



A Passionate Voice for Compassionate Care

June 24, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G Herbert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

REF: CMS-1716-P

Re: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long- Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals

Dear Ms. Verma:

The Catholic Health Association of the United States (CHA) is pleased to submit these comments on the referenced Centers for Medicare & Medicaid Services' (CMS) proposed rule published in the Federal Register on May 3, 2019. (84 Federal Register 19158).

We appreciate the ongoing efforts of CMS to administer and improve the payment systems for acute inpatient hospital services, especially considering the agency's many competing demands and limited resources. CHA offers the following comments on the proposed rule.

- **FY 2020 Medicare-Severity Diagnosis-Related Group (MS-DRG) Documentation and Coding Adjustment**

The proposed rule would make an adjustment to IPPS payment rates of +0.5 percentage points as the third step in a six-year process of restoring prior year downward adjustments to IPPS payment rates that were required by the American Taxpayer Relief Act of 2012 (ATRA). The ATRA adjustments were intended to recoup prior year spending increases attributed by CMS to documentation and coding changes which CMS believed did not reflect real changes in case-mix.

As was made clear in prior comment letters, CMS made recoupment adjustments totaling 3.9 percentage points but only intends to return 2.96 percentage points of those adjustments to IPPS

rates by FY 2023. The difference between the amounts recouped and restored to IPPS rates is a result of a change in CMS' estimates of the adjustment necessary in FY 2017 to complete recoupment of the \$11 billion required by ATRA and two legislative enactments (the Medicare Access and CHIP Reauthorization Act of 2015 and the 21st Century Cures Act) that mandated specific adjustments to IPPS rates when restoring prior recoupment adjustments.

CHA believes that an approximate permanent 1.0 percentage point reduction in IPPS rates is both unfair and harmful to hospitals. **CHA urges CMS to make every effort to interpret and apply the statutory provisions related to documentation and coding to restore fully and permanently all recoupment adjustments to IPPS rates by FY 2024.**

- **FY 2020 Outlier Threshold**

CMS proposes an FY 2020 outlier threshold of \$26,994. This compares to an FY 2019 outlier threshold of \$25,743, a 4.9 percent increase. CHA remains concerned about the high level of the outlier threshold and the rate at which CMS proposes to increase it in FY 2020 compared to FY 2019, particularly considering that CMS estimates paying less than the 5.1 percent removed from the standardized amounts to fund outliers for both FY 2018 (4.94 percent) and FY 2019 (4.6 percent).

CHA remains concerned about the potential effect on the outlier threshold of Medicare payment for chimeric antigen receptor therapy (CAR-T). CMS reports in the proposed rule (84 FR 19278) that the cost of a CAR-T product is \$373,000. CHA further understands that patients in need of this therapy could have significant additional inpatient hospital expenses as a result of being severely ill and the potential for high costs associated with potentially fatal side effects.

In the FY 2019 IPPS proposed rule, CMS indicated that it was considering using a cost-to-charge ratio (CCR) of 1.0 rather than the hospital specific CCR to determine the costs associated with CAR-T products when determining new technology add-on and outlier payments. Ultimately, CMS did not make this change. In the FY 2020 IPPS rule (84 FR 19182), CMS again requests comments on whether to use a CCR of 1.0 when determining outlier payments, new technology add-on payments, and payments to IPPS-excluded cancer hospitals.

Unless cases involving CAR-T therapy are appropriately paid consistent with their high costs, these cases will be highly likely to result in outlier payments and substantial losses to hospitals. Outlier payments are intended for cases that are unusually expensive compared to the typical case. As cases sharing similar clinical characteristics and costs are grouped together to create an MS-DRG, only unusually expensive cases compared to other cases within that same MS-DRG should be receiving outlier payments. If all cases of a particular type like CAR-T are receiving outliers, it suggests that CMS is not accurately valuing these types of cases.

CHA has strong reservations about the potential for CAR-T cases to result in yet a further rise in the outlier threshold at the expense of other cases. Deviating from its traditional methodologies to use a CCR of 1.0 for CAR-T raises yet further concerns about how payments will be affected for other cases and hospitals that do not provide this therapy. Rather than focus on better recognition of CAR-T costs when these cases are paid as outliers, CHA believes CMS should examine how to value payment accurately for all CAR-T cases so they are less likely to be paid as outlier cases to begin with.

Absent any special issues with CAR-T therapies, **CHA requests that CMS examine the reasons for the continuing rise in the outlier threshold and whether there are any interventions it can take to ensure that outlier payments remain equitable and continue to protect hospitals from high cost cases where Medicare's IPPS payments are insufficient to adequately compensate the hospital.**

- **CAR-T and the MS-DRGs**

CMS does not propose to create a new MS-DRG for cases involving CAR-T therapy for FY 2020 but seeks comment on the appropriate way to develop the relative weight for a CAR-T MS-DRG if it were to make such a proposal in future rulemaking.

If it should do so, **CHA recommends that CMS exclude clinical trials CAR-T cases when developing the relative weight.** As CMS states, the absence of drug costs on claims for cases involving clinical trials could have a significant impact on the relative weight. If a hospital does not have cost for the CAR-T product, CMS would be averaging cases with a \$373,000 cost with those that do not have the same cost and the result would be underpayment for CAR-T cases not in a clinical trial. **CHA also recommends that CMS refrain from trimming the CAR-T data when setting the weight for a new MS-DRG. CHA reiterates that CAR-T cases should be recognized in the relative weight methodology based on the actual costs to the hospital of acquiring the product.** Using a method that reflects the actual costs of acquiring the product rather than a CCR would result in accurate valuation of CAR-T cases. Finally, CHA has great concerns with CMS' suggestion that it might not include indirect medical education (IME) and Medicare disproportionate share (DSH) adjustments in a potential new CAR-T MS-DRG because of the additional payment that would require. These programs were intended to address the additional costs faced by, respectively, teaching hospitals and hospitals that serve lower-income patients and not meant to be applied on a case-by-case basis. **CHA supports the continued application of IME and Medicare DSH adjustments to CAR-T cases under any new MS-DRG.**

- **New Technology Add-On Payments and CAR-T Payments**

CMS proposes to raise the marginal cost factor for determining the maximum add-on payment for a qualifying new technology from 50 percent to 65 percent. The increase in the marginal cost

factor would not be limited to CAR-T and would apply to all technologies approved for add-on payment. Under CMS' proposal, Medicare would 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. **CHA strongly supports proposal to raise the new technology add-on from 50% to 65%. With respect to CAR-T, however, we reiterate that hospitals should be paid based on their full costs.** CMS indicates that raising the marginal cost factor to 65 percent would result in a maximum add-on payment of \$242,450 for a CAR-T case or nearly \$130,000 less than the cost of the product itself. Even if the marginal cost factor were raised to 80 percent (a common past comment among public commenters), hospitals would still only be receiving \$298,400 for a product that costs \$373,000.

The logic behind a marginal cost factor of less than 1.0 is that hospitals should be insured for losses on new technologies above a fixed threshold but should also be in the position of balancing the cost of the technology with the improvement in clinical care that is brought to the patient. However, balancing is not a factor for CAR T patients because conventional cancer treatments have not proven effective. Moreover, the need to insure hospitals against losses is significant given the magnitude of the losses hospital assume for these therapies.

Finally, CMS should consider extending the add-on for CAR-T beyond FY 2020 if a new MS-DRG or pass through payment is not developed before CAR-T "newness" expires.

- **Disproportionate Share Hospitals (DSH)**

Since FY 2014, hospitals that qualify for Medicare DSH payments receive two separately calculated payments. The first payment equals 25 percent of the amount they would have received under the Medicare DSH formula required by statute prior to the Affordable Care Act. The second payment is based on the remaining 75 percent of the total Medicare DSH payments that would have been paid under the old formula, adjusted by the change in the number of uninsured individuals since FY 2013. The amount received by a given hospital from this financing is based upon that hospital's share of national uncompensated care costs.

CMS estimates that the amount available in FY 2020 to distribute as uncompensated care will increase from \$8.273 billion in FY 2019 to \$8.489 billion in FY 2020, an increase of about 2.6 percent. From FY 2014 through FY 2017, CMS distributed uncompensated care payments to hospitals based on each hospital's share of national uncompensated costs using low-income patient days—Medicare inpatient days when the patient was eligible for Supplemental Security Income and Medicaid inpatient days where the patient was not also eligible for Medicare—as proxy data for uncompensated care. For FY 2018, CMS began a 3-year transition period to use Worksheet S-10 of the Medicare Hospital Cost Report in place of low-income patient days to distribute Medicare uncompensated care payments.

CMS is currently using two years of Worksheet S-10 data (FY 2014 and FY 2015) and one year of low-income patient days. For FY 2020, CMS proposes to use one year of Worksheet S-10 data from FY 2015 for distributing uncompensated care payments. However, CMS requests comment on whether it should use only FY 2017 Worksheet S-10 to distribute FY 2020 uncompensated care payments. CMS proposes to move from three years of data to one year of data because it has one year of partially audited data. CMS audited FY 2015 Worksheet S-10s for about one-quarter of DSH hospitals representing more than half of uncompensated care payments, and FY 2015 data are the most recent for which resubmission has been allowed. CMS offers its concerns about mixing audited and unaudited data to explain why it does not propose to continue using a three-year average of data as it did in the past.

In the past, CHA has commented that CMS should only use audited cost report data in the distribution of uncompensated care payments. CHA thanks CMS for being responsive to our concerns regarding auditing Worksheet S-10 data. CHA supports CMS using FY 2015 audited Worksheet S-10 data in the uncompensated care distribution.

While FY 2017 data is not audited, CMS indicates that it could consider using that data because of improvements in the cost report instructions effective for cost reports beginning on or after October 1, 2016. In September of 2017, CMS provided revised instructions for completion of Worksheet S-10 that addressed a number of concerns about cost reporting that were raised in during the FY 2018 IPPS rulemaking process. We urge CMS to make auditing the FY 2017 data for use in uncompensated care payments a priority.

In past years, CHA recommended a longer phase-in of the use of S-10 cost report data than the 3-year transition period proposed by CMS to mitigate wide swings in hospital payments from year-to-year. Because of potential instability from moving from payment based on a three-year average to payment based on a single year of data, if CMS transitions to using one year of data it should monitor payments over time and consider using more than one year of data. In either case, CMS should be attentive to significant negative impact at the hospital level and consider adopting transition policies so that no hospital experiences more than a five percent change in overall uncompensated care payments in any given year.

CMS does not propose any changes to its definition of uncompensated care from prior years. Under this definition, CMS would recognize non-Medicare bad debt and charity care. However, CMS would not recognize payment shortfalls from public health programs like Medicaid, the Children's Health Insurance Program and state and local indigent care programs. **CHA believes that uncompensated care should also include the unreimbursed costs of public health care programs, including Medicaid, the Children's Health Insurance Program and state and local indigent care programs.** This approach would be a fairer way to allocate uncompensated care dollars to hospitals, especially given that analyses we have reviewed suggest that hospitals located in states that opted out of Medicaid expansion do significantly better under the CMS proposed approach than hospitals located in states that have expanded Medicaid. Broadening the

definition to include Medicaid shortfalls and other forms of unreimbursed costs of other public health care programs would help make the allocation more equitable.

- **Changes to the Wage Index**

Beginning in FY 2020, CMS proposes to increase the wage index values for hospitals with a wage index in the lowest quartile. CMS proposes to increase wage index values for low-wage hospitals, those below the 25th percentile, by one-half the difference between a low wage index hospital's wage index and the 25th percentile. To make the proposal budget neutral, CMS would also lower the wage index values for hospitals above the 75th percentile. It would keep this policy in place for a minimum of four years or the time CMS says is necessary for low wage index hospitals to pay higher wages that would then be incorporated into hospital reported data used to set the FY 2025 wage index.

CHA believes that CMS is correct to be analyzing revisions to the wage index as concerns about its equity and accuracy have long been documented. While CHA strongly agrees with raising the wage index for those low wage hospitals disadvantaged by the current system, we question whether CMS is required to or has the legal authority to apply budget neutrality selectively to only some hospitals. For high wage hospitals, the current system is providing an accurate result. It seems inequitable and potentially outside of CMS' authority to override that result by penalizing those hospitals because a flawed system results in underpayment to a different group of hospitals, which is what the application of budget neutrality would do. Therefore, **CHA supports the proposal to increase the wage index values for low-wage hospitals but urges CMS not to decrease arbitrarily the wage index for higher wage index hospitals in the name of budget neutrality.**

- **Comprehensive CC/MCC Analysis**

CMS reviews and updates the codes that are defined as either a complication or comorbidity (CC) or a major complication or comorbidity (MCC) when used as a secondary diagnosis under the MS-DRG system. MCCs in particular reflect the highest level of severity and resource use. For FY 2020 CMS has proposed changes in the severity level designation for an overwhelming 1,492 diagnosis codes. Specifically, CMS proposes decreasing the number of MCCs by 145 codes, decreasing the number of CCs by 837 codes, and increasing the number of non-CCs by 982 codes.

CHA has received input from its members opposing many of the proposed severity level changes. There are also concerns that CMS has not provided sufficient information on the proposed changes, has applied its methodology inconsistently and has not conducted enough analysis to finalize this proposal in its entirety. It appears CMS has not adequately considered the substantial administrative and financial consequences of changing 1,492 codes would have for hospitals. **CHA urges CMS not to finalize its proposed CC/MCC changes.**

- **Hospital Readmissions Reduction Program**

In considering whether to remove a measure from the Hospital Readmissions Reduction Program (HRRP) CMS proposes to apply the same eight factors that it has adopted for this purpose in the Inpatient Quality Reporting Program and the inpatient Hospital Value-Based Purchasing Program. CHA agrees that these are appropriate factors for CMS to consider and appreciates the consistency in applying these across all quality programs.

A subregulatory process is proposed for making nonsubstantive changes to the HRRP adjustment. **CHA agrees that CMS should be able to make minor program changes without having to resort to notice and comment rulemaking. However, CMS should ensure that that this authority would not be used in cases where a hospital's HRRP adjustment would be affected by clarifying that it would use notice and comment rulemaking for any change affecting hospital performance.** CMS should also work to ensure that any appropriate subregulatory changes are communicated widely and with enough time for hospitals to raise concerns to CMS before implementation.

CMS proposes to modify the definition of dual eligible beneficiary to avoid undercounting the dual eligible status of beneficiaries who die in the month of a hospital discharge. **CHA supports this proposed change in the definition of dual eligible beneficiary to ensure that all dual eligible beneficiaries are appropriately counted for purposes of calculating the HRRP adjustment.**

CHA is pleased that as early as the spring of 2020 CMS will confidentially report to hospitals with hospital-specific data on the six readmission measures stratified by dual eligible status using two disparity methodologies. One method will compare within-hospital readmission rates for dual eligibles and other Medicare beneficiaries. The second method will compare performance in care for dual eligibles across hospitals. This information will supplement the stratification by dual eligible status that is now part of the HRRP adjustment calculation. CHA believes that the more hospitals understand about the extent to which their readmission measure performance varies by dual eligible status, the better they can target quality improvement activities to improve care for this vulnerable population.

- **Hospital-Acquired Condition Reduction Program**

The proposed changes to data validation policies for the HAC Reduction Program are reasonable and CHA supports them. In particular, the proposed filtering that would exclude from the selection of cases for validation of the Central Line Bloodstream Infection (CLABSI) and Catheter-Associated Urinary Tract Infection (CAUTI) measures cases where positive cultures were collected on the first or second day of the hospital stay. CHA agrees that this proposed approach will better exclude community-onset events and target validation to “true events” of hospital-acquired infections. In addition, the proposed targeting of *up to* 200 hospitals instead of

exactly 200 is a reasonable proposal for ensuring appropriate targeted selection of hospitals for validation without unnecessary burden.

In addition, consistent with our comments above with respect to the HRRP, **CHA supports the proposal to apply to the HAC Reduction Program the same eight factors for measure removal that it has adopted for this purpose in the Inpatient Quality Reporting Program and other hospital quality programs.**

- **Inpatient Hospital Quality Reporting Program**

Opioid-related eQMs. **CHA supports the proposed addition of the NQF-endorsed Safe Use of Opioids—Concurrent Prescribing electronic clinical quality measure (eCQM) to the IQR Program beginning with reporting in 2021 (FY 2023 payment). However, we do not support the proposal to make reporting of this eCQM mandatory beginning in 2022 (for FY 2024 payment).** Currently hospitals must report four eQMs of their choice from a list of eight eQMs; under the proposed rule, this list would increase to ten eQMs. While EHRs must be certified to all available eQMs, it takes time for vendors and hospitals to modify systems to incorporate new measures, engage in training and testing of new eCQM reporting, and institute appropriate workflows. While we appreciate the importance of addressing opioid prescribing, CMS should allow vendors and hospitals more time to adapt systems and gain experience with reporting this eCQM on a voluntary basis before considering proposing it as a mandatory measure.

CHA does not support adding the other proposed new eCQM, Hospital Harm—Opioid-Related Adverse Events at this time. CMS acknowledges there may be potential for the measure to disincentivize use of naloxone as well as appropriate opioid prescribing in the hospital setting. Review by NQF of the reliability and validity testing of this measure and the potential unintended consequences of its adoption should be complete and endorsement receive before it is considered for addition. In its earlier review, the Measure Applications Partnership noted that this measure might need to be balanced with other measures assessing appropriate use of naloxone and adequate pain control.

Hybrid Readmission. CHA appreciates that the proposed Hybrid Hospital-Wide Readmissions (HWR) measure provides for more specific risk adjustment than the current measure, which is based entirely on claims data. **However, CHA believes it is premature to mandate electronic reporting of core clinical data elements and linking variables for this measure.** CMS should proceed with the proposed voluntary reporting periods and review that experience before proposing it as a mandatory measure.

- **Medicare and Medicaid Promoting Interoperability Programs**

CHA supports the proposed changes to the opioid-related measures. We agree that the Verify Opioid Treatment optional measure should be removed because it is not well defined or

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workable. Like other quality measures, eCQMs have no value if they are not meaningful, clearly specified, and data collection reasonably worked into hospital workflows. In addition, we support the change in the Query of Prescription Drug Management Programs measure to yes/no reporting and its maintenance as an optional measure instead of becoming mandatory in 2020 as previously finalized. The proposed rule points out the lack of integration of PDMPs into the EHR workflow and the ongoing development of state programs, which are barriers to making this a workable mandatory measure.

In addition, **CHA supports the proposal to continue into 2021 the current continuous 90-day reporting period for meeting meaningful use objectives and measures.** Maintaining a consistent reporting period allows hospitals to focus on the substance of the program's performance requirements.

CMS proposes that the option for hospitals and CAHs to report the eCQMs by attestation be eliminated beginning with the 2023 reporting period. At that time all eligible hospitals and CAHs would have to submit eCQM data electronically. CMS should assure that the hardship exceptions process is sufficient to capture all the situations where a hospital is unable to report eCQMs. This is of particular concern for small rural hospitals and CAHs that have meet other Promoting Interoperability Program requirements but for whom electronic reporting of eCQMs is not feasible.

In closing, thank you for the opportunity to share these comments in regard to the proposed FY 2020 IPPS rule. We look forward to working with you on these and other issues that continue to challenge and strengthen the nation's hospitals. If you have any questions about these comments or need more information, please do not hesitate to contact me or Kathy Curran, Senior Director Public Policy, at 202-721-6300.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa A. Smith". The signature is fluid and cursive, with the first name "Lisa" being the most prominent part.

Lisa A. Smith
Vice President
Public Policy and Advocacy