1,969)

The final FY 2021 rate-of-increase percentage for updating the target amounts for the 11 cancer hospitals, 97 children's hospitals, the 6 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, 16 religious nonmedical health care institutions, and 1 extended neoplastic disease care hospitals is the estimated percentage increase in the IPPS operating market basket for FY 2021, that is 2.4 percent.

II. CHANGES TO THE HOSPITAL AREA WAGE INDEX (Page 934)

CMS will implement revised OMB delineations as described in the September 14, 2018 OMB Bulletin No. 18–04, effective October 1, 2020. CMS has already finalized this change for other PPS updates for FY 2021, and is now doing so for the IPPS.

Urban Counties that Will Become Rural under the Revised OMB Delineations

CMS' analysis shows that a total of 34 counties (and county equivalents) and 10 hospitals that were once considered part of an urban Core-Based Statistical Area (CBSA) will be considered to be located in a rural area. The areas are as follows; (Page 949)

FIPS County Code	County/County Equivalent	State	Current CBSA	Labor Market Area
01127	Walker	AL	13820	Birmingham-Hoover, AL
12045	Gulf	FL	37460	Panama City, FL
13007	Baker	GA	10500	Albany, GA
13235	Pulaski	GA	47580	Warner Robins, GA
15005	Kalawao	HI	27980	Kahului-Wailuku-Lahaina, HI
17039	De Witt	IL	14010	Bloomington, IL
17053	Ford	IL	16580	Champaign--Urbana, IL
18143	Scott	IN	31140	Louisville/Jefferson County, KY-IN
18179	Wells	IN	23060	Fort Wayne, IN
19149	Plymouth	IA	43580	Sioux City, IA-NE-SD
20095	Kingman	KS	48620	Wichita, KS
21223	Trimble	KY	31140	Louisville/Jefferson County, KY-IN
22119	Webster	LA	43340	Shreveport-Bossier City, LA
26015	Barry	MI	24340	Grand Rapids-Wyoming, MI
26159	Van Buren	MI	28020	Kalamazoo-Portage, MI
27143	Sibley	MN	33460	Minneapolis-St. Paul-Bloomington, MN-WI
28009	Benton	MS	32820	Memphis, TN-MS-AR
29119	Mc Donald	MO	22220	Fayetteville-Springdale-Rogers, AR-MO
30037	Golden Valley	MT	13740	Billings, MT
31081	Hamilton	NE	24260	Grand Island, NE
38085	Sioux	ND	13900	Bismarck, ND
40079	Le Flore	OK	22900	Fort Smith, AR-OK
45087	Union	SC	43900	Spartanburg, SC
46033	Custer	SD	39660	Rapid City, SD
47081	Hickman	TN	34980	Nashville-Davidson-Murfreesboro-Franklin, TN
48007	Aransas	TX	18580	Corpus Christi, TX
48221	Hood	TX	23104	Fort Worth-Arlington, TX
48351	Newton	TX	13140	Beaumont-Port Arthur, TX

FIPS County Code	County/County Equivalent	State	Current CBSA	Labor Market Area
48425	Somervell	TX	23104	Fort Worth-Arlington, TX
51029	Buckingham	VA	16820	Charlottesville, VA
51033	Caroline	VA	40060	Richmond, VA
51063	Floyd	VA	13980	Blacksburg-Christiansburg-Radford, VA
53013	Columbia	WA	47460	Walla Walla, WA
53051	Pend Oreille	WA	44060	Spokane-Spokane Valley, WA

With respect to determining Disproportionate Share Hospital (DSH) payments in the first year after a hospital loses urban status, the hospital will receive an adjustment to its DSH payment that equals two thirds of the difference between the urban DSH payments applicable to the hospital before its redesignation from urban to rural and the rural DSH payments applicable to the hospital subsequent to its redesignation from urban to rural. In the second year the hospital will receive an adjustment to its DSH payment that equals one third of the difference between the urban DSH payments applicable to the hospital before its redesignation and the rural DSH payments applicable to the hospital subsequent to its redesignation from urban to rural.(Page 950)

Rural Counties that Will Become Urban under the Revised OMB Delineations

CMS says that a total of 47 counties (and county equivalents) and 17 hospitals that were located in rural areas will now be located in urban areas. The following chart lists the 47 rural counties. (Page 951)

FIPS County Code	County/County Equivalent	State Name	New CBSA	Counties
01063	Greene	AL	46220	Tuscaloosa, AL
01129	Washington	AL	33660	Mobile, AL
05047	Franklin	AR	22900	Fort Smith, AR-OK
12075	Levy	FL	23540	Gainesville, FL
13259	Stewart	GA	17980	Columbus, GA-AL
13263	Talbot	GA	17980	Columbus, GA-AL
16077	Power	ID	38540	Pocatello, ID
17057	Fulton	IL	37900	Peoria, IL
17087	Johnson	IL	16060	Carbondale-Marion, IL
18047	Franklin	IN	17140	Cincinnati, OH-KY-IN
18121	Parke	IN	45460	Terre Haute, IN
18171	Warren	IN	29200	Lafayette-West Lafayette, IN
19015	Boone	IA	11180	Ames, IA
19099	Jasper	IA	19780	Des Moines-West Des Moines, IA
20061	Geary	KS	31740	Manhattan, KS
21043	Carter	KY	26580	Huntington-Ashland, WV-KY-OH
22007	Assumption	LA	12940	Baton Rouge, LA
22067	Morehouse	LA	33740	Monroe, LA

FIPS County Code	County/County Equivalent	State Name	New CBSA	Counties
25011	Franklin	MA	44140	Springfield, MA
26067	Ionia	MI	24340	Grand Rapids-Kentwood, MI
26155	Shiawassee	MI	29620	Lansing-East Lansing, MI
27075	Lake	MN	20260	Duluth, MN-WI
28031	Covington	MS	25620	Hattiesburg, MS
28051	Holmes	MS	27140	Jackson, MS
28131	Stone	MS	25060	Gulfport-Biloxi, MS
29053	Cooper	MO	17860	Columbia, MO
29089	Howard	MO	17860	Columbia, MO
30095	Stillwater	MT	13740	Billings, MT
37007	Anson	NC	16740	Charlotte--Concord-Gastonia, NC-SC
37029	Camden	NC	47260	Virginia Beach-Norfolk-Newport News, VA-NC
37077	Granville	NC	20500	Durham-Chapel Hill, NC
37085	Harnett	NC	22180	Fayetteville, NC
39123	Ottawa	OH	45780	Toledo, OH
45027	Clarendon	SC	44940	Sumter, SC
47053	Gibson	TN	27180	Jackson, TN
47161	Stewart	TN	17300	Clarksville, TN-KY
48203	Harrison	TX	30980	Longview, TX
48431	Sterling	TX	41660	San Angelo, TX
51097	King and Queen	VA	40060	Richmond, VA
51113	Madison	VA	47894	Washington-Arlington-Alexandra, DC-VA-MD-WV
51175	Southampton	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
51620	Franklin City	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
54035	Jackson	WV	16620	Charleston, WV
54065	Morgan	WV	25180	Hagerstown-Martinsburg, MD-WV
55069	Lincoln	WI	48140	Wausau-Weston, WI
72001	Adjuntas	PR	38660	Ponce, PR
72083	Las Marias	PR	32420	Mayagüez, PR

In the proposed rule, CMS also noted that due to the adoption of the revised OMB delineations, some CAHs that were previously located in rural areas may be located in urban areas. The regulations at §§ 412.103(a)(6) and 485.610(b)(5) provide affected CAHs with a two-year transition period that begins from the date the redesignation becomes effective. CMS stated that the affected CAHs must reclassify as rural during this transition period in order to retain their CAH status after the two-year transition period ends. (Page 953)

Urban Counties that Will Move to a Different Urban CBSA under the Revised OMB Delineations

In other cases, counties would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. The following chart lists the urban counties that would move from one urban CBSA to a newly proposed or modified CBSA. (Page 956)

FIPS County Code	County Name	State	Current CBSA	Current CBSA Name	New CBSA Code	Proposed CBSA Name
17031	Cook	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17043	Du Page	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17063	Grundy	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17093	Kendall	IL	16974	Chicago-Naperville-Arlington Heights, IL	20994	Elgin, IL
17111	Mc Henry	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
17197	Will	IL	16974	Chicago-Naperville-Arlington Heights, IL	16984	Chicago-Naperville-Evanston, IL
34023	Middlesex	NJ	35614	New York-Jersey City-White Plains, NY-NJ	35154	New Brunswick-Lakewood, NJ
34025	Monmouth	NJ	35614	New York-Jersey City-White Plains, NY-NJ	35154	New Brunswick-Lakewood, NJ
34029	Ocean	NJ	35614	New York-Jersey City-White Plains, NY-NJ	35154	New Brunswick-Lakewood, NJ
34035	Somerset	NJ	35084	Newark, NJ-PA	35154	New Brunswick-Lakewood, NJ
36027	Dutchess	NY	20524	Dutchess County-Putnam County, NY	39100	Poughkeepsie-Newburgh-Middletown, NY
36071	Orange	NY	35614	New York-Jersey City-White Plains, NY-NJ	39100	Poughkeepsie-Newburgh-Middletown, NY
36079	Putnam	NY	20524	Dutchess County- Putnam County, NY	35614	New York-Jersey City-White Plains, NY-NJ
47057	Grainger	TN	28940	Knoxville, TN	34100	Morristown, TN
54043	Lincoln	WV	26580	Huntington-Ashland, WV-KY-OH	16620	Charleston, WV
72055	Guanica	PR	38660	Ponce, PR	49500	Yauco, PR
72059	Guayanilla	PR	38660	Ponce, PR	49500	Yauco, PR
72111	Penuelas	PR	38660	Ponce, PR	49500	Yauco, PR
72153	Yauco	PR	38660	Ponce, PR	49500	Yauco, PR

Transition for Hospitals Negatively Impacted (Page 960)

For FY 2021, CMS will provide for a 5.0 percent cap on any decrease in a hospital's wage index from the hospital's final wage index from the prior fiscal year (FY 2020). The FY 2021 5.0 percent cap would be applied to all hospitals that have any decrease in their wage indexes, regardless of the circumstance causing the decline, so that a hospital's final wage index for FY 2021 will not be less than 95 percent of its final wage index for FY 2020.

Comment

Based on comments received, CMS says it appears that the above changes will have a major impact on New York and New Jersey hospitals.

Worksheet S-3 (Page 970)

The FY 2021 wage index values are based on the data collected from Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2017.

Occupational Mix Adjustment for FY 2021 (Page 989)

The FY 2021 occupational mix adjustment is based on the calendar year (CY) 2016 survey. The FY 2022 occupational mix adjustment will be based on a new calendar year (CY) 2019 survey.

The FY 2021 Occupational Mix Adjusted National Average Hourly Wage is **$45.23**. (Page 995)

The FY 2021 national average hourly wages for each occupational mix nursing subcategory of the occupational mix calculation are as follows;

Occupational Mix Nursing Subcategory	Average Hourly Wage
National RN	$41.63
National LPN and Surgical Technician	$24.66
National Nurse Aide, Orderly, and Attendant	$16.96
National Medical Assistant	$18.21
National Nurse Category	$34.97

Rural Floor (Page 997)

By statute, no urban hospital can have a wage index lower than the statewide rural amount. CMS estimates that 285 hospitals will receive an increase in their FY 2021 wage index due to the application of the rural floor.

State Frontier Floor for FY 2021 (Page 999)

Forty-four (44) hospitals will receive the frontier floor value of 1.0000 for their FY 2021 wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming.

The areas affected by the rural and frontier floor policies are identified in Table 2 which is available on the CMS website.

Continuation of the Low Wage Index Hospital Policy (Page 1,000)

For FY 2020, CMS finalized policies to reduce the disparity between high and low wage index hospitals by increasing the wage index values for certain hospitals with low wage index values and doing so in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals, as well as by changing the calculation of the rural floor.

CMS notes that this policy will continue in FY 2021. Based on the data for this rule, for FY 2021, the 25th percentile wage index value across all hospitals will be **0.8465**. The proposed value was 0.8420. Hospitals with a wage index lower than 0.8465 will have their wage index increased by half the difference between their index and 0.8465.

MGCRB Reclassification and Redesignation Issues for FY 2021 (Page 1,014)

At the time the proposed rule was constructed, the Medicare Geographic Classification Review Board (MGCRB) had completed its review of FY 2021 reclassification requests. Based on such reviews, there were 435 hospitals approved for wage index reclassifications starting in FY 2021. In this final rule, the MGCRB now says 392 hospitals are approved beginning in FY 2021.

Because MGCRB wage index reclassifications are effective for 3 years, for FY 2021, hospitals reclassified beginning in FY 2019 or FY 2020 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 245 hospitals approved for wage index reclassifications in FY 2019 that will continue for FY 2021, and 269 hospitals approved for wage index reclassifications in FY 2020 that will continue for FY 2021.

CMS says 895 hospitals are in a MGCRB reclassification status for FY 2021. However, the numbers above equal 906 hospitals.

Hospitals with One or Two Years of Wage Data Seeking MGCRB Reclassification (Page 1,019)

CMS is modifying the regulation at § 412.230(d)(2)(ii)(A) to clarify that a hospital may qualify for an individual wage index reclassification by the MGCRB under § 412.230 to another labor market area if the hospital only has 1 or 2 years of wage data.

Assignment Policy for Hospitals Reclassified to CBSAs where One or More Counties Move to a New or Different Urban CBSA (Page 1,021)

CMS says that hospitals with current reclassifications are encouraged to verify area wage indexes in Table 2, and confirm that the areas to which they have been reclassified for FY 2021 would continue to provide a higher wage index than their geographic area wage index.

Further, hospitals could have withdrawn or terminated their FY 2021 reclassifications by contacting the MGCRB within 45 days from the date the proposed rule.

CMS says that if CBSAs are split apart, or if counties shift from one CBSA to another under the revised OMB delineations, it must determine which reclassified area to assign to the hospital for the remainder of a hospital's 3-year reclassification period.

The final rule has 2 tables. The first (Page 1,034) lists the CBSAs where one or more counties will be relocated to a new or different urban CBSA. The second (Page 1,035) lists hospitals subject to the reclassification assignment policy.

Lugar Status Determinations (Page 1,039)

CMS is updating the CBSA labor market delineations to reflect the changes made in the September 14, 2018 OMB Bulletin 18-04. CMS is finalizing its list of rural counties containing hospitals redesignated as urban under section 1886(d)(8)(B) of the Act. The table is at page 1,046.

Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees (Page 1,049)

Table 2 includes the out-migration adjustments for the FY 2021 wage index. Table 4A consists of the following: A list of counties that will be eligible for the out-migration adjustment for FY 2021 identified by FIPS county code, the FY 2021 out-migration adjustment, and the number of years the adjustment will be in effect.

III. CHANGES TO THE MEDICARE SEVERITY DIAGNOSIS-RELATED GROUP (MS-DRG) CLASSIFICATIONS AND RELATIVE WEIGHTS (Page 49)

FY 2021 MS-DRG Documentation and Coding Adjustment (Page 50)

CMS is finalizing its proposal to implement a 0.5 percentage point adjustment to the standardized amount for FY 2021 for prior documentation and coding reductions.

Changes to Specific MS-DRG Classifications (Page 56)

Comment

This is an extensive and detailed section regarding the MS-DRGs and their coding. The section is 370 pages. The material that follows is but a guide for the items being addressed. To fully comprehend the changes requires an in-depth review.

Bone Marrow Transplants (Page 67)

CMS will redesignate MS-DRGs 014, 016, and 017 from surgical to medical MS-DRGs under the Pre-MDC category and will redesignate 8 ICD-10-PCS procedure codes from O.R. to non-O.R. procedures, affecting their current MS-DRG assignment for MS-DRGs 016 and 017 for FY 2021. CMS will maintain the current structure of MS-DRG 014 for FY 2021.

Chimeric Antigen Receptor (CAR) T-Cell Therapies (Page 74)

CMS will assign cases reporting ICD-10-PCS procedure codes XW033C3 or XW043C3 to a new MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy) and will 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".

Carotid Artery Stent Procedures (Page 83)

CMS will reassign 6 procedure codes from MS-DRGs 037, 038, and 039 to MS-DRGs 034, 035, and 036 because the 6 procedure codes are consistent with the other procedures describing dilation of a carotid artery with an intraluminal device that are currently assigned to MS–DRGs 034, 035, and 036. Additionally, CMS will add 36 ICD-10-PCS codes that are currently assigned in MDC 05 to MS-DRGs 252, 253, and 254 to the GROUPER logic for MS-DRGs 034, 035, and 036 in MDC 01.

Epilepsy with Neurostimulator (Page 92)

CMS will maintain the assignment of cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS© neurostimulator) in MS-DRG 023 in MDC 01.

Temporomandibular Joint Replacements (Page 102)

CMS is creating two new base MS-DRGs, 140 and 143, with a three-way severity level split for new MS-DRGs 140, 141, and 142 and new MS-DRGs 143, 144, and 145. CMS will delete MS-DRGs 129, 130, 131, 132, 133, and 134.

CMS refers readers to Tables 6P.2a, 6P.2b, and 6P.2c for the finalized list of procedure codes that define the logic for the finalized MS-DRGs.

Left Atrial Appendage Closure (LAAC) (Page 124)

CMS will reassign ICD-10-PCS procedure codes 02L70CK, 02L70DK, and 02L70ZK from MS-DRGs 250 and 251 to MS-DRGs 273 and 274, and is finalizing a revision to the titles for MS-DRG 273 and 274 to Percutaneous and Other Intracardiac Procedures with and without MCC, respectively.

Endovascular Cardiac Valve Replacement and Supplement Procedures (Page 142)

CMS will maintain the structure of MS-DRGs 266 and 277.

Insertion of Cardiac Contractility Modulation Device (Page 147)

CMS will add 24 ICD-10-PCS code combinations to MS-DRGs 222, 223, 224, 225, 226 and 227. CMS is also finalizing its proposal to delete 12 clinically invalid code combinations from the GROUPER logic of MS-DRGs 222, 223, 224, 225, 226 and 227 that describe the insertion of contractility modulation device and the insertion of a cardiac lead into the left ventricle under the ICD-10 MS-DRGs Version 38, effective October 1, 2020.

Acute Appendicitis (Page 154)

CMS is not finalizing its proposal to reassign diagnosis code K35.32 (Acute appendicitis with perforation and localized peritonitis, without abscess) to MS-DRGs 341, 342, and 343; and CMS is not finalizing its proposal to remove diagnosis code K35.32 from the complicated principal diagnosis list in MS-DRGs 338, 339, and 340.

Cervical Radiculopathy (Page 164)

CMS is maintaining the current assignment of diagnosis codes M54.11, M54.12, and M54.13 describing cervical radiculopathy in MDC 01.

Hip and Knee Joint Replacements (Page 171)

CMS is finalizing its proposal to create MS-DRGs 521 and 522 (Hip Replacement with Principal Diagnosis of Hip Fracture with and without MCC, respectively). CMS refers readers to table 6P.1d for the list of procedure codes describing hip replacements and table 6P.1e for the list of diagnosis codes describing hip fractures.

Kidney Transplants (Page 197)

CMS is creating new Pre-MDC MS-DRG 019 (Simultaneous Pancreas/Kidney Transplant with Hemodialysis) for cases describing the performance of hemodialysis during an admission where the patient received a simultaneous pancreas/kidney transplant. CMS is also creating a new MS-DRG 650 (Kidney Transplant with Hemodialysis with MCC) and a new MS-DRG 651 (Kidney Transplant with Hemodialysis without MCC) for cases describing the performance of hemodialysis in an admission where the patient received a kidney transplant in MDC 11. Accordingly, CMS will designate procedure codes 5A1D70Z, 5A1D80Z, and 5A1D90Z that describe hemodialysis as non-O.R. procedures affecting the MS-DRG.

Addition of Diagnoses to Other Kidney and Urinary Tract Procedures Logic (Page 217)

CMS will reassign ICD-10-CM diagnosis codes T82.41XA, T82.42XA, T82.43XA, and T82.49XA from MDC 05 in MS-DRGs 314, 315, and 316 (Other Circulatory System Diagnoses with MCC, with CC, and without CC/MCC, respectively) to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) assigned to MS-DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and

without CC/MCC, respectively) and 698, 699, and 700 (Other Kidney and Urinary Tract Diagnoses with MCC, with CC, and without CC/MCC, respectively) under the ICD-10 MS-DRGs Version 38, effective October 1, 2020.

Inferior Vena Cava Filter Procedures (Page 232)

Under the ICD-10 MS-DRGs Version 38, effective October 1, 2020, CMS 1) will change the designation of ICD-10-PCS procedure code 06H03DZ from an O.R. procedure to a non-O.R. procedure and 2) will maintain the O.R. designation of procedure codes 06H00DZ and 06H04DZ.

Horseshoe Abscess with Drainage (Page 242)

CMS is will add ICD-10-PCS procedure code 0J9B0ZZ to MDC 06 in MS-DRGs 356, 357, and 358.

Chest Wall Deformity with Supplementation (Page 245)

CMS will add ICD-10-PCS procedure codes 0WU807Z and 0WU80KZ to MDC 08 in MS-DRGs 515, 516, and 517.

Hepatic Malignancy with Hepatic Artery Embolization (Page 248)

CMS will add ICD-10-PCS procedure codes 04V33DZ and 04L33DZ to MDC 07 in MS-DRGs 423, 424 and 425.

Hemoptysis with Percutaneous Artery Embolization (Page 251)

CMS will add ICD-10-PCS procedure codes 03LY0DZ, 03LY3DZ and 03LY4DZ to MDC 04 in MS-DRGs 166, 167, and 168.

Acquired Coagulation Factor Deficiency with Percutaneous Artery Embolization (Page 256)

CMS will maintain the assignment of ICD-10-CM diagnosis code D68.4 in MDC 16.

Epistaxis with Percutaneous Artery Embolization (Page 261)

CMS will add ICD-10-PCS procedure codes 03LM3DZ, 03LN3DZ, and 03LR3DZ to MDC 03 in new MS–DRGs 143, 144, and 145.

Revision or Removal of Synthetic Substitute in Peritoneal Cavity (Page 267)

CMS will add ICD-10-PCS procedure codes 0WWG0JZ, 0WWG4JZ, and 0WPG0JZ to MDC 01 (Diseases and Disorders of the Nervous System) in MS-DRGs 031, 032, and 033.

Revision of Totally Implantable Vascular Access Devices (Page 269)

CMS will add 9 ICD-10-PCS procedure codes describing TIVADs to the MS-DRGs describing "Other" procedures within each of MDCs 04, 06, 07, 08, 13, and 16, specifically: MDC 04 in MS-DRGs 166, 167, and 168, MDC 06 in MS-DRGs 356, 357, and 358, MDC 07 in MS-DRGs 423, 424, and 425, MDC 08 in MS-DRGs 515, 516, and 517, MDC 13 in MS-DRGs 749 and 750, and MDC 16 in MS-DRGs 802, 803, and 804.

Multiple Trauma with Internal Fixation of Joints (Page 273)

CMS will add 161 ICD-10-PCS codes shown in Table 6P.1f associated to MDC 24 in MS-DRGs 957, 958, and 959. Accordingly, cases that would be assigned to MDC 24 based on their diagnoses, that also

report one of the 161 ICD-10-PCS codes included in table 6P.1f, will group to MDC 24 in MS-DRGs 957, 958, and 959 under the ICD-10 MS-DRGs Version 38, effective October 1, 2020.

Reassignment of Procedures among MS-DRGs 981 through 983 and 987 through 989 (Page 277)

CMS will reassign ICD-10-PCS codes 0W3G3ZZ and 0W3G4ZZ from MS-DRGs 981 through 983 to 987 through 989**.**

CMS will reassign ICD-10-PCS code 0WBC0ZX from MS-DRGs 981 through 983 to 987 through 989.

CMS will change the designation of ICD-10-PCS codes 0DB90ZZ, 0DBA0ZZ and 0DBB0ZZ from non-extensive O.R. procedures to extensive O.R. procedures.

Endoscopic Revision of Feeding Devices (Page 291)

CMS will change the designation of procedure codes 0DW08UZ, 0DW68UZ, and 0DWD8UZ from O.R. procedures to non-O.R. procedures.

Percutaneous/Endoscopic Biopsy of Mediastinum (Page 292)

CMS will add procedure codes 0WBC4ZX and 0WBC3ZX as O.R. procedures assigned to MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/ MCC, respectively) in MDC 04 (Diseases and Disorders of the Respiratory System); MS–DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders); MS-DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedure with MCC, with CC, and without CC/MCC, respectively) and MS-DRGs 826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedure with MCC, with CC, and without CC/MCC, respectively) in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms); and to MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without MCC/CC, respectively). CMS is will reassign procedure codes 0WBC0ZZ, 0WBC3ZZ, and 0WBC4ZZ from MS-DRGs 163, 164, and 165 to MS-DRGs 166, 167, and 168.

Percutaneous Endoscopic Chemical Pleurodesis (Page 298)

CMS will change the designation of procedure code 3E0L4GC from non-O.R. procedure to O.R. procedure.

Percutaneous Endoscopic Excision of Stomach (Page 300)

CMS will change the designation of procedure codes 0DB64ZZ and 0DB64ZX from non-O.R procedures to O.R. procedures.

Percutaneous Endoscopic Drainage (Page 306)

CMS will change the designation of ICD-10-PCS procedure codes 0D9W4ZZ, 0D9W40Z, 0W9G4ZZ 0W9G40Z, 0F944ZZ and 0F9440Z from non-O.R. procedures to O.R. procedures.

Control of Bleeding (Page 313)

CMS will add ICD-10-PCS procedure code 0W3G0ZZ to the ICD-10 MS-DRG Version 38 Definitions Manual in Appendix E--Operating Room Procedures and Procedure Code/MS-DRG Index as an O.R. procedure.

Inspection of Penis (Page 315)

CMS will add ICD-10-PCS procedure code 0VJS0ZZ (Inspection of penis, open approach) to the FY2021 ICD-10 MS-DRG Version 38 Definitions Manual in Appendix E Operating Room Procedures and Procedure Code/MS-DRG Index as an O.R. procedure to MS-DRGs 709 (Penis Procedures with CC/MCC) and 710 (Penis Procedures without CC/MCC) in MDC 12 (Diseases and Disorders of the Male Reproductive System) for FY2021.

Changes to the MS-DRG Diagnosis Codes for FY 2021 (Page 316)

The following tables associated with this final rule reflect the finalized severity levels under Version 38 of the ICD-10 MS-DRGs for FY 2021 and are available via the internet at; https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

Table 6I. — Complete MCC List--FY 2021;
Table 6I.1—Additions to the MCC List--FY 2021;
Table 6I.2—Deletions to the MCC List--FY 2021;
Table 6J. — Complete CC List--FY 2021;
Table 6J.1—Additions to the CC List--FY 2021; and
Table 6J.2—Deletions to the CC List--FY 2021.

CMS is making available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html the following tables associated with this final rule:

Table 6A.—New Diagnosis Codes–FY 2021;
Table 6B.—New Procedure Codes–FY 2021;
Table 6C.—Invalid Diagnosis Codes–FY 2021;
Table 6E.—Revised Diagnosis Code Titles–FY 2021;
Table 6G.1.— Secondary Diagnosis Order Additions to the CC Exclusions List–FY 2021;
Table 6G.2.— Principal Diagnosis Order Additions to the CC Exclusions List–FY 2021;
Table 6H.1.— Secondary Diagnosis Order Deletions to the CC Exclusions List–FY 2021;
Table 6H.2.— Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2021;
Table 6K.— Complete List of CC Exclusions –FY 2021.14. Changes to the Medicare Code Editor (MCE)

Changes to the Medicare Code Editor (MCE) (Page 384)

Changes to Surgical Hierarchies (Page 399)

Replaced Devices Offered without Cost or with a Credit (Page 424)

The final list of MS-DRGs subject to the IPPS policy for replaced devices offered without cost or with a credit will be issued to providers in the form of a Change Request (CR).

Comment

The first 2 items listed above contain extensive changes.

IV. ADD-ON PAYMENTS FOR NEW SERVICES AND TECHNOLOGIES FOR FY 2021 (Page 445)

Beginning with discharges on or after October 1, 2019 (FY 2020), CMS finalized an increase in the new technology add-on payment percentage, as reflected at § 412.88(a)(2)(ii).

For a new technology *other than* a medical product designated by FDA as a Qualified Infectious Disease Products (QIDP), beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment.

For a new technology *that is* a medical product designated by FDA as a QIDPs, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. (Page 462)

FY 2021 Status of Technologies Approved for FY 2020 New Technology Add-On Payments (Page 469)

For FY 2020, CMS provided new technology add-on payments for 18 items. For FY 2021, 8 items will be discontinued and 10 continued as shown in the table below. (Page 507)

Summary Table of FY 2021 Status of Technology Add-on Payments (NTAP)				
Technology	**Newness Start Date**	**Continue or Discontinue NTAP for FY 2021**	**Maximum NTAP Amount for FY 2021**	**Coding Used to Identify Cases Eligible for NTAP**
KYMRIAH® and YESCARTA®	November 22, 2017	Discontinue	None	XW033C3 or XW043C3
VYXEOSTMT™	August 3, 2017	Discontinue	None	XW033B3 or XW043B3
VABOMERE™	August 29, 2017	Discontinue	None	XW033N5 or XW043N5 or National Drug Codes (NDC) 65293–0009–01 or 70842– 0120–01
remedē® System	October 6, 2017	Discontinue	None	0JH60DZ and 05H03MZ in combination with 05H33MZ or 05H43MZ
ZEMDRI™	June 25, 2018	Continue	$4,083.75	XW033G4 or XW043G4
GIAPREZ™	December 21, 2017	Discontinue	None	XW033H4 or XW043H4
Sentinel®Cerebral Protection System	June 1, 2017	Discontinue	None	X2A5312
AQUABEAM System	December 21, 2017	Discontinue	None	XV508A4
AndexXa™	May 3, 2018	Continue	$18,281.25	XW03372 or XW04372
AZEDRA®	July 30, 2018	Continue	$98,150	XW033S5 and XW043S5
CABLIVI®	February 6, 2019	Continue	$33,215	XW013W5, XW033W5 and XW043W5
ELZONRIS™	December 21, 2018	Continue	$125,448.05	XW033Q5 and XW043Q5
Balversa™	April 12, 2019	Continue	$3,563.23	XW0DXL5
ERLEADA™	February 14, 2018	Discontinue	None	XW0DXJ5
SPRAVATO™	March 5, 2019	Continue	$1,014.79	XW097M5
XOSPATA®	November 28, 2018	Continue	$7,312.50	XW0DXV5
JAKAFI™	May 24, 2019	Continue	$3,977.06	XW0DXT5
T2Bacteria® Panel	May 24, 2018	Continue	$97.50	XXE5XM5

FY 2021 Applications for New Technology Add-On Payments (Traditional Pathway) (Page 508)

CMS says it received 17 applications for new technology add-on payments for FY 2021. Two (2) applicants withdrew their applications prior to the issuance of the proposed rule. Three applicants, Accelerate Diagnostics, Inc (the applicant for Accelerate PhenoTest™ BC kit), Kite Pharma (the applicant

for KTE-X19) and Juno Therapeutics, a Bristol-Myers Squibb Company (the applicant for Liso-cel) did not meet the deadline of July 1 for FDA approval or clearance of the technology and, therefore, the technologies are not eligible for consideration for new technology add-on payments for FY 2021.

A brief discussion of the remaining "12" applications, is presented below.

- BioFire® FilmArray® Pneumonia Panel (Page 508) Not approved.
- Supersaturated Oxygen (SSO2) Therapy (DownStream® System) (Page 568) Not Approved.
- GammaTile (Page 646) Not approved.
- WavelinQ™ (4F) EndoAVF System (Page 792.) Not approved.
- Zulresso™ (Page 820) Not approved.
- ContaCT (Page 528) Approved, with a maximum new payment of $1,040 for FY 2021.
- Eluvia™ Drug-Eluting Vascular Stent System (Eluvia) (Page 602) Approved, with a maximum add-on payment of $3,646.50.
- Hemospray® Endoscopic Hemostat (Page 669) Approved, with a maximum add-on payment of $1,625.00.
- IMFINZI® (durvalumab) and TECENTRIQ® (atezolizumab) (Page 696) Approved, with a maximum add-on payment of $6,875.90.
- Soliris (Page 733) Approved, with a maximum add-on payment of $21,199.75.
- The SpineJack® System (Page 750) Approved, with a maximum add-on payment of $3,654.72.

Comment

Please note that CMS said it was explaining the results of 12 applications above. However, there are only 11 posted. The material does not start with an "a" but with a "b." Further, the listings of the applications are not in alphabetic order. The material reports on "k" (Spinejack) before "j" WavelinQ.

FY 2021 Applications for New Technology Add-On Payments (Alternative Pathways) (Page 844)

CMS received 10 applications for new technology add-on payments for FY 2021 under the alternative new technology add-on payment pathway. One applicant withdrew its application prior to the issuance of the proposed rule. Of the remaining 9 applications, 3 of the technologies received a Breakthrough Device designation from FDA and 6 have been designated as a Qualified Infectious Disease Product (QIDP) by the FDA.

Alternative Pathway for Breakthrough Devices

- BAROSTIM NEO® System (Page 845): CMS considers the beginning of the newness period to commence on August 16, 2019 which is when the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation. The maximum new technology add-on payment is $22,750.
- NanoKnife® System (Page 849): The NanoKnife® System did not receive FDA clearance or approval by July 1, 2020. Therefore, CMS is not approving.

- Optimizer System (Page 861): CMS considers the newness period to commence on October 23, 2019. The maximum new technology add-on payment is $14,950.

Alternative Pathways for Qualified Infectious Disease Products (QIDPs)

- Cefiderocol (Fetroja) (Page 865): CMS considers the beginning of the newness period to commence when the technology became commercially available on February 24, 2020. The maximum new technology add-on payment is $7,919.86.

- Contepo™ (Page 870): CMS is granting a conditional approval for CONTEPO™ for new technology add-on payments, subject to the technology receiving FDA marketing authorization by July 1, 2021. The maximum new technology add-on payment is $2,343.75.

- NUZYRA® for Injection (Page 877): Approved with a maximum new technology add-on payment of $1,552.50.

- RECARBRIO™ (Page 883): Approved with a maximum new technology add-on payment of $3,532.78.

- XENLETA (Page 889): Approved with a maximum new technology add-on payment of $1,275.75.

- ZERBAXZ® (Page 895): Approved with a maximum new technology add-on payment of $1,836.98. CMS considers the beginning of the newness period to be June 3, 2019.

Comment

The new technology material is one of the longer sections of this rule extending some 465 pages. It contains much detail about each item's technical components and its application process. It would appear more focused to manufactures than to hospitals. Hospitals need to know if new technologies are covered by Medicare. Most do not need to know the developmental issues. Such information should be placed in an appendix.

V. OTHER DECISIONS AND CHANGES TO THE IPPS FOR OPERATING SYSTEM

Changes to MS-DRGs Subject to Post-acute Care Transfer Policy and MS-DRG Special Payments Policies (§ 412.4) (Page 1,074)

CMS will add MS-DRGs 521 and 522 to the list of MS-DRGs that are subject to the post-acute care transfer policy and the MS DRG special payment methodology for transfers.

Rural Referral Centers (RRCs)—Annual Updates to Case-Mix Index and Discharge Criteria (§ 412.96) (Page 1,093)

A rural hospital with less than 275 beds may be classified as an RRC if—

- The hospital's case-mix index (CMI) is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and

- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. (The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges.)

Rural hospitals with fewer than 275 beds can qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2020. They must have a CMI value for FY 2019 that is at least--

- 1.7049; or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The CMI values by region are set forth in the following table:

Region		Case Mix Index Value
1	New England (CT, ME, MA, NH, RI, VT)	1.4447
2	Middle Atlantic (PA, NJ, NY)	1.5005
3	South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.60875
4	East North Central (IL, IN, MI, OH, WI)	1.62455
5	East South Central (AL, KY, MS, TN)	1.5577
6	West North Central (IA, KS, MN, MO, NE, ND, SD)	1.54085
7	West South Central (AR, LA, OK, TX)	1.74375
8	Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7833
9	Pacific (AK, CA, HI, OR, WA)	1.6913

A hospital must also have the number of discharges for its cost reporting period that began during FY 2017 a figure that is at least—

- 5,000 (3,000 for an osteopathic hospital); or
- The median number of discharges for urban hospitals in the census region in which the hospital is located.

All census regional discharge numbers are greater than 5,000.

Payment Adjustment for Low-Volume Hospitals (§ 412.101) (Page 1,100)

Section 50204 of the ***Bipartisan Budget Act of 2018*** amended section 1886(d)(12) of the Act to provide for certain temporary changes to the low-volume hospital payment adjustment policy for FYs 2018 through 2022.

The proposed deadline of September 1, 2020 for receipt of a hospital's written request to its MAC in order for the low-volume hospital payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2020, is being modified. CMS is establishing that a hospital's written request must be received by its MAC no later than September 15, 2020. Hospitals approved for FY 2020 do not need to reapply as long as their status hasn't changed.

Qualifying hospitals with 500 or fewer total discharges will receive a low-volume hospital payment adjustment of 25 percent. For qualifying hospitals with fewer than 3,800 discharges but more than 500 discharges, the low-volume payment adjustment is calculated by subtracting from 25 percent the proportion of payments associated with the discharges in excess of 500. The low-volume hospital payment adjustment for FYs 2019 through 2022 is calculated using the following formula:

Low-Volume Hospital Payment Adjustment = 0.25 – [0.25/3300] x (number of total discharges - 500) = (95/330) - (number of total discharges/13,200).

For this purpose, CMS specified that the "number of total discharges" is determined as total discharges, which includes Medicare and non-Medicare discharges during the fiscal year, based on the hospital's most recently submitted cost report.

Indirect Medical Education (IME) Payment Adjustment Factor (§ 412.105) (Page 1,108)

No change here; the IME formula multiplier remains at 1.35. Any change requires legislation.

VI. PAYMENT ADJUSTMENTS FOR MEDICARE DISPROPORTIONATE SHARE HOSPITALS (DSHS) FOR FY 2021 (§ 412.106) (Page 1,108)

Beginning with discharges in FY 2014, hospitals that qualified for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments.

Section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the remaining estimate of 75 percent of uncompensated care payment is the product of three factors.

The 3 factors in determining the amount of such payments are as follows.

Calculation of Factor 1 for FY 2021 (Page 1,119)

The July 2020 Office of the Actuary (OACT) estimate for Medicare DSH payments for FY 2021, without regard to the application of section 1886(r)(1) of the Act, was approximately $15.171 billion. This estimate excluded Maryland hospitals participating in the Maryland All-Payer Model, hospitals participating in the Rural Community Hospital Demonstration, and SCHs paid under their hospital-specific payment rate.

Based on the July 2020 estimate, the estimate of empirically justified Medicare DSH payments for FY 2021, with the application of section 1886(r)(1) of the Act, was approximately $3.793 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2021).

Under § 412.106(g)(1)(i) of the regulations, Factor 1 is the difference between these two estimates. Therefore, in this final rule, Factor 1 for FY 2021 is **$11,378,005,107.01**, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2021 ($15,170,673,476.01 minus $ 3,792,668,369.00).

Calculation of Factor 2 for FY 2021 (Page 1,132)

The statute states that, for FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available.

The calculation of the final Factor 2 for FY 2021 using a weighted average of OACT's updated projections for CY 2020 and CY 2021 is as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2020: 10.3 percent.
- Percent of individuals without insurance for CY 2021: 10.2 percent.
- Percent of individuals without insurance for FY 2021 (0.25 times 0.103) + (0.75 times 0.102): 10.2 percent.
- 1-|((0.0102-0.14)/0.14)| = 1-0.2714 = 0.7286 (72.86 percent).

Therefore, the final Factor 2 for FY 2021 is 72.86 percent. The final FY 2021 uncompensated care amount is $ 11,378,005,107.01 * 0.7286 = **$8,290,014,520.96.**

The following shows the 75 percent yearly amounts for DSH payments.

- The FY 2014 "pool" was $9.033 billion
- The FY 2015 "pool" was $7.648 billion
- The FY 2016 "pool" was $6.406 billion
- The FY 2017 "pool" was $6.054 billion
- The FY 2018 "pool" was $6.767 billion
- The FY 2019 "pool" was $8.273 billion
- The FY 2020 "pool" is $8.351 billion
- The FY 2021 "pool" will be $8.290 billion

Calculation of Factor 3 for FY 2021 (Refer page 1,145)

Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made.

CMS will use a single year of Worksheet S–10 data from FY 2017 cost reports to calculate Factor 3 in the FY 2021 methodology for all eligible hospitals with the exception of Indian Health Service (IHS) and Tribal hospitals and Puerto Rico hospitals.

VII HOSPITAL READMISSIONS REDUCTION PROGRAM (HRRP) (Page 1,258)

The Hospital Readmissions Reduction Program currently includes six applicable conditions/procedures: acute myocardial infarction (AMI); heart failure (HF); pneumonia; elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass graft (CABG) surgery program. CMS did not propose to remove or adopt any additional measures.

This rule describes the general framework for the implementation of the Hospital Readmissions Reduction Program, including: (1) The selection of measures for the applicable conditions/procedures; (2) the measure removal factors policy; (3) the calculation of the excess readmission ratio (ERR), which is used, in part, to calculate the payment adjustment factor; (4) the calculation of the proportion of ''dually eligible'' Medicare beneficiaries which is used to stratify hospitals into peer groups and establish the peer group median ERRs; (5) the calculation of the payment adjustment factor, specifically addressing the base operating DRG payment amount, aggregate payments for excess readmissions (including calculating the peer group median ERRs), aggregate payments for all discharges, and the neutrality modifier; (6) the opportunity for hospitals to review and submit corrections using a process similar to what is currently used for posting results on Hospital Compare or its successor; (7) the extraordinary circumstances exception policy to address hospitals that experience a disaster or other extraordinary circumstance; (8) the clarification that the public reporting of ERRs will be posted on an annual basis to the Hospital Compare website or its successor as soon as is feasible following the review and corrections period; and (9) the specification that the definition of ''applicable hospital'' does not include hospitals and hospital units excluded from the IPPS, such as LTCHs, cancer hospitals, children's hospitals, IRFs, IPFs, CAHs, and hospitals in United States territories and Puerto Rico

Beginning in FY 2021, a "dual-eligible" is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in data sourced from the State MMA files for the month the beneficiary was discharged from the hospital, except for those patient beneficiaries who die in the month of discharge, who will be identified using the previous month's data sourced from the State MMA files.

For FY 2021, a hospital subject to the Hospital Readmissions Reduction Program would have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction).

CMS estimates **2,545** hospitals will be subject to a payment reduction of up to 3.0 percent. (Page 2,072)

VIII. HOSPITAL VALUE-BASED PURCHASING (VBP) PROGRAM: POLICY CHANGES (Page 1,271)

The Hospital VBP Program adjusts payments to IPPS hospitals for inpatient services based on their performance on an announced set of measures. Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. The FY 2021 program year will be 2.00 percent. CMS estimates that the total amount available for value-based incentive payments for FY 2021 will be approximately $1.9 billion.

CMS says that it did not propose to add new measures or remove current measures from the Hospital VBP Program.

CMS has displayed previously adopted measures for the FY 2023 and FY 2024 program years. (Page 1,274)

Previously established and newly established performance standards for the measures in the FY 2023 program year are set out in tables beginning on page 1,286.

IX. HOSPITAL-ACQUIRED CONDITION (HAC) REDUCTION PROGRAM (Page 1,296)

The HAC Reduction Program establishes an incentive for hospitals to reduce hospital-acquired conditions by requiring the Secretary to reduce applicable IPPS payment by 1.0 percent to all subsection (d) hospitals that rank in the worst-performing 25 percent of all eligible hospitals.

HAC Reduction Program Measures for FY 2021		
Short Name	Measure Name	NQF #
CMS PSI 90	CMS Patient Safety and Adverse Events Composite (PSI)	0531
CAUTI	CDC NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CDI	CDC NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717
CLABSI	CDC NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	CDC NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus*(MRSA) Bacteremia Outcome Measure	1716

CMS is not proposing to adopt or remove any measures. CMS says that it expects **777** hospitals will be in the Worst-Performing Quartile.

X. QUALITY DATA REPORTING REQUIREMENTS FOR SPECIFIC PROVIDERS AND SUPPLIERS (Page 1,524)

CMS did not propose to adopt any new measures. The measures set forth in the final FY 2020 rules are not changing for FY 2021

The following table summarizes the previously finalized Hospital IQR Program measure set for the FY 2022 payment determination:

Measures for the FY 2022 Payment Determination		
Short Name	**Measure Name**	NQF #
National Healthcare Safety Network Measures		
HCP	Influenza Vaccination Coverage Among Healthcare Personnel	0431
Claims-Based Patient Safety Measures		
COMP-HIP-KNEE *++	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
CMS PSI 04	CMS Death Rate among Surgical Inpatients with Serious Treatable Complications	+
Claims-Based Mortality Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke	N/A
Claims-Based Coordination of Care Measures		
READM-30-HW R	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	N/A
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
Sepsis	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
EHR-based Clinical Process of Care Measures (that is, Electronic Clinical Quality Measures (eCQMs))		
ED-2	Admit Decision Time to ED Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
Patient Experience of Care Survey Measures		
HCAHPS**	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)

* Finalized for removal from the Hospital IQR Program beginning with the FY 2023 payment determination, as discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41558 through 41559).

***In the CY 2019 OPPS/ASC PPS final rule with comment period (83 FR 59140 through 59149), CMS finalized removal of the Communication About Pain questions from the HCAHPS Survey effective with October 2019 discharges, for the FY 2021 payment determination and subsequent years.

+ Measure is no longer endorsed by the NQF, but was endorsed at time of adoption.

Section 1886(b)(3)(B)(viii)(IX)(bb) of the Act authorizes the Secretary to specify a measure that is not endorsed by the NQF as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. CMS attempted to find available measures for each of these clinical topics that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topics for the inpatient setting.

++ CMS has updated the short name for the Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure (NQF #1550) measure from Hip/Knee Complications to COMP-HIP-KNEE in order to maintain consistency with the updated Measure ID and hospital reports for the *Hospital Compare* website.

Comment

Once again, the quality material is extensive. The simple part is CMS is not changing the measures, but many changes focus on Form, Manner, Timing of Quality Data Submission, Validations and periods of time. The material extends more than 100 pages.

XI. CHANGES TO THE PAYMENT RATES FOR THE LTCH PPS FOR FY 2021 (Page 1,971)

Updates to the Payment Rates for the LTCH PPS for FY 2021

CMS is establishing an annual update to the LTCH PPS standard Federal payment rate of 2.3 percent. Thus, CMS is applying a factor of 1.023 to the FY 2020 LTCH PPS standard Federal payment rate of $42,677.64 in determining the FY 2021 LTCH PPS standard Federal payment rate.

Further, CMS is applying a permanent budget neutrality adjustment factor of 0.991249 for the cost of the elimination of the 25-percent threshold policy for FY 2021 and subsequent years after removing the temporary budget neutrality adjustment factor of 0.990737 that was applied to the LTCH PPS standard Federal payment rate for the cost of the elimination of the 25-percent threshold policy for FY 2020 (or a factor of 1.000517, calculated as 1/0.990737x 0.991249).

CMS also is applying an area wage level budget neutrality factor of 1.0016837.

The LTCH PPS standard Federal payment rate for FY 2021 is calculated as $42,677.64 x 1.000517 x 1.023 x 1.0016837 = **$43,755.34.**

The FY 2021 wage index values are presented in Table 12A (for urban areas) and Table 12B (for rural areas), available via the.

CMS is, as proposed, adopting the revised delineations announced in OMB Bulletin No. 18-04. CMS will apply a 5.0 cap to any provider whose wage index is reduced by more than 5.0 percent in FY 2021 compared to FY 2020.

CMS is adopting a total labor related share for FY 2021 of 68.1 percent (the sum of 63.7 percent for the operating cost and 4.4 percent for the labor-related share of capital-related costs). The current value is 68.0 percent.

Adjustment for High-Cost Outlier (HCO) Cases

The fixed-loss amount for HCO payments is set each year so that the estimated aggregate HCO payments for LTCH PPS standard Federal payment rate cases are 99.6875 percent of 8 percent (that is, 7.975 percent) of estimated aggregate LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

CMS is establishing a fixed-loss amount of **$27,195** for LTCH PPS standard Federal payment rate cases for FY 2021. The current amount is $26,778. It was proposed at $30,006.

High-Cost Outlier Payments for Site Neutral Payment Rate Cases

Approximately 75 percent of LTCH cases were paid the LTCH PPS standard Federal payment rate and approximately 25 percent of LTCH cases were paid the site neutral payment rate for discharges occurring in FY 2019. CMS says it continues to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2021 is the IPPS fixed-loss amount, which is $29,051.

FINAL COMMENTS

Many parts of the rule, even with much excessive history and redundancy, are fairly well written. Nonetheless, the rule appears to contain numerous errors in reporting significant items, listing wrong critical payment amounts, and discussing many sections that the agency said it wasn't making any changes and noting it received no comments. Examples of errors include 2 items in the table on page 1,944. We identified one of the items in the proposed rule, CMS did not correct the error for this final rule – the budget neutrality factor for the Lowest Quartile Budget Neutrality Factor. CMS reported the amount as 0.997894 and the correct factor should be 0.997984. Doing the math with the CMS value does not equal CMS' results. However, the results are correct as posted. Second, the non-labor amount for hospitals in wage areas with a value of 1.0000 or less is reported as $2,264.25 whereas it should be $2,265.25. The correct amount is shown in Table 1B on page 2020.

In the new technology material CMS says it is discussing 12 applications received for FY 2021 considerations. However, only 11 are presented. The material starts at "b" and there is no "a".

One can appreciate the need to carefully review the rule. But the sheer size makes this more difficult each year. Again, too much old history and redundancy are creating excessive burdens for all.

We note that CMS is increasing its referrals to readers to older ***Federal Register*** cites for additional information. While this is an excellent way to help reduce historical information. The process is burdensome.

First, the reader will not find the material if the cite is placed into a browser. The reader needs to open the ***Federal Register*** home page at: https://www.federalregister.gov/. The cite should be inserted into the "Search Federal Register Documents Since 1994" space as one item – no spaces. For example, 85 FR 32472 needs to be entered as 85FR32472. This should bring up the entire rule. Open the rule, and find and open the "pdf" file. Then you need to locate the page number. In this example, the rule begins on page 32460. The specific material for this cite is on page 32472. CMS needs to hyper-link the citations.

There are too many items that cannot be covered in this analysis. This analysis has not discussed a number of issues, in-depth, relating to eCQMs, timing reporting, validations, PPS Cancer Hospitals, LTCH hospitals quality, and other related quality items.

It's surprising that the Medicare payment pool is decreasing in the DSH area considering the increasing numbers of people without insurance resulting from the pandemic.

CMS did not update its previous analysis of statewide changes to the area wage index and, therefore, we are unable to show such as provided in previous years.

We found only 1 discussion area that contained a "Final Action" summary. CMS needs to clearly identify all final actions/ decisions throughout the rule.

TABLES (Page 2,016)

The following IPPS tables for this rule are generally available on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html Click on the link on the left side of the screen titled, "FY 2021 IPPS Final Rule Home Page" or "Acute Inpatient-Files- for Download."

Table 2.	Case-Mix Index and Wage Index Table by CCN--FY 2021
Table 3.	Wage Index Table by CBSA--FY 2021
Table 4A.	List of Counties Eligible for the Out-Migration Adjustment under Section 886(d)(13) of the Act--FY 2021

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Table 6I.	Complete MCC List--FY 2021
Table 6I.1.	Additions to the MCC List--FY 2021
Table 6I.2.	Deletions to the MCC List--FY 2021
Table 6J.	Complete CC List--FY 2021
Table 6J.1.	Additions to the CC List--FY 2021
Table 6J.2.	Deletions to the CC List--FY 2021
Table 6K.	Complete List of CC Exclusions--FY 2021
Table 6P.	ICD-10-CM and ICD-10-PCS Codes for MS-DRG Change--FY 2021 (Table 6P contains multiple tables, 6P.1a. through 6P.4a., that include the ICD-10-CM and ICD-10-PCS code lists relating specific MS-DRG changes. These tables are referred to throughout section II.D. of the preamble of final rule.)
Table 7A.	Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2019 MedPAR Update--March 2020 GROUPER Version 37 MS-DRGs
Table 7B.	Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2019 MedPAR Update--2020 GROUPER Version 38 MS-DRGs
Table 8A.	FY 2021 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)
Table 8B.	FY 2021 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals
Table 16A.	Updated Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2021
Table 18.	FY 2021 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2021 proposed rule are available on the CMS website at: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html under the list item for Regulation Number CMS-1735-P:

Table 8C.	FY 2021 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)
Table 11.	MS-LTC-DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges Occurring from October 1, 2020 through September 30, 2021
Table 12A.	LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2020 through September 30, 2021
Table 12B.	LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2020 through September 30, 2021

DRG WEIGHTS

The following table identifies those MS-DRGs with 100,000 or more discharges from the final rule's tables 5 and 7B.

LIST OF MEDICARE SEVERITY DIAGNOSIS-RELATED GROUPS (MS-DRGS) RELATIVE WEIGHTING FACTORS					
MS-DRG	MS-DRG Title	Discharges	Final FY 2021 Weights	Final FY 2020 Weights	Percentage Change
65	INTRACRANIAL HEMORRHAGE OR CEREBRAL INFARCTION W CC OR TPA IN 24 HRS	107,760	1.0182	1.0277	-0.92%
189	PULMONARY EDEMA & RESPIRATORY FAILURE	145,640	1.2248	1.2157	0.75%
190	CHRONIC OBSTRUCTIVE PULMONARY DISEASE W MCC	129,211	1.1239	1.1440	-1.76%
193	SIMPLE PNEUMONIA & PLEURISY W MCC	150,046	1.3107	1.3335	-1.71%
194	SIMPLE PNEUMONIA & PLEURISY W CC	102,529	0.8630	0.8886	-2.88%
291	HEART FAILURE & SHOCK W MCC	394,461	1.3409	1.3458	-0.36%
378	G.I. HEMORRHAGE W CC	127,177	0.9932	0.9881	0.52%
392	ESOPHAGITIS, GASTROENT & MISC DIGEST DISORDERS W/O MCC	136,972	0.7644	0.7615	0.38%
470	MAJOR JOINT REPLACEMENT OR REATTACHMENT OF LOWER EXTREMITY W/O MCC	359,626	1.8999	1.9684	-3.48%
682	Renal FAILURE W MCC	103,533	1.4702	1.4780	-0.53%
683	RENAL FAILURE W CC	126,959	0.8781	0.8973	-2.14%
690	KIDNEY & URINARY TRACT INFECTIONS W/O MCC	128,544	0.7922	0.7908	0.18%
871	SEPTICEMIA OR SEVERE SEPSIS W/O MV 96+ HOURS W MCC	609,373	1.8682	1.8564	0.64%

Most FY 2021 weights for these DRGs would be less than those in FY 2020.

These 13 MS-DRGs contain 2.6 million discharges or approximately 29 percent of the 9.1 million MS-DRG discharges. Note, many of this year's discharges are less than for FY 2020. The DRG with the third most occurring discharges – DRG 470 – will lose 3.48 percent. This is a significant change payment wise.