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Regulatory Update: CMS Proposed Rule – Fiscal Year (FY) 2020 Medicare Hospital Inpatient Prospective Payment System (IPPS) & Long Term Care Hospital (LTCH) Prospective Payment System

May 13, 2019

On Tuesday, April 23, the Centers for Medicare & Medicaid Services (CMS) issued the annual proposed rule to update the Fiscal Year (FY) 2020 Medicare payment and policies for the hospital inpatient prospective payment system (IPPS) and the long-term care hospital (LTCH) prospective payment system (PPS). Comments are due June 24, 2019, and Vizient looks forward to working with members to help inform our letter to the agency. For the purposes of this summary, content is focused primarily on inpatient acute-care hospitals and does not include provisions related to long-term care hospitals.

Background & Summary

In addition to the annual standard payment updates, CMS has also included various policy proposals that will impact hospitals and health systems. Some of these policies include proposals to address wage index disparities between high and low wage index hospitals, providing an alternative new technology add-on payment (NTAP) pathway for certain devices, and revisions to the calculation of the IPPS NTAP. CMS is also proposing several new policies regarding quality reporting by various providers, including eligible hospitals and critical access hospitals (CAHs) participating in the Medicare and Medicaid Promoting Interoperability (PI) Programs.

After accounting for inflation and other adjustments required by law, the proposed rule would increase IPPS rates by 3.2 percent in FY 2020. The chart below details factors CMS includes in their estimate.

Proposed IPPS Payment Rate Update for FY 2020

Proposed Policy	Average Impact on Payments (Rate)
Estimated market-basket update	3.2%
ACA productivity adjustment	- 0.5%
ACA market-basket cut	0
Documentation & coding cut mandated by ATRA, altered by 21st Century Cures Act	0.5%
Estimated payment rate update for FY 2020	**3.2%**

The proposed rule includes an initial market-basket update of 3.2 percent, minus 0.5 percentage points for productivity mandated by the Affordable Care Act (ACA). The ACA required an additional payment reduction each year only for FYs 2010 through 2019, meaning this will be the first year this reduction is no longer required to be applied to the overall IPPS. Additionally, CMS proposes an increase of 0.5 percentage points to partially restore cuts as a result of the American Taxpayer Relief Act (ATRA). The ACA and ATRA payment adjustments would be applied to all hospitals.

For FY 2020, depending on whether a hospital submits quality data under the rules established (referred to as a hospital that submits quality data) and is a meaningful EHR user under statute (referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount as specified in the following table.

FY 2020	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
Proposed Market Basket Rate-of-Increase	3.2	3.2	3.2	3.2
Proposed Adjustment for Failure to Submit Quality Data	0	0	-0.8	-0.8
Proposed Adjustment for Failure to be a Meaningful EHR User	0	-2.4	0	-2.4
Proposed Multi-Factor Productivity Adjustment	-0.5	-0.5	-0.5	-0.5
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.7**	**0.3**	**1.9**	**-0.5**

Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSH) for FY 2020

The ACA required changes starting in 2014 to the way disproportionate share hospital (DSH) payments are made to hospitals. Under this payment formula, hospitals receive 25 percent of the Medicare DSH funds that they would have received under the prior formula ("empirically justified"). The other 75 percent flows into a separate pool that is reduced relative to the number of uninsured and then distributed based on the proportion of total uncompensated care each Medicare DSH provides. This pool is distributed based on three factors:

- **Factor 1:** Office of the Actuary estimated of 100% of Medicare DSH payments
- **Factor 2:** Change in the percentage of uninsured
- **Factor 3:** Proportion of total uncompensated care each Medicare DSH provides

For FY 2020, the agency estimates that it will distribute $8.49 billion in DSH payments, an increase of approximately $216 million compared to FY 2019. The payments have redistributive effects, based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are projected to be eligible to receive Medicare DSH payments. The calculated payment amount is not directly tied to a hospital's number of discharges.

CMS is proposing to update their estimates of the three factors used to determine uncompensated care payments for FY 2020. CMS is proposing to continue to use the National Health Expenditure Accounts (NHEA) to calculate the number of uninsured (Factor 2), as finalized in previous IPPS/LTCH PPS rulemaking. In using NHEA data, the total amount (in the 75 percent pool) available to Medicare DSH hospitals increases – thus increasing overall Medicare DSH payments to hospitals.

Proposal to Use Audited FY 2015 Data

For the purposes of calculating Factor 3 and uncompensated care costs in FY 2019, CMS is proposing to continue to define "uncompensated care" as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29). However, unlike previous years, for FY 2020 CMS is proposing to use a single year of data on uncompensated care costs from Worksheet S-10 for FY 2015 to determine Factor 3 but is seeking public

comments on whether the agency should alternatively use a single year of Worksheet S-10 data from the FY 2017 cost reports, instead of the FY 2015 Worksheet S-10 data, to calculate Factor 3 for FY 2020.

CMS currently believes that the FY 2015 Worksheet S-10 data are the best available data to use for calculating Factor 3 for FY 2020. Accordingly, CMS is proposing to use a single year of Worksheet S-10 data from FY 2015 cost reports to calculate Factor 3 in the FY 2020 methodology. The agency notes that the proposed uncompensated care payments to hospitals whose FY 2015 Worksheet S-10 data were audited represent approximately half of the proposed total uncompensated care payments for FY 2020. For purposes of this proposed rule, CMS used the most recent available Health Care Provider Cost Report Information System (HCRIS) extract available, which is the HCRIS data updated through February 15, 2019. The agency expects to use the March 2019 update of HCRIS for the final rule.

Alternative Proposal – Consideration to Use FY 2017 Data

Although CMS is proposing to use Worksheet S-10 data from the FY 2015 cost reports, the agency notes that "some hospitals have raised concerns regarding some of the adjustments made to the FY 2015 cost reports following the audits of these reports", and is seeking feedback on whether the changes in the reporting instructions between FY 2015 and FY 2017 have provided hospitals with a better understanding on how to report uncompensated care costs and have improved consistency and accuracy in reporting. As such, the agency is also seeking feedback on whether it should consider using the data from the FY 2017 reports (versus FY 2015) to calculate Factor 3 for FY 2020. If CMS implements a final policy in which it uses Worksheet S-10 data from the FY 2017 cost reports to determine Factor 3 for FY 2020, it would also use the March 2019 update of HCRIS for the final rule. CMS is providing a table listing the Factor 3 proposed methodology, including the Factor 3 values for each hospital and the impact information on their website, under Table 18 (number 10).

In order to improve the quality of the Worksheet S-10 data generally (as well as to support the alternative policy the agency is considering), CMS is currently in the process of conducting outreach to hospitals related to potentially aberrant data reported in their FY 2017 cost reports. Although hospitals could see fluctuations in their uncompensated care costs from year to year – if a hospital sees a significant change compared to other similar hospitals, this could be an indication of potentially aberrant data. Hospitals would have the opportunity to justify their reporting fluctuations to the Medicare Administrative Contractor (MAC), and, if necessary, amend their FY 2017 cost reports. Under the alternative policy the agency is considering, if a hospital's FY 2017 cost report remains unchanged without an acceptable response or explanation from the provider, CMS would trim the data in the provider's FY 2017 cost report using data from the provider's FY 2015 cost report in order to determine Factor 3 for purposes of the final rule.

Hospitals have 60 days from the date of public display of the proposed rule (June 22, 2019) to review the table and supplemental data file – and to notify CMS in writing of any inaccuracies. Comments that are specific to the information included in the table and supplemental data file should be submitted to the CMS inbox. After the publication of the final rule, hospitals will have until August 31, 2019, to review and submit comments on the accuracy of the table and supplemental data files, and any changes to Factor 3 will be posted on the CMS website prior to October 1, 2019.

Proposed Add-On Payments for New Services and Technologies for FY 2020

CMS has established a process for identifying and ensuring proper payment for new medical services and technologies under IPPS and laid out criteria for determining if these "new technologies" are, in fact, new. For a new technology to be eligible for an additional payment three criteria must be met: 1) the technology must be new; 2) the DRG is considered to be inadequate; and 3) the technology must demonstrate a substantial clinical improvement over existing services or technologies.

CMS notes that applicants for add-on payments for new medical services or technologies for FY 2021 must submit a formal request, "including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement, along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold." Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS website. In order for interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2021, the CMS website will also post the tracking forms completed by each applicant.

Request for Information (RFI) – New Technology Add-On Payment Substantial Clinical Improvement Criterion

The third criterion for determining whether a new technology is appropriate for additional payment – the "substantial clinical improvement criterion" – is the area that CMS is considering potential revisions to and is seeking feedback on, both under the IPPS new technology add-on payment and the OPPS transitional pass-through payment for the additional costs of innovative devices. Specifically, the agency is seeking feedback on the kind of additional details and guidance that would be the most useful for the public and applicants for new technology add-on payments. Both categories of technologies under IPPS and OPPS are hereafter collectively referred to as "new technology".

Current law provides that a new technology is appropriate for additional payment "when it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries." CMS acknowledges that prior feedback has indicated that it would be helpful for the agency to provide greater guidance and clarity regarding what would substantiate the requirements on what constitutes "substantial clinical improvement" and notes that they are interested in broad feedback to help inform a foundation for potential future rulemaking. CMS is also seeking input on specific changes or clarifications to the IPPS and OPPS substantial clinical improvement criterion that the agency might consider making in the FY 2020 IPPS/LTCH PPS final rule, in order "to provide greater clarity and predictability."

CMS currently uses the following criteria to determine whether a new medical service or technology would represent a substantial clinical improvement:

1) The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;
2) The technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient; and
3) Use of the technology significantly improves clinical outcomes for a patient population as compared to currently available treatments.

CMS "considers the totality of the substantial clinical improvement claims and supporting data, as well as public comments, when evaluating this aspect of each application." CMS is seeking input on whether new or changed regulatory provisions or new or changed guidance regarding additional aspects of the substantial clinical improvement evaluation process would be helpful. Comments the agency receives in response to the list of general questions in the proposed rule (pages 722 – 724) will inform future rulemaking after the issuance of the final rule for FY 2020.

Potential Revisions to the New Technology Add-On Payment and Transitional Device Pass-through Payment Substantial Clinical Improvement Criterion for Applications Received Beginning in FY 2020 for IPPS and CY 2020 for OPPS

In addition to future possible rulemaking and further guidance based on the responses to the general questions listed, CMS is also considering adopting, in the FY 2020 IPPS/LTCH PPS final rule, potential regulatory changes (pages 725 – 730) to the substantial clinical improvement criteria for applications received beginning in FY 2020 for IPPS (i.e., for FY 2021 and subsequent new technology add-on payment) and beginning in CY 2020 for OPPS – after consideration of the comments received in response to this proposed rule. Further, CMS is seeking comments on whether any or all of these potential regulatory changes might be more appropriate as changes in guidance rather than, or in addition to, changes to existing regulations.

Proposed Alternative Inpatient New Technology Add-On Payment Pathway for Transformative New Devices

Under current statute, a medical service or technology will be considered a "new medical service or technology" if the service or technology meets criteria established by the HHS Secretary after public notice and comment. In 2001 rulemaking[1], CMS finalized the "substantial improvement" criterion to limit new technology add-on payments under the IPPS to technologies that offered clear improvements over technologies that were previously available. The previous section highlights the criteria used by CMS to determine if a new technology represents a substantial clinical improvement.

[1] September 7, 2001 final rule (66 FR 46913)

At the time in which this criterion was developed (2001), devices represented the predominant new technologies entering the market, and therefore it was developed with innovative new devices as the primary focus. However, at that same, the FDA had three expedited programs for drugs and biologicals – but none for devices. Currently, as established by the 21st Century Cures Act, the FDA now has a Breakthrough Devices Program – which was established to expedite the development of medical devices and give them priority review if they allow for more effective treatment or diagnosis of serious diseases/conditions, and meet one of the following four criteria:

1) It represents a breakthrough technology;
2) There is no approved or cleared alternative in existence;
3) It offers significant advantages over existing approved or cleared alternatives that includes the potential to reduce or eliminate the need for hospitalization, improve quality of life, facilitate patients' ability to manage their own care, or establish long term clinical efficiencies; or
4) The availability of the product would be in the best interest of the patient.

Over the years, stakeholders have argued that the processes by which products meet the standard for priority review are so similar to that of the substantial clinical improvement criteria that devices used in the inpatient setting that have been determined to eligible for expedited review and approved by the FDA should thus also be automatically considered as meeting the substantial clinical improvement criteria without any further consideration by CMS. Therefore, CMS has concluded that it is appropriate to develop an alternative pathway for transformative medical devices. In situations where a new medical device is part of the Breakthrough Devices Program and has received FDA marketing authorization (i.e., the device has received Premarket Approval (PMA), 510(k) clearance, or the granting of a De Novo classification request), CMS is proposing an alternative inpatient new technology add-on payment. The agency is proposing that, "for applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, if a medical device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization, it would be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS."

Taking into account the criteria applied under the FDA's Breakthrough Device Program, and because the technology may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization, CMS is proposing that it would not need to meet the requirements of representing an advance that substantially improves the diagnosis or treatment of Medicare beneficiaries. However, under the proposed alternative pathway, a medical device that has received FDA marketing authorization and that is part of the FDA's Breakthrough Devices Program would need to meet the cost criterion under the current statute[2] and would be considered new (i.e., the product is sufficiently different from existing products for purposes of newness). CMS is seeking feedback on how the agency should weigh the benefits versus the risks of this proposed alternative pathway. In other words, while it may assist beneficiary access to "transformative new medical devices", the agency wants to ensure it appropriately mitigates possible delayed access against any potential risks – such as adverse events or negative outcomes that may be found later.

CMS is seeking feedback on whether the newness period under the proposed alternative new technology add-on payment pathway for transformative new medical devices should be limited to be sufficient for the new device to develop to the point where a determination can be made as to whether there is substantial clinical improvement. Current statute provides for the collection of data with respect to the costs of a new medical service or technology for a period of not less than two years and not more than three years – beginning on the date on which an inpatient hospital code is issued with respect to the service or technology. The agency notes that, if in the future they do adopt such a policy, the newness period for these new devices cannot exceed three years, "regardless of whether it is approved under the current eligibility criteria, the proposed alternative pathway, or potentially first under the proposed alternative pathway, and subsequently under the current eligibility criteria later in its newness period."

Proposed Change to the Calculation of the Inpatient New Technology Add-On Payment

Current statute specifies that a new medical service or technology may be considered for a new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving the service or technology, the DRG prospective payment rate otherwise applicable is inadequate. In previous rulemaking[3],

[2] § 412.87(b)(3)
[3] May 4, 2001 proposed rule (66 FR 22695)

CMS stated that it believed limiting the additional payment to 50 percent of the additional cost of the new technology was necessary in order to appropriately balance the incentives. This limit is intended to provide hospitals an incentive for "continued cost-effective behavior". Thus, the current calculation of the new technology add-on payment is based on the cost to hospitals for the new medical service or technology.

Specifically, under current statute[4], if the costs of the discharge (determined by applying cost-to-charge-ratios or CCRs) 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) 50 percent of the costs of the new medical service or technology; or
2) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

In other words, unless the discharge qualifies for an outlier payment, the additional new technology add-on payment is limited to the full MS–DRG payment plus 50 percent of the estimated costs of the new technology or medical service. After consideration of significant stakeholder feedback which indicated that current policy did not adequately reflect the costs of new technology or support health care innovation, the agency agrees that it may be time to increase the maximum add-on amount and that the 50 percent cap may not be sufficient.

The agency acknowledges challenges in determining a precise payment percentage that would be the most appropriate between the current 50 percent and 100 percent payment, but believes that 65 percent would balance potentially misaligned incentives with continued development of new technologies. Beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs) 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.

Under this proposal, unless the discharge qualifies for an outlier payment, the additional new technology add-on payment remains limited to the full MS-DRG payment plus 65 percent of the estimated costs of the new technology or medical service.

Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In previous rulemaking, CMS initiated a request for information (RFI) regarding changes to the Medicare wage index. In response, the agency received a significant number of comments regarding wage index disparities between high and low wage index hospitals as well as concern that the current calculation of the rural floor has allowed many states to manipulate the system to achieve higher wages for many urban hospitals in their states, at the expense of other states (and hospitals therein). CMS states that its proposals for FY 2020 are made to address wage index disparities, particularly for rural hospitals, to the extent permitted under current law but that broader statutory wage index reform is needed.

Current law requires that the Secretary adjust for area differences in hospital wages by a factor that reflects the relative hospital wage level in the geographic area of that hospital compared to the national average. Hospital labor markets are based on statistical areas established by the Office of Management and Budget (OMB) and the wage index is assigned to hospitals on the basis of the labor market in which it resides. Under current law, CMS delineates hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). The wage index must be updated annually and any updates or adjustments must be budget neutral – meaning the overall, aggregate payment to hospitals cannot change.

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. Currently, CMS uses the Federal Information Processing Standard (FIPS) codes associated with counties (or county equivalent entities) to identify and crosswalk them to CBSA codes for the purposes of the hospital wage index. Given that FIPS codes continue to be maintained by the U.S. Census Bureau – CMS believes that using the latest FIPS codes allows the agency to "maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions." For FY 2020, CMS is continuing to use the FIPS county codes for purposes of crosswalking counties to CBSAs.

[4] § 412.88

The FY 2019 wage indexes were based on data from cost reporting periods beginning during FY 2015; thus, the proposed FY 2020 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2016. CMS performed an extensive review of the wage data, largely via the use of edits designed to identify aberrant data. After excluding critical access hospitals (CAHs) and hospitals with aberrant data, CMS calculated the proposed wage index using the Worksheet S-3, Parts II and III wage data of 3,221 hospitals. For FY 2020, CMS is 1) proposing to change the calculation of the Overhead Rate; 2) proposing to modify their methodology with regard to how dollar amounts, hours, and other numerical values in the unadjusted and adjusted wage index calculation are rounded; and 3) proposing a methodology for calculating the urban areas without wage data.

CMS is proposing to calculate the occupational mix adjustment factor using the same methodology that the agency has used since the FY 2012 wage index[5] and to apply the occupational mix adjustment to 100 percent of the FY 2020 wage index. Table 2 of the proposed rule contains the proposed FY 2020 occupational mix adjusted wage index, as well as the separate wage data for the campuses of multicampus hospitals.

CMS compared the proposed FY 2020 occupational mix adjusted wage indexes for each CBSA to the proposed unadjusted wage indexes for each CBSA. Applying the proposed occupational mix adjustment to the wage data resulted in the following:

Comparison of the FY 2020 Proposed Occupational Mix Adjusted Wage Indexes to the Proposed Unadjusted Wage Indexes by CBSA	
Number of Urban Areas Wage Index Increasing	233 (56.8%)
Number of Rural Areas Wage Index Increasing	23 (48.9%)
Number of Urban Areas Wage Increasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	113 (27.6%)
Number of Urban Areas Wage Index Increasing by 5 Percent or More	7 (1.7%)
Number of Rural Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	10 (21.3%)
Number of Rural Areas Wage Index Increasing by 5 Percent or More	0 (0%)
Number of Urban Areas Wage Index Decreasing	175 (42.7%)
Number of Rural Areas Wage Index Decreasing	24 (51.1%)
Number of Urban Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less Than 5 percent	80 (19.5%)
Number of Urban Areas Wage Index Decreasing by 5 Percent or More	1 (0.2%)
Number of Rural Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less than 5 Percent	7 (14.9%)
Number of Rural Areas Wage Index Decreasing by 5 Percent or More	0 (0%)
Largest Proposed Positive Impact for an Urban Area	6.39%
Largest Proposed Positive Impact for a Rural Area	3.82%
Largest Proposed Negative Impact for an Urban Area	5.90%
Largest Proposed Negative Impact for a Rural Area	1.66%
Urban Areas Unchanged by Application of the Proposed Occupational Mix Adjustment	2
Rural Areas Unchanged by Application of the Proposed Occupational Mix Adjustment	0

[5] 76 FR 51582 through 51586

These results indicate that a larger percentage of urban areas (56.8 percent) would benefit from the occupational mix adjustment than would rural areas (48.9 percent).

Proposed Application of the Rural Floor, Summary of Expired Imputed Floor Policy, and Proposed Application of the State Frontier Floor

Current law requires that the wage index of any hospital in an urban area of a state may not be less than the wage index of any hospital located in a rural area in that same state. This policy is known as the "rural floor". Based on the proposed FY 2020 wage index to calculate the rural floor without the wage data of hospitals that have reclassified as rural under current statute, CMS estimated that 166 hospitals would receive an increase in their FY 2020 proposed wage index due to the application of the rural floor. As explained in the FY 2019 IPPS/LTCH PPS final rule[6], the imputed floor under both the original methodology and the alternative methodology expired on September 30, 2018. Thus, the wage index and impact tables released in conjunction with this proposed rule do not reflect the imputed floor policy – and CMS is not applying a national budget neutrality adjustment for the imputed floor for FY 2020. However, CMS is seeking feedback on how the expiration of the imputed floor has impacted hospitals in FY 2019. CMS is not proposing any changes to the frontier floor policy for FY 2020. In this proposed rule, 45 hospitals would receive the frontier floor value of 1.0000 for their FY 2020 wage index. These hospitals are located in Montana, Nevada, North Dakota, South Dakota, and Wyoming. The areas affected by the proposed rural and frontier floor policies for the proposed FY 2020 wage index are identified in Table 2 on the CMS website.

Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

Any changes to the wage index that result from withdrawals of requests for reclassification, terminations, wage index corrections, appeals, and the Administrator's review process for FY 2020 will be incorporated into the wage index values – and published in the FY 2020 IPPS/LTCH PPS final rule. CMS notes that "these changes affect not only the wage index value for specific geographic areas, but also the wage index value that redesignated/reclassified hospitals receive; that is, whether they receive the wage index that includes the data for both the hospitals already in the area and the redesignated/reclassified hospitals. Further, the wage index value for the area from which the hospitals are redesignated/reclassified may be affected."

For FY 2021 reclassifications[7], applications are due to the Medicare Geographic Classification Review Board (MGCRB) by September 3, 2019 (the first working day of September 2019). CMS notes that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination. Applications and other information about MGCRB reclassifications can be obtained on the CMS website beginning in mid-July 2019.

Process for Requests for Wage Index Data Corrections

Hospitals have the opportunity to examine Table 2 associated with this proposed rule (available on the CMS website). Table 2 contains each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past three years, including the FY 2016 data used to construct the proposed FY 2020 wage index. The proposed hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data that were transmitted to CMS by early February 2019. The agency will post the final wage index data public use files (PUFs) in late April 2019 on the CMS website. After the release of the April 2019 wage index data PUFs, changes to the wage and occupational mix data can only be made in "very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files." If, after reviewing the April 2019 final wage index data PUFs, a hospital believes that its wage or occupational mix data are incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital will be given the opportunity to notify both its MAC and CMS regarding why the hospital believes an error exists and provide all supporting information, including relevant dates (e.g., when it first became aware of the error). The May appeals must be sent via mail and email to CMS and the MACs; the wage index timeline contains complete details. Verified corrections to the wage index data received by May 30, 2019 will be incorporated into the final FY 2020 wage index, which will be effective October 1, 2019.

Proposed Labor-Related Share for the Proposed FY 2020 Wage Index

The labor-related share is used to determine the proportion of the base payment rate to which the area wage index should be applied and includes a cost category if such costs are labor intensive and vary with the local market. For FY 2020, CMS is not proposing to make any further changes to the national average proportion of

[6] 83 FR 41376 through 41380
[7] OMB control number 0938-0573

operating costs that are attributable to wages and salaries, employee benefits, professional fees, labor-related, administrative and facilities support services, installation, maintenance, and repair services, and all other labor-related services. Thus, for FY 2020, CMS is proposing to continue to use a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2019. Tables 1A and 1B, available on the CMS website, reflect the proposed national labor-related share, which is also applicable to Puerto Rico hospitals. CMS is proposing that for FY 2020, all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000 apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, CMS is proposing to apply the wage index to a proposed labor-related share of 68.3 percent of the national standardized amount.

Proposals to Address Wage Index Disparities Between High and Low Wage Index Hospitals

In order to alleviate wage index disparities, including those resulting from the inclusion of hospitals with rural reclassifications[8] in the rural floor, CMS is proposing to increase the wage index values for certain hospitals with low wage index values, and decrease the wage index values for certain hospitals with high wage index values for budget neutrality purposes – and change the calculation of the rural floor. CMS is also proposing a transition for hospitals that may experience significant decreases in their wage index values as a result of these proposals.

Specifically, effective in FY 2020, and lasting four years, CMS is proposing to "increase the wage index for hospitals with a wage index value below the 25th percentile wage index value for a fiscal year by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals." Four years is the minimum amount of time before increases in employee compensation from a hospital's Medicare cost report could be reflected in wage index data, and CMS intends to revisit the issue of the duration of the policy in the future. CMS is proposing to use data from the FY 2016 cost reports for the FY 2020 wage index. In order to offset this increase (and retain budget neutrality), CMS proposes to decrease the wage index for hospitals with high wage index values (those above the 75th percentile). Based on the analysis of the proposed budget neutrality adjustment factor starting on page 826 of the proposed rule, CMS expects the adjustment factor to be 3.4 percent for FY 2020.

Additionally, CMS is proposing to remove urban to rural reclassifications from the calculation of the rural floor. CMS notes that the original intent of the rural floor was to correct the 'anomaly' that occurred when some urban hospitals were being paid less than the average rural hospital in their state. However, CMS notes that MedPAC has stated that they have found no support for this policy and that, in fact, it is based on the false assumption that wage rates in all urban markets are always higher than those in rural areas of that same state.

Beginning in FY 2020, the rural floor would be calculated without including the wage data of hospitals that have reclassified as rural under current statute[9]. In order to apply provisions of the current statute[10], CMS is proposing to remove urban to rural reclassifications from the calculation of "the wage index for rural areas in the State in which the county is located" as referred to in the statute. In other words, under this proposal, beginning in FY 2020, the rural floor would be calculated without including the wage data of urban hospitals that have reclassified as rural under current statute. CMS is proposing that for FY 2020, a 5 percent cap would be placed on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019. In other words, a hospital's final wage index for FY 2020 would not be less than 95 percent of its final wage index for FY 2019. CMS notes that this transition would allow the effects of these proposed policies to be phased in over 2 years (i.e., no cap would be applied the second year). The agency believes that "5 percent is a reasonable level for the cap because it would effectively mitigate any significant decreases in the wage index for FY 2020." Nonetheless, CMS is seeking comment on alternative cap levels.

Proposed Changes to MS-DRG Classifications – Chimeric Antigen Receptor (CAR) T-Cell Therapies

In this proposed rule, CMS notes that it has received a request to create a new MS-DRG for procedures involving chimeric antigen receptor (CAR) T-cell therapies to improve payment for these therapies in the inpatient setting. Currently, procedures involving CAR T-cell therapies are identified with ICD-10-PCS procedure codes XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into

[8] 42 CFR 412.103
[9] Section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103)
[10] Section 1886(d)(8)(C)(iii) of the Act

peripheral vein, percutaneous approach, new technology group 3) and XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3), which became effective October 1, 2017. Last year, CMS finalized policies to assign cases reporting these ICD-10-PCS procedure codes to Pre-MDC MS-DRG 016 for FY 2019, and to revise the title of this MS-DRG to "Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy". Also in the FY 2019 IPPS/LTCH PPS final rule[11], CMS indicated it would collect "more comprehensive clinical and cost data before considering assignment of a new MS–DRG to these therapies."

The FY 2018 Medicare Provider Analysis and Review (MedPAR) data contains some claims that include those procedure codes that identify CAR T-cell therapies, but the number of cases is limited, and the submitted costs vary widely due to differences in provider billing and charging practices. Therefore, CMS asserts that it does not have the clinical or cost data it needs to create a new MS-DRG. Further, due to the relative newness of CAR T-cell therapy and CMS' proposal to continue new technology add-on payments for FY 2020 for the two CAR T-cell therapies that currently have FDA approval (KYMRIAH™ and YESCARTA™), at this time, CMS believes it is premature to create a new MS-DRG specifically for cases involving CAR T-cell therapy for FY 2020.

Thus, for FY 2020, CMS is proposing not to modify the current MS-DRG assignment for cases reporting CAR T-cell therapies. Cases reporting ICD-10-PCS codes XW033C3 and XW043C3 would continue to be eligible to receive new technology add-on payments (NTAPs) for discharges occurring in FY 2020 if the agency's proposal to continue such payments is finalized. CMS expects that in future years it may have data to enable the potential creation of a new MS-DRG specifically for cases involving CAR T-cell therapy. That said, CMS is still seeking feedback on payment alternatives for CAR T-cell therapies and how these alternatives may impact access to care and incentives to encourage lower drug prices.

CMS is also seeking comment on "the most appropriate way to develop the relative weight if we were to finalize the creation of a new MS-DRG." CMS notes it may be possible to create a relative weight by dividing the average costs of cases that include CAR T-cell therapy by the average costs of all cases, consistent with the agency's current methodology for setting the relative weights for FY 2020 and using the same applicable data sources used for other MS-DRGs. CMS is specifically requesting feedback on whether this is the most accurate way to determine the relative weight, given claims data variation for these procedures, and also how to address clinical trial cases. While clinical trial cases are not typically excluded when determining relative weights, the absence of drug costs on clinical trial claims could have a significant impact on the relative weight. CMS notes that there is uncertainty around whether calculating a relative weight using cases for which hospitals do and do not incur drug costs would accurately reflect the overall cost of caring for patients who are not involved in clinical trials.

CMS notes an alternative approach – which would be to "develop a relative weight using an appropriate portion of the average sales price (ASP) for these drugs as an alternative way to reflect the costs involved in treating patients receiving CAR T-cell therapies." The agency is seeking feedback on this approach or other approaches for setting the relative weight if they were to finalize a new MS-DRG. CMS states that any such new MS-DRG would be established in a budget neutral manner, so that aggregate payments to hospitals are not affected.

CMS is also seeking input on whether (and by how much) to adjust payment based on the geographic areas of the hospital in which the treatment is provided. However, given the agency's understanding that geography does not impact the cost of CAR T-cell therapy, which would be an extremely high portion of the costs for the MS-DRG, CMS is seeking input on whether they should not geographically adjust the payment for cases assigned to any potential new MS-DRG for CAR-T cell therapy procedures. Rather, CMS is seeking input on if they should "instead apply the geographic adjustment to a lower proportion of payments under any potential new MS-DRG and, if so, how that lower proportion should be determined." The agency notes that "while the prices of other drugs may also not vary significantly among geographic areas, generally speaking, those other drugs would not have estimated costs as high as those of CAR T-cell therapies, nor would they represent as significant a percentage of the average costs for the case."

Additionally, CMS is requesting input on whether indirect medical education and disproportionate share hospital payments should potentially not be made for cases assigned to any new MS-DRG for CAR T-cell therapy, given that these add-on payments could result in unreasonably high reimbursement for CAR T-cell therapy that is, in no way, related to the cost of the hospital providing care. Further, the agency is also requesting input on

[11] 83 FR 41172 through 41174

whether CMS should instead "reduce the applicable percentages used to determine these add-ons and, if so, how those lower percentages should be determined."

CMS is also requesting input on other payment alternatives for these cases, including eliminating the use of the CCR in calculating the new technology add-on payment for KYMRIAH® and YESCARTA® by making a uniform add-on payment that equals the proposed maximum add-on payment (i.e., 65 percent of the cost of the technology which would be $242,450, and/or using a higher percentage than the proposed 65 percent to calculate the maximum new technology add-on payment (NTAP) amount).

In light of the additional experience with billing and payment for cases involving CAR T-cell therapies to Medicare patients, CMS is seeking feedback on whether the agency should "consider utilizing a specific CCR for ICD-10-PCS procedure codes used to report the performance of procedures involving the use of CAR T-cell therapies." The agency provides the example of "a CCR of 1.0, when determining outlier payments, when determining the new technology add-on payments, and when determining payments to IPPS-excluded cancer hospitals for CAR T-cell therapies." CMS considered this payment alternative in last year's rulemaking.

Hospital Readmissions Reduction Program: Proposed Updates and Changes

The Hospital Readmissions Reduction Program (HRRP) requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. The 21st Century Cures Act requires comparing peer groups of hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries (dual-eligibles) in determining the extent of excess readmissions.

Currently, the payment reduction is based on a hospital's risk-adjusted readmission rate during a three year period for six applicable conditions/procedures. For FY 2020, CMS is not proposing to remove or adopt any additional measures.

CMS is not proposing any changes to the payment adjustment methodology for FY 2020 or subsequent years. For FY 2020, a hospital subject to the HRRP would have an adjustment factor that is between 1.0 (no reduction) and 0.9700 (greatest possible reduction). For FY 2020, CMS is proposing to use MedPAR data from July 1, 2015 through June 30, 2018 for the FY 2020 HRRP calculations. The three year periods from which data are collected to calculate excess readmission ratios (ERRs) and payment adjustment factors for the fiscal year are called the "applicable periods". The "applicable period" for dual-eligibles is the same as the "applicable period" that CMS uses for the HRRP. For FY 2022, CMS is proposing that the "applicable period" for the HRRP and dual-eligibles would be the three year period from July 1, 2017 through June 30, 2020.

While CMS is not removing any measures from HRRP for FY 2020, it is proposing to adopt a "measure removal factors" policy to help ensure that the HRRP measure set will help improve beneficiary outcomes while minimizing costs. Additionally, adopting measure removal factors will help align the program with other quality payment and reporting programs. In the FY 2019 IPPS/LTCH PPS final rule, CMS updated a number of its programs' considerations for removing measures from the respective programs. Specifically, the agency finalized eight measure removal factors for the Hospital Inpatient Quality Reporting (IQR) Program[12] and the Hospital Value-Based Purchasing (VBP) Program[13]. CMS believes that these removal factors are also appropriate for the HRRP – and that alignment among quality programs helps to ensure stakeholders have a clear and transparent process. Thus, CMS is proposing to adopt the same measure removal factors for the HRRP, beginning in FY 2020.

Proposed Updated Definition of "Dual-Eligible" Beginning in FY 2021

In prior rulemaking, CMS finalized the definition of dual eligible as a patient beneficiary who has full benefit status in both the Medicare and Medicaid programs files for the month the beneficiary was discharged from the hospital. CMS is proposing to update this definition for FY 2021 to account for patients who died during the month of discharge so that the definition now includes, "…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." The agency states that it was unaware that there are times when the data may underreport the number of beneficiaries with dual-eligibility status for the month in which the beneficiaries dies, making the data not fully accurate for the month in which a beneficiary dies.

[12] 83 FR 41540 through 41544
[13] 83 FR 41441 through 41446

Due to lack of subregulatory guidance to address this issue, CMS is utilizing a formal notice-and-comment rulemaking process to solicit feedback. However, CMS believes that an analogous subregulatory process for addressing non-substantive data issues such as this one could be used for similar situations in the future. This would provide flexibility to rapidly implement non-substantive updates to implement data sourcing and other minor changes when payment adjustment factor components are impacted. CMS is proposing to adopt a policy under which they would use a subregulatory process to make non-substantive changes to the payment adjustment factor components used for the HRRP. CMS would publish any non-substantive data changes in the Hospital Specific Report (HSR) User Guide annually, and would continue to use notice-and-comment rulemaking for substantive changes.

Confidential Reporting of Stratified Data for Hospital Quality Measures

Beginning as early as the spring of 2020, CMS plans to include in confidential HSR data stratified by patient dual eligible status for the six readmissions measures included in the HRRP. These data will include two disparity methodologies designed to illuminate potential disparities within individual hospitals and across hospitals nationally and will supplement the measure data currently publicly reported on the *Hospital Compare* website. The first methodology, the "Within-Hospital Disparity Method highlights differences in outcomes for dual eligible versus non-dual eligible patients within an individual hospital, while the second methodology, the Dual-Eligible Outcome Method, allows for a comparison of performance in care for dual-eligible patients across hospitals[14]."

These two disparity methods are separate from the stratified methodology used by the HRRP, and would not be used in payment adjustment factors calculations. CMS believes that providing the results of both disparity methods, along with a hospital's measure data, allows for a more meaningful comparison and assessment of quality of care for patients with social risk factors and may also help identify providers where disparities in health care may exist. Additionally, CMS believes they provide additional perspectives on health care equity. The two disparity methods and the stratified methodology used by the HRRP are part of CMS' broader effort to account for social risk factors in quality measurement and quality payment programs.

Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes

The ACA established a hospital value-based purchasing program (the Hospital VBP Program) under which value-based incentive payments are made to hospitals that meet performance standards during specific performance periods. The applicable percent for the FY 2020 program year as required by statute is 2.00 percent, or $1.9 billion in total amount available.

CMS published proxy value-based incentive payment adjustment factors in Table 16 of the proposed rule. The proxy factors are based on the Total Performance Score (TPS) from the FY 2019 program year; these performance scores are the most recently available performance scores hospitals have been given the opportunity to review and correct. CMS intends to update this table as Table 16A in the final rule (which will be available on the CMS website) to reflect changes based on the March 2019 update to the FY 2018 MedPAR file. CMS will also update the slope of the linear exchange function used to calculate those updated proxy value-based incentive payment adjustment factors. The updated proxy value-based incentive payment adjustment factors for FY 2020 will continue to be based on historic FY 2019 program year TPSs because hospitals will not have been given the opportunity to review and correct their actual TPSs for the FY 2020 program year until after the FY 2020 IPPS/LTCH PPS final rule is published. After hospitals have been given an opportunity to review and correct their actual TPSs for FY 2020, the agency will add Table 16B (which will be available on the CMS website in the fall of 2019) to display the actual value-based incentive payment adjustment factors.

CMS is not proposing to add new measures to or remove measures from the Hospital VBP Program in this proposed rule. A chart and summaries of previously adopted measures for the FY 2022 and FY 2023 program years are available in the proposed rule (on pages 960 – 962). Additionally, tables in the proposed rule summarize the baseline and performance periods previously adopted for the FY 2022 through FY 2025 program years (pages 966 – 969). CMS is not proposing any changes to these time frames. In prior rulemaking, CMS finalized a proposal to retain the equal weight of 25 percent for each of the four domains in the Hospital VBP Program for the FY 2020 program year and subsequent years for hospitals that receive a score in all domains. CMS is not proposing any changes to these domain weights in this proposed rule.

[14] 84 FR 19427

To streamline and simplify processes across hospital programs, CMS is proposing that the Hospital VBP Program will use the same data to calculate the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Healthcare-Associated Infection (HAI) measures (CDC NHSN HAI) that the HAC Reduction Program uses for purposes of calculating the measures under that program. This would begin on January 1, 2020 for CY 2020 data collection – applying to the Hospital VBP Program for the FY 2022 program year performance period. This proposed start date aligns with the effective date of the removal of the measures from the IQR Program and the date when data on those measures will begin to be reported for the Hospital-Acquired Condition (HAC) Reduction Program, "allowing for a seamless transition." CMS notes that the data used by the HAC Reduction Program will be the same data previously used by the Hospital IQR Program – and thus the agency does not expect any changes in the use of this data for the Hospital VBP Program. Additionally, CMS is proposing to use the same processes adopted by the HAC Reduction Program in the Hospital VBP Program to review and correct data for the CDC NHSN HAI measures – and will rely on HAC Reduction Program validation to ensure the accuracy of CDC NHSN HAI measure data used in the Hospital VBP Program. CMS notes that the processes for hospitals to submit, review, and correct their data for these measures are the same processes previously used by the Hospital IQR Program.

Hospital-Acquired Condition (HAC) Reduction Program: Proposed Updates and Policy Changes

The ACA established the Hospital-Acquired Condition (HAC) Reduction Program to incentivize hospitals to reduce the incidence of HACs in their institutions. Hospitals in the worst performing quartile (25 percent) would receive a one percent payment reduction. A hospital's Total HAC Score and its ranking in comparison to other hospitals in any given year will depend on several different factors. CMS is proposing to adopt the measure removal factors policy so that the HAC program would align with other quality reporting and quality payment programs and help ensure consistency in the agency's measure evaluation methodology across programs. Corresponding with what the agency is proposing for the HRRP, CMS is proposing to adopt the same measure removal factors for the HAC Reduction Program, beginning in FY 2020. In this proposed rule, CMS is not proposing to add or remove any measures.

In the FY 2019 IPPS/LTCH PPS final rule[15], for the Hospital IQR Program, as part of the Meaningful Measures Initiative, CMS "deduplicated" their Patient Safety and Adverse Events Composite (CMS PSI 90) beginning with the Hospital IQR Program's FY 2020 payment determination, and the CDC NHSN HAI measures from the Hospital IQR Program beginning in CY 2020/FY 2022 payment determination. However, the agency retained these measures in the HAC Reduction Program. Thus, CMS was required to adopt numerous HAC Reduction Program-specific CDC NHSN HAI measure policies – "including data collection, validation requirements, and scoring associated with data completeness, timeliness, and accuracy, to transition the administrative processes on which the HAC Reduction Program had historically relied on the Hospital IQR Program to support."

For FY 2020, CMS proposes to clarify policies that were finalized last year, specifically to 1) adopt a measure removal policy that aligns with those previously adopted in other quality reporting/payment programs; 2) clarify administrative policies for validation of the CDC NHSN HAI measure; 3) adopt the data collection periods for FY 2022; and 4) update regulations for the HAC reduction program to reflect those policies finalized in last year's final rule.

CMS is proposing to adopt the eight measure removal factors finalized last year for the Hospital IQR Program and the Hospital VBP Program for the HAC Reduction Program as well. These factors include:

1) Measure performance among hospitals is so high and unvarying that there can be no meaningful distinctions made or improvements in performance (topped out);
2) Measure does not align with current clinical guidelines or practice;
3) Measure can be replaced by a more broadly applicable measure or one that is more proximal in time to desired patient outcome;
4) Measure performance or improvement does not result in better outcomes;
5) Measure can be replaced by one that is more strongly associated with desired outcome;
6) Measure collecting/reporting leads to negative, unintended consequence (other than patient harm);
7) Measure is not feasibly implemented; and
8) The costs associated with the measure outweigh the benefits of its continued use.

[15] 83 FR 41547 through 41553

Additionally, CMS is not proposing any changes to the current administrative policies regarding the review and correction of claims data or chart-abstracted CDC NHSN HAI data. CMS finalized the HAC Reduction Program's processes "to reflect, to the greatest extent possible, the processes previously established under the Hospital IQR Program." However, CMS is proposing to change the number of hospitals selected under the validation targeting methodology and provides two clarifications to this validation process.

In last year's final rule[16], CMS implemented a policy to select 200 additional hospitals for targeted validation and five targeting criteria. CMS is not proposing any changes to the targeting criteria – however, they are proposing to change the number of hospitals targeted from exactly 200 hospitals to "up to 200 hospitals," The agency received feedback from some stakeholders that were concerned hospitals would be selected for validation under both the Hospital IQR Program and the HAC Reduction Program during the same reporting period – increasing the burden to those selected hospitals. Thus, CMS is also clarifying their selection process for both the random and targeted sample of hospitals subject to HAC Reduction Program validation.

CMS is proposing that the HAC Reduction Program, in conjunction with the Hospital IQR Program, will use an aggregated random sample selection methodology through which the validation team would select one pool of 400 subsection (d) hospitals for validation of chart-abstracted measures in both Programs. CMS believes the approach of randomly selecting one pool of 400 hospitals and their proposal to select up to 200 targeted hospitals will "avoid increasing provider burden because the total number of hospitals selected for validation is not increasing, nor are the measures that were subject to validation for the selected hospitals prior to deduplication." Further, the agency is not increasing the number of cases selected for validation.

CMS is not proposing any changes to the HAC Reduction Program scoring methodology, nor are they proposing any changes to policies regarding the scoring calculations review and correction period. Consistent with prior rulemaking, CMS will calculate each hospital's Total HAC Score as the equally weighted average of the hospital's measure scores. All other scoring aspects will also remain the same, including the determination of the 75th percentile Total HAC Score and the determination of the worst-performing quartile.

Weight Applied to Each Measure by Number of Measures with Measure Score for Hospitals With and Without a CMS PSI 90 Score Under Equal Measure Weights Approach

Number of CDC NHSN HAI Measures with Measure Score	Weight Applied To:	
	CMS PSI 90	Each CDC NHSN HAI Measure
0	100.0	N/A
1	50.0	50.0
2	33.3	33.3
3	25.0	25.0
4	20.0	20.0
5	16.7	16.7
Any number	N/A	100.0 (equally divided among each CDC NHSN HAI measure with measure score)

[16] 83 FR 41480

Proposed Policy Changes Related to Critical Access Hospitals (CAHs) as Nonproviders for Direct GME and IME Payment Purposes

To support the training of residents in rural and underserved areas, CMS is proposing that, "effective with portions of cost reporting periods beginning October 1, 2019, a hospital may include full-time equivalent (FTE) residents training at a CAH in its FTE count as long as it meets the nonprovider setting requirements" under current statute[17]. Under current policy, CAHs that train residents in approved residency training programs are paid 101 percent of the reasonable costs for any costs they incur associated with training residents in approved programs. The agency notes they are not proposing to change any policy with respect to CAHs incurring the costs of training residents. If finalized, CMS will work with the Health Resources and Services Administration (HRSA) and the Federal Office of Rural Health Policy to communicate the increased regulatory flexibility to CAHs – as well as existing residency programs and the options it affords for increasing rural residency training.

Hospital Inpatient Quality Reporting (IQR) Program – Proposed Updates and Policy Changes

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 authorized CMS to pay hospitals that successfully report designated quality measures a higher annual update to their payment rates. In order to receive the full payment increase, hospitals must report data on measures selected by the Secretary for each fiscal year. CMS is proposing a number of changes and new policies for the Hospital IQR Program. These include: 1) the addition of two opioid-related electronic clinical quality measures (eCQM); 2) adoption of the Hybrid Hospital-Wide All Cause Readmission (Hybrid HWR) measure; and 3) removal of the Claims-Based Hospital-Wide All-Cause Unplanned Readmission Measure.

Proposed New Measures for the Hospital IQR Program Measure Set – Opioid-Related eCQMs

CMS is proposing to add the following two opioid-related eCQMs to the Hospital IQR Program measure set, beginning with the CY 2021 reporting period/FY 2023 payment determination:

1) Safe Use of Opioids – Concurrent Prescribing eCQM (NQF #3316e); and
2) Hospital Harm – Opioid-Related Adverse Events eCQM.

CMS believes that these measures reflect stakeholder feedback regarding higher priority measurement areas and patient outcomes while also being valuable patient safety measures. Though both are designed to reduce adverse events associated with opioid use, the main focus of each measure's intent is different.

The first proposed measure, "Safe Use of Opioids – Concurrent Prescribing" is focused on the concurrent prescription of opioids and benzodiazepines at discharge to hopefully reduce preventable mortality and costs of adverse events associated with prescription opioid use. This concept is based on the *2016 CDC Guideline for Prescribing Opioids for Chronic Pain*, which recommends that clinicians should avoid prescribing opioids and benzodiazepines concurrently whenever possible. The eCQM is "a process measure that calculates the proportion of patients age 18 years and older prescribed two or more opioids or an opioid and benzodiazepine concurrently at discharge from a hospital-based encounter (inpatient or emergency department [ED], including observation stays)." A decrease in the measure score indicates an improvement in the quality of care. CMS acknowledges that there "may be some clinically appropriate situations for concurrent prescriptions of two unique opioids or an opioid and benzodiazepine." Therefore, CMS does not expect the measure rate to be zero – but rather the goal is to help systems identify and monitor patients at risk, and reduce the risk of harm to patients across the continuum of care.

The measure's cohort includes all patients aged 18 years and older who were prescribed a new or continued opioid or a benzodiazepine at discharge from a hospital-based encounter that ended during the measurement period. CMS notes that the definition of "hospital-based encounter" is aligned with that of other eCQMs in the Hospital IQR Program to reduce hospital burden. "Patients are included in the numerator if their discharge medications include two or more active opioids or an active opioid and benzodiazepine resulting in concurrent therapy at discharge from the hospital-based encounter. Patients are included in the denominator if they were discharged from a hospital-based encounter during the measurement period (which includes inpatient stays less than or equal to 120 days or ED visits, including observation stays) and their medications at discharge included a new or continued Schedule II or III opioid, or a new or continued Schedule IV benzodiazepine prescription. Patients are excluded from the denominator if they have an active diagnosis of cancer or order for palliative care

[17] 42 CFR 412.105(f)(1)(ii)(E) and 413.78(g)

during the encounter." CMS is proposing that all participating hospitals report the Safe Use of Opioids – Concurrent Prescribing eCQM (NQF #3316e) as one of the four required eCQMs beginning with the CY 2022 reporting period/FY 2024 payment determination. Additionally, CMS is proposing to adopt the Safe Use of Opioids – Concurrent Prescribing eCQM (NQF #3316e) for the PI Program beginning with the reporting period in CY 2021.

The second proposed measure, "Hospital Harm – Opioid-Related Adverse Events eCQM" was designed by CMS to reduce the rates of adverse events associated with opioid administration in the inpatient setting by utilizing the administration of naloxone as an indicator of harm.

The intent of this measure is for hospitals to track and improve their monitoring and response to patients administered opioids during hospitalization, and to avoid harm. It focuses specifically on inpatient opioid-related adverse events versus those adverse events that occur outside of the hospital but where a patient may present at an emergency department. The goal of this measure is to incentivize hospitals to closely monitor patients who receive opioids during their hospitalization to prevent respiratory depression. The measure "requires evidence of hospital opioid administration prior to the naloxone administration during the first 24 hours after hospital arrival to ensure that the harm was hospital acquired and not due to an overdose that happened outside of the hospital." Additionally, "the aim of this measure is not to identify preventability of an individual harm instance or whether each instance of harm was an error, but rather to assess the overall rate of harm within a hospital by incorporating a definition of harm that is likely to be reduced as a result of hospital best practice."

CMS is proposing that this measure would be added to the eCQM measure set from which hospitals could choose to report. For hospitals that select this measure, the measure would provide them with measurement of opioid-related adverse event rates and incentivize improved clinical workflows and monitoring when administering opioids. Currently, the Hospital IQR Program is comprised entirely of process measures; CMS notes that adoption of this measure would introduce the first outcomes measure to the eCQM measure set. If finalized, the initial reporting of this measure would only require hospitals to submit one self-selected calendar quarter of data – and hospitals could submit more than one quarter of data if they choose to do so. The agency is considering a one year measurement period for the future public reporting of this measure.

The Hospital Harm – Opioid Related Adverse Events eCQM's data source is entirely electronic health record (EHR) data, and it is designed to be calculated by the hospitals' EHRs, as well as by CMS using the patient level data. It is an outcome measure that assesses, by hospital, the proportion of patients who had an opioid-related adverse event during an admission to an acute care hospital by assessing the administration of naloxone. It includes inpatient admissions that were initiated in the emergency department (ED) or in observational status followed by a hospital admission. The measure denominator includes all patients 18 years or older discharged from an inpatient hospital admission during the measurement period. The numerator is the "number of patients who received naloxone outside of the operating room either: 1) after 24 hours from hospital arrival; or 2) during the first 24 hours after hospital arrival with evidence of hospital opioid administration prior to the naloxone administration."

CMS is not including naloxone use in the operating room – as it could be part of the sedation plan as administered by an anesthesiologist or nurse anesthetist. CMS notes that uses of naloxone for procedures outside of the operating room (e.g., bone marrow biopsy) are counted in the numerator as its use would indicate the patient was over sedated. The agency asserts that "these criteria exist to ensure patients are not considered to have experienced harm if they receive naloxone in the first 24 hours due to an opioid overdose that occurred in the community prior to hospital arrival." CMS is not requiring the "the administration of an opioid prior to naloxone after 24 hours from hospital arrival because an event occurring 24 hours after admission is most likely due to hospitals' administration of opioids." CMS notes that "by limiting the requirement of documented opioid administration to the first 24 hours of the encounter, [they] are reducing the complexity of the measure logic, and therefore, the burden of implementation for hospitals." Further, CMS states that the measure is not risk adjusted for chronic opioid use, "as most instances of opioid-related adverse events should be preventable for all patients regardless of prior exposure to opioids or chronic opioid use." However, CMS is seeking feedback on this measure's potential to "disincentivize the appropriate use of naloxone in the hospital setting or withholding opioids when they are medically necessary in patients requiring palliative care or who are at end of life out of an overabundance of caution."

Proposed Adoption of Hybrid Hospital-Wide Readmission Measure With Claims & EHR Data (NQF #2879)

In order to increase the use of electronic health record (EHR) data in quality measurement, and "in response to stakeholder feedback encouraging the use of clinical data in outcome measures", CMS developed the Hybrid Hospital-Wide Readmission (HWR) measure (NQF #2879). This measure is designed to "capture all unplanned readmissions that arise from acute clinical events requiring urgent rehospitalization within 30 days of discharge." Planned readmissions are not considered readmissions in the measure outcome, and "all unplanned readmissions are considered an outcome, regardless of cause." CMS further notes that: "For the July 1, 2016 through June 30, 2017 measurement period (the most recent data available), the readmission rate from the hospital-wide population ranged from 10.6 percent to 20.3 percent, showing a performance gap across hospitals with wide variation and an opportunity to improve quality[18]."

CMS is proposing to adopt the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data (NQF #2879) (i.e., the "Hybrid HWR measure") into the Hospital IQR Program in "a stepwise fashion." To begin, the agency would accept data submissions for the Hybrid HWR measure during two voluntary reporting periods. CMS would collect data on the Hybrid HWR measure during those periods in accordance with, and to the extent permitted by, the HIPAA Privacy and Security Rules[19] and other applicable law. CMS is proposing that the first voluntary reporting period would run from July 1, 2021 through June 30, 2022, and the second would run from July 1, 2022 through June 30, 2023. The agency is proposing to expand upon the 2018 Voluntary Reporting Period for the Hybrid HWR measure – which only collected two quarters of data – and both voluntary reporting periods would last four quarters. CMS is proposing that immediately after the voluntary reporting periods, reporting of the Hybrid HWR measure would be required. In other words, reporting would be required beginning with the reporting period which runs from July 1, 2023 through June 30, 2024, impacting the FY 2026 payment determination, and for subsequent years.

This proposal is being made in conjunction with the agency's proposal to remove the Claims Claims-Based Hospital-Wide All-Cause Unplanned Readmission Measure (NQF #1789) (HWR claims-only measure) beginning with the FY 2026 payment determination. "Both the previously finalized HWR claims-only measure and proposed Hybrid HWR measure capture the hospital-level, risk-standardized readmission rate (RSRR) of unplanned, all-cause readmissions within 30 days of hospital discharge for any eligible condition." The proposed Hybrid HWR measure "reports a single summary RSRR, derived from the volume-weighted results of five different models, one for each of the following specialty cohorts based on groups of discharge condition categories or procedure categories: 1) surgery/gynecology; 2) general medicine; 3) cardiorespiratory; 4) cardiovascular; and 5) neurology." Further, the measure also indicates the hospital-level standardized readmission ratios (SRR) for each of these five specialty cohorts.

Data sources for the Hybrid HWR measure are a combination of administrative data and core clinical data (extracted from EHRs), which is why it is referred to as a "hybrid" measure. Additionally, the Hybrid HWR measure "requires a set of linking variables which are present in both the EHR and claims data, so each patient's core clinical data elements can be matched to the claim for the relevant admission" (e.g., patient unique identifier and patient date of birth).

The administrative data consist of Medicare Part A and Part B claims data and Medicare beneficiary enrollment data, and are used to identify index admissions included in the measure cohort, to create a risk-adjustment model, and to assess the 30-day unplanned readmission outcome. The claims data are merged with EHR-based core clinical data elements, which are routinely collected on hospitalized adults, and are used in this hybrid measure for risk-adjustment of patients' severity of illness. CMS notes that an important distinguishing factor about hybrid measure results are that they must be "calculated by [the agency] to determine hospitals' risk-adjusted rates relative to national rates using data from all reporting hospitals." In other words, hospitals submit data extracted from the EHR, and CMS performs the measure calculations and disseminates results.

CMS tested the electronic specifications in four separate health systems that used three different EHR systems. CMS notes that they "demonstrated the use of the core clinical data elements to risk-adjust the Hybrid HWR measure improves the discrimination of the measure, or the ability to distinguish patients with a low risk of

[18] Centers for Medicare & Medicaid Services. (2018). *2018 All-Cause Hospital-Wide Measure Updates and Specifications Report: Hospital-Wide Readmission.* Available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

[19] 45 CFR Parts 160 and 164, Subparts A, C, and E

readmission from those at high risk of readmission, as assessed by the c-statistic[20]." Further, inclusion of patients' clinical information from EHRs is responsive to those who prefer to use clinical information available to the clinical care team at the time treatment is rendered to account for patients' severity of illness – rather than relying solely on data from claims[21]. CMS affirms that the "Hybrid HWR measure is now fully developed, tested, and NQF-endorsed (NQF #2879)."

The proposed Hybrid HWR measure adjusts both for case-mix differences (i.e., how severely ill patients are when they are admitted), as well as differences in hospitals' service-mix (i.e., the types of conditions that cause patients' admissions). "The case-mix variables include patients' ages and comorbidities as well as laboratory test results and vital signs" – specifically, the measure uses 13 core clinical data elements from EHRs – seven laboratory test results (hematocrit, white blood cell count, sodium, potassium, bicarbonate, creatinine, glucose) and six vital signs (heart rate, respiratory rate, temperature, systolic blood pressure, oxygen saturation, weight). CMS notes that the "service-mix variables include principal discharge diagnoses grouped into AHRQ Clinical Classification Software" and "patient comorbidities are based on the index admission, the admission included in the measure cohort, and a full year of prior history." The risk-adjustment variables (which were also included in the development and testing of the proposed Hybrid HWR measure) are derived from both claims and clinical EHR data and can be found on page 1147 of the proposed rule.

CMS is proposing that hospitals use Quality Reporting Data Architecture (QRDA) Category I files for each Medicare FFS beneficiary who is 65 years and older (the same as with the 2018 Voluntary Reporting Period). The agency notes that submission of data to the agency using QRDA I files is the current EHR data and measure reporting standard adopted for eCQMs implemented in the Hospital IQR Program. This would also be used for reporting the core clinical data elements to the CMS data receiving system via the QualityNet Secure Portal. To successfully submit the Hybrid HWR measure, hospitals would need to submit the core clinical data elements as described in the measure specifications, for all Medicare FFS beneficiaries 65 and older discharged from an acute care hospitalization in the 1-year measurement period (July 1 to June 30 of each year) – which is the same measurement period as the HWR claims-only measure. Additionally, "hospitals would also be required to successfully submit the following six linking variables that are necessary in order to merge the core clinical data elements with the CMS claims data to calculate the measure":

1) CMS Certification Number;
2) Health Insurance Claims Number or Medicare Beneficiary Identifier;
3) Date of birth;
4) Sex;
5) Admission date; and
6) Discharge date

Each hospital would also "need to report vital signs for 90 percent or more of the hospital discharges for Medicare Fee-for-Service (FFS) patients, 65 years or older in the measurement period (as determined from the claims submitted to CMS for admissions that ended during the same reporting period)." Hospitals would also be "required to submit the laboratory test results for 90 percent or more of discharges for non-surgical patients, meaning those not included in the surgical specialty cohort of the HWR measure." Laboratory test results are not used in the risk adjustment of the surgical cohort because for many patients admitted following elective surgery – there are no laboratory values available in the appropriate time window.

CMS notes that the six linking variables are required for billing, should be available on all Medicare FFS patients, and are ideally suited to support merging claims and EHR data (and should be submitted for 100 percent of discharges in the measurement period). However, hospitals would meet Hospital IQR Program requirements if they "submit linking variables on 95 percent or more of discharges with a Medicare FFS claim for the same hospitalization during the measurement period." Beginning with the first mandatory reporting period, "a hospital that does not submit any EHR data for the Hybrid HWR measure, or that submits data for less than the specified percentage of applicable patients, would be considered as not having met this Hospital IQR Program requirement and would receive a one-fourth reduction of its Annual Payment Update (APU) for the applicable fiscal year."

[20] Hybrid 30-day Risk-standardized Acute Myocardial Infarction Mortality Measure with Electronic Health Record Extracted Risk Factors (Version 1.1); Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.1); 164 2013 Core Clinical Data Elements Technical Report (Version 1.1); all available at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.
[21] 80 FR 49702

During the voluntary reporting periods, if a hospital submits data for this proposed measure, a hospital's annual payment determination would not be affected. Hospitals would, in fact, benefit by virtue of being able to provide feedback on the measure specifications and to troubleshoot any outstanding issues with CMS. Hospitals that submit data during the voluntary reporting periods would also receive "confidential hospital-specific reports that detail submission results from the applicable reporting period, as well as the Hybrid HWR measure results assessed from merged files created by [the agency's] merging of the EHR data elements submitted by each participating hospital with claims data from the same set of index admissions." To support voluntary hospital reporting, CMS intends to publish the electronic specifications for this reporting period in the 2021 Annual Update[22] in the spring of 2020, providing hospitals and vendors with the electronic specifications approximately 15 months before the beginning of the voluntary reporting period on July 1, 2021. The agency plans to deliver the first set of confidential hospital-specific feedback reports in the spring of 2023.

If the proposal to adopt the Hybrid HWR measure is finalized, "updated implementation guidance, schematrons, and sample files will become available on the eCQI Resource Center website." CMS is proposing to allow hospitals to meet the hybrid measure reporting and submission requirements "by submitting any combination of data via QRDA I files, zero denominator declarations, and/or case threshold exemptions." CMS is proposing that "hospitals must submit the core clinical data elements and linking variables within three months following the end of the applicable reporting period (submissions would be required no later than the first business day three months following the end of the reporting period) for hybrid measures in the Hospital IQR Program."

At the end of the proposed voluntary reporting periods, CMS is proposing to begin public reporting of the Hybrid HWR measure results (with data collected from the July 1, 2023 through June 30, 2024 reporting period, impacting the FY 2026 payment determination). This would be the first set of Hybrid HWR measure data to be publicly reported on the *Hospital Compare* website – which the agency expects would be included in the July 2025 refresh of *Hospital Compare*. "The EHR data would be merged with the associated claims data, and then Hybrid HWR measure results would be shared with hospitals in the confidential hospital-specific feedback reports planned for the spring of 2025, providing hospitals a 30-day review period prior to public reporting." CMS is also requesting feedback on whether or not the agency should consider adopting the Hybrid HWR measure for the Promoting Interoperability Program.

Potential Future Quality Measures

CMS is seeking feedback on the possible future inclusion of the following three measures in the Hospital IQR Program (which are also being considered for inclusion in the PI Program): 1) Hospital Harm – Severe Hypoglycemia eCQM; 2) Hospital Harm – Pressure Injury eCQM; and 3) Cesarean Birth (PC-02) eCQM (NQF #0471e). The Severe Hypoglycemia eCQM is an outcome measure which focuses "specifically on in-hospital severe hypoglycemic events in the setting of hospital administered antihyperglycemic medications." For more information on the Hospital Harm – Severe Hypoglycemia eCQM, CMS refers to the measure specifications available on the CMS Measure Methodology website. The second measure under consideration is the Pressure Injury eCQM, which is to "reduce pressure injury prevalence by creating transparency in the rate of these harms which should encourage hospitals to promote best practices such as frequent monitoring of patients at high risk, documenting skin assessments, frequent repositioning, proper skin care, and use of specialized cushions or beds." For more information on the Hospital Harm – Pressure Injury eCQM, CMS refers to the measure specifications available on the CMS Measure Methodology website. The third measure under consideration for inclusion in the eCQM measure set is the "Cesarean Birth (PC-02) eCQM (NQF #0471e) which CMS believes would enable hospitals to "track C-sections and reduce unnecessary instances of C-sections."

Accounting for Social Risk Factors: Update on Confidential Reporting of Stratified Data for Hospital Quality Measures

In the FY 2019 IPPS/LTCH PPS final rule, CMS considered policies pertaining to social risk factors for the Hospital IQR Program. Specifically, the agency considered implementing two methods that would promote health equity and health care quality for patients with social risk factors. The first method – a hospital-specific disparity method – would calculate differences in outcome rates among patient groups within a hospital, taking into account their clinical risk factors. CMS noted that this would allow for a comparison of those differences, or disparities, across hospitals – so that hospitals could assess how well they are closing disparities gaps compared to other hospitals. The second methodological approach would assess hospitals' outcome rates for

[22] Electronic Clinical Quality Improvement (eCQI) Resource Center. 2018 Measure Specifications. Available at: https://ecqi.healthit.gov/ecqm/measures/cms529v0. Note that the measure specifications may be further refined in the 2021 Annual Update.

subgroups of patients (e.g., dual-eligibles) across hospitals, allowing for a comparison among hospitals on their performance caring for their patients with social risk factors. CMS finalized[23] and planned – as a first step – to provide hospitals with confidential HSRs containing stratified results of the Pneumonia Readmission measure only, using both disparity methods during a month-long confidential reporting period in late summer of 2018.

CMS also noted that they would continue to consider 1) expanding efforts to provide stratified data in confidential HSRs for other measures; 2) including other social risk factors beyond dual-eligible status in confidential HSRs; and 3) eventually, making stratified data publicly available on the *Hospital Compare* website. Although the agencies preliminary efforts have focused on the Pneumonia Readmission measure, CMS states that the two disparity methods previously used can be applied to other outcome measures. The agency believes that expanding their efforts to provide disparity results for additional outcome measures – that is, "providing the results of both disparity methods alongside a hospital's measure data, as a point of reference" – allows for a more meaningful comparison.

In the spring of 2019, CMS will continue to provide confidential reporting of disparity results for the Pneumonia Readmission measure in the confidential HSRs for claims-based measures that are made available for hospitals to download through the QualityNet Secure Portal.

CMS is also planning to expand their efforts to apply the two disparity methods to additional outcome measures for confidential reporting in a phased manner. In the spring of 2020, CMS plans to add to the confidential HSRs for claims-based measures for the confidential reporting of disparity results for five additional claims-based condition- and procedure-specific readmission measures as follows:

1) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505) (AMI Readmission measure);
2) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF #2515) (CABG Readmission measure);
3) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891) (COPD Readmission measure);
4) Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure (HF) Hospitalization (NQF #0330) (HF Readmission measure); and
5) Hospital-Level 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551) (THA/TKA Readmission measure).

CMS is planning to include hospitals' disparity results in the regular annual confidential HSRs for claims-based measure results (made available for hospitals to download through the QualityNet Secure Portal each spring). The agency believes that this will simplify and minimize the number of confidential HSRs that hospitals receive, as opposed to a separate confidential HSR for each, as was done for the first confidential reporting for the Pneumonia Readmission measure in late summer of 2018.

Although the disparity results for the six condition and procedure-specific readmission measures is calculated differently than those used in the HRRP, CMS believes that expanding its efforts "complements the stratified methodology used to assess a hospital's performance on these measures for payment penalty scoring purposes" under the HRRP. In other words, although the two disparity methods are intended to account for social risk factors by providing additional information that identifies potential disparities in care provided to dual-eligible patients within individual hospitals and across hospitals nationally – CMS believes that providing the data is complementary to the payment stratification approach under the HRRP.

The two disparity methods and the stratified methodology used by the HRRP are part of the agency's overall efforts to account for social risk factors in quality measurement and value-based purchasing programs. In the future, CMS plans to provide confidential reporting of disparity results for additional outcome measures included in other quality programs. Additionally, the agency will continue to solicit feedback from hospitals in order to allow them to better understand their results prior to any potential public reporting, which the agency does not yet have plans for at this time (and which would be made through formal rulemaking).

[23] 83 FR 41598

Reporting and Submission Requirements for eCQMs

In the last two years of rulemaking, CMS has required hospitals to report only one, self-selected calendar quarter of data for four self-selected eCQMs; CMS is proposing to extend the current eCQM reporting and submission requirements for the CY 2020 reporting period/FY 2024 payment determination year.

However, CMS is proposing to modify the eCQM reporting and submission requirements for the CY 2022 reporting period/FY 2024 payment determination. Hospitals would be required to report one, self-selected calendar quarter of data for: a) three self-selected eCQMs, and b) the proposed Safe Use of Opioids – Concurrent Prescribing eCQM (NQF #3316e), for a total of four eCQMs. The number of calendar quarters of data and total number of eCQMs required would remain the same. This proposal is being made in conjunction with the agency's proposal to adopt the Safe Use of Opioids – Concurrent Prescribing eCQM (NQF #3316e) beginning with the CY 2021 reporting period/FY 2023 payment determination. If the proposal to adopt the Safe Use of Opioids – Concurrent Prescribing eCQM is finalized, CMS is proposing that "while this measure would be available for hospitals to select as one of their four self-selected eCQMs for the CY 2021 reporting period, all hospitals would be required to report this eCQM beginning with the CY 2022 reporting period/FY 2024 payment determination."

In last year's final rule, CMS finalized aligning the Hospital IQR Program with the Promoting Interoperability Program by requiring hospitals to use the 2015 Edition certification criteria for certified EHR technology (CEHRT) for the CY 2019 reporting period/FY 2021 payment determination and subsequent years. CMS is not proposing any changes to this policy in this proposed rule.

Proposed Changes to the Medicare and Medicaid Promoting Interoperability Programs

In 2011, the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs were established to encourage eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) to adopt, implement, upgrade and demonstrate meaningful use of certified EHR technology (CEHRT). Last year, CMS finalized renaming the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs as the "Medicare and Medicaid Promoting Interoperability Programs", or "Promoting Interoperability (PI) Programs".

For CQM reporting under the Medicare and Medicaid PI Programs, CMS is generally proposing to align the agency's requirements with requirements under the Hospital IQR Program. "Specifically, CMS is proposing to: 1) adopt the two opioid-related eCQMs previously discussed; 2) extend current eCQM reporting and submission requirements for the reporting periods in CY 2020 and CY 2021; and 3) establish eCQM reporting and submission requirements for the reporting period in CY 2022, which would require all eligible hospitals and CAHs to report on the proposed Safe Use of Opioids – Concurrent Prescribing eCQM (NQF #3316e) beginning with the reporting period in CY 2022."

CMS is also seeking feedback on whether they should, in future rulemaking, propose to adopt Hybrid HWR measure for the PI Program beginning with the reporting period in CY 2023 (as they are proposing to adopt under the Hospital IQR Program). CMS is also seeking "information on a variety of issues regarding the future direction of the Medicare and Medicaid Promoting Interoperability Programs."

Proposed Changes to Measures Under the Electronic Prescribing Objective

In the FY 2019 IPPS/LTCH PPS final rule[24], CMS adopted two opioid measures as for the Electronic Prescribing objective: 1) Query of Prescription Drug Monitoring Program (PDMP), which is optional in CY 2019 and required beginning in CY 2020; and 2) Verify Opioid Treatment Agreement, which is optional in CY 2019 and 2020. Additionally, CMS stated that they intended to propose this year that "EHR-PDMP integration would be required beginning in CY 2020 as part of the Query of PDMP measure[25]. CMS continues to believe that including the requirement for integration between PDMPs and the CEHRT utilized by eligible hospitals and CAHs would "advance access to and usability of PDMP data by health care providers" and reduce provider burden. CMS notes that "integration could reflect a variety of different approaches for interaction between EHRs and PDMPs that are currently being pursued in different locations and settings."

[24] 83 FR 41648 through 41656
[25] 83 FR 41652

CMS further notes that significant legislative changes – specifically the SUPPORT for Patients and Communities Act[26] – have the potential to positively impact the PI Program. Although this legislation is not the main reason for the agency's proposals, they believe it "may significantly affect the maturation, requirements, and use of PDMPs and State networks upon which the Query of PDMP measure is dependent." CMS is proposing to make certain changes to the Query of PDMP and Verify Opioid Treatment Agreement measures. Additionally – as previously described, CMS is also proposing to adopt two opioid clinical quality measures beginning with the reporting period in CY 2021.

Query of PDMP Measure

In the FY 2019 IPPS/LTCH PPS final rule[27], CMS finalized that the Query of PDMP measure is optional and available for bonus points for CY 2019, and required in CY 2020. Since then, CMS has received substantial feedback "from health IT vendors and hospitals that this flexibility presents unintended challenges, such as the significant burden associated with IT system design and development needed to accommodate the measure and any future changes to it." Additional challenges faced by providers are due to the current lack of integration of PDMPs into the EHR workflow; providers have to go outside the EHR workflow in order to separately log in to and access the state PDMP. Other feedback CMS received was that there is a large variation in whether PDMP data can be stored in the EHR. Furthermore, CMS notes that: "Specifically, with respect to PDMPs, the SUPPORT for Patients and Communities Act includes new requirements and federal funding for PDMP enhancement, integration, and interoperability, and establishes mandatory use of PDMPs by certain Medicaid providers, in an effort to help reduce opioid misuse and overprescribing, and in an effort to help promote the overall effective prevention and treatment of opioid use disorder."

CMS acknowledges that how health care providers are implementing and integrating PDMP queries into health IT and clinical workflows varies widely across the country. Additionally, CMS has heard from developers that the "costs of additional development will likely be passed on to health care providers without additional benefit as this development would be solely for the purpose of calculating the measure rather than furthering the clinical goal of the measure." CMS believes that more time is needed in order to evaluate the changing PDMP landscape "before requiring a Query of PDMP measure, or introducing requirements related to EHR-PDMP integration." Thus, CMS is proposing to make the Query of PDMP measure optional in CY 2020 and eligible for five bonus points. CMS notes that by making this measure optional in CY 2020 it would allow time for further integration of PDMPs and EHRs and minimize the burden on providers reporting this measure – while still giving providers the opportunity to report on and earn points for the measure. CMS is further proposing that if the proposed changes to the Query of PDMP measure are finalized, the e-Prescribing measure would be worth up to ten points in CY 2020 and subsequent years.

Verify Opioid Treatment Agreement Measure

CMS finalized in the FY 2019 IPPS/LTCH PPS final rule[28] that the Verify Opioid Treatment Agreement measure would be optional in both CYs 2019 and 2020. Since then, CMS has heard from stakeholders multiple concerns – including the "lack of defined data elements, structure, standards and criteria for the electronic exchange of opioid treatment agreements and how this impacts verifying whether there is an opioid treatment agreement to meet this measure." Thus, CMS is proposing to remove the Verify Opioid Treatment Agreement measure from the PI Program beginning with the EHR reporting period in CY 2020. The agency is also requesting information on potential new opioid use disorder (OUD) prevention and treatment-related measures.

[26] The Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act). (Pub. L. 115-271).
[27] 83 FR 41637 through 41645
[28] 83 FR 41653 through 41656

Proposed Performance-based Scoring Methodology EHR Reporting Period in CY 2020

Objective	Measure	Maximum Points
Electronic Prescribing	e-Prescribing*	10 points
	Bonus: Query of PDMP*	5 points (*bonus*)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Choose any two: ● Syndromic Surveillance Reporting ● Immunization Registry Reporting ● Electronic Case Reporting ● Public Health Registry Reporting ● Clinical Data Registry Reporting ● Electronic Reportable Laboratory Result Reporting	10 points

Note. The Security Risk Analysis measure is required, but will not be scored.
*** Measures with proposed changes to scoring are denoted with an asterisk (*).**

Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare and Medicaid Promoting Interoperability Programs

CMS asserts that "continuing the same CQM reporting and submission requirements is appropriate because it continues to offer hospitals reporting flexibility and does not increase the information collection burden on data submitters." The CQMs available for eligible hospitals and CAHs to report under the Medicare and Medicaid PI Programs beginning with the reporting period in CY 2020 are listed in the following table:

CQMs for Eligible Hospitals and CAHs Beginning With CY 2020

ED-2	Admit Decision Time to ED Departure Time for Admitted Patients (ED-2)	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

CMS is continuing to align the CQM reporting requirements for the PI Programs with similar requirements under the Hospital IQR Program. Thus, the agency is proposing to adopt two new opioid-related clinical quality measures (the same as those proposed for the Hospital IQR program), and is seeking feedback on whether the agency should propose in future rulemaking to adopt the Hybrid HWR Measure with Claims and EHR Data for the PI Program – specifically for reporting periods beginning with CY 2023.

CMS is proposing that for CY 2022 – the CQM reporting period and criteria under the Medicare PI Program for eligible hospitals and CAHs reporting CQMs electronically would be: "for eligible hospitals and CAHs participating only in the PI Program or participating in both the PI Program and in the Hospital IQR Program, report one, self-selected calendar quarter of data for: (a) three self-selected CQMs from the set of available CQMs; and (b) the proposed Safe Use of Opioids – Concurrent Prescribing CQM (NQF #3316e), for a total of four CQMs." CMS would not change the number of CQMs that hospitals must report under this proposal.

For eligible hospitals and CAHs that report CQMs by attestation under the Medicare PI Program because electronic reporting is not feasible, CMS is proposing that they would report on all CQMs from the set of available CQMs, with a reporting period that lasts a full calendar year. For CY 2022, CMS is proposing that the submission period for the Medicare PI Program would be the 2 months following the close of the CY 2022, ending February 28, 2023.

What's Next?

The IPPS tables for this FY 2020 proposed rule are available on the CMS website. CMS publishes the final IPPS regulation around Aug. 1, 2019 and the changes are effective at the beginning of the federal fiscal year (Oct. 1, 2019). The 60-day comment period closes on June 24, 2019. Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this proposed rule. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern.

It is possible there will be substantial shifts between the proposed and final rule based on public comments and further analysis by CMS. Look for more information from our office when the final rule is released in August.

Additional Resources

Chelsea Arnone, Regulatory Affairs and Government Relations Director in Vizient's Washington, D.C. office, can be reached at (202) 354-2608, and is monitoring this rule and other regulatory developments. Please reach out to her if you have any questions or if Vizient can provide any assistance as you consider these issues.