June 25, 2018

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-1694-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 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims

Dear Ms. Verma:

The Catholic Health Association of the United States (CHA) is pleased to submit these comments on the Centers for Medicare & Medicaid Services’ (CMS) proposed rule entitled 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 2019 Rates; Proposed Quality Reporting Requirements for Specific Providers; Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs (Promoting Interoperability Programs) Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Medicare Cost Reporting Requirements; and Physician Certification and Recertification of Claims (83 Federal Register 20164, May 7, 2018).

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 2019 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 second 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). ATRA instructed CMS to recoup $11 billion in payments to IPPS hospitals between FYs 2014 and 2017. CMS had estimated that $11 billion in IPPS payments were made in FYs 2010, 2011 and 2012 due to documentation and coding changes which CMS believed did not reflect real changes in case-mix.

As was made clear in prior comment letters from CHA and others, CMS made recoupment adjustments totaling 3.9 percentage points between FY 2014 and FY 2017. However, CMS only intends to return 2.96 percentage points of those recoupment adjustments to IPPS rates by FY 2023 leaving hospital inpatient rates nearly 1.0 percentage points short of the amounts recouped for documentation and coding. 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 entire $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. While CHA recognizes that CMS’ flexibility may be limited during the FY 2018 through FY 2023 when specific adjustments to IPPS rates are mandated by statute, CHA urges CMS to make every effort to interpret and apply the statutory provisions related to documentation and coding to fully and permanently restore all recoupment adjustments to IPPS rates after FY 2023.

FY 2019 Outlier Threshold

CMS proposes an FY 2019 outlier threshold of $27,545. This compares to an FY 2018 outlier threshold of $26,601, a 3.5 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 2019 compared to FY 2018. While CMS has not made any methodological changes to its determination of the outlier threshold, its rise is resulting in hospitals having to experience higher losses in order to receive any payment relief. Further, to the extent that outlier payments go to fewer cases and hospitals, other cases and hospitals are subsidizing these outlier payments through the 5.1 percent reduction in IPPS rates for budget neutrality.

CHA remains concerned about the potential effect on the outlier threshold of Medicare payment for chimeric antigen receptor therapy (CAR-T). This new drug therapy was approved by the Food and Drug Administration in 2017. Addendum B of the April 1, 2018 outpatient prospective payment system indicates that the cost of the drug itself will be over $500,000 for
one product and nearly $400,000 for the other product. 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 outlier section of the proposed rule, CMS provides a brief discussion of its proposed policy that would use a hospital 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 payments (if these products are determined eligible) and outliers. The proposed policy would raise new technology add-on payments or outlier payments relative to using a hospital-specific CCR that will be lower than 1.0.

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. CHA strongly urges CMS to proceed cautiously when deciding how to make outlier payments for CAR-T cases. 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

For FY 2019, CMS proposes to assign CAR-T cases to MS-DRG 016 with a revised title of “Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy.” CMS discusses an alternative suggestion to create a new MS-DRG for CAR-T cases rather than making a new technology add-on payment. However, a new MS-DRG must be budget neutral. CMS expresses concern in the proposed rule with redistributive effects away from core hospital services over time toward specialized hospitals and how that may affect payment for core services if a new MS-DRG is created. CHA shares these concerns.

CMS also invites public comments on alternative approaches to setting payment including using a CCR of 1.0 for charges associated with CAR-T products and taking into account an appropriate portion of the average sales price (ASP) for these drugs when determining IPPS payment. CMS is also interested in comments about how payment alternatives would affect access to care and how they would affect incentives to encourage lower drug prices.

As detailed in our comments regarding outliers, CHA remains concerned about the high cost of CAR-T products and its potential under a budget neutral IPPS payment system to result in redistribution of payments away from all other hospitals services to these cases. We also share CMS’ concerns about potential adverse effects on beneficiaries’ access to care. Further, concerns about incentives on drug prices are also legitimate. If CMS were to deviate from its traditional methodologies and apply a CCR of 1.0 in situations where a product has an
extraordinarily high cost, it provides very strong incentives for drug and device manufacturers to raise the price of their products to hospitals to facilitate arguments that their products should also be exempted from CMS’ traditional pricing methodologies and have a CCR of 1.0 applied. CHA does not believe a budget neutral system like the IPPS was designed to accommodate technologies that are so costly and significantly more costly than other cases treated under the IPPS. For comparison, the highest FY 2019 IPPS proposed base payment (not including any add-on payments) is about $160,000 for a heart transplant. The CAR-T product alone, not considering any other IPPS costs, has costs that more than two to three times the highest paying MS-DRG.

CMS’ suggestion to consider use of ASP pricing should be explored further. CHA notes that CAR-T consists of drawing cells from the patient during a hospital outpatient encounter. The cells are then reengineered in a laboratory and administered to the patient about two weeks later. One option to consider is whether the cost of the CAR-T product itself could be considered an outpatient service while its later administration and any associated costs following the administration are paid under the IPPS. In this scenario, CMS would pay for the CAR-T products at ASP + 6 percent (the amounts shown above) and concerns about these cases drawing payments from all other IPPS cases would be ameliorated. A further advantage of this approach is that it would ensure hospitals are fully compensated for their costs without subjecting the Medicare beneficiary to very high coinsurance. 42 CFR §419.41, limits beneficiary coinsurance on any single OPPS service to the inpatient deductible ($1,340 in 2018) and Medicare’s program payment would make up the difference due to the beneficiary copayment limitation.

CHA urges CMS to use ASP pricing to compensate hospitals for CAR-T products to avoid redistribution of payment from all other hospital services to CAR-T cases.

■ 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 (ACA). 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 fund is based upon that hospital’s share of national uncompensated care costs.

CMS estimates that the amount available in FY 2019 to distribute as uncompensated care will increase from $6.767 billion in FY 2018 to $8.250 billion in FY 2019, an increase of about 21.9 percent. The higher amount available for uncompensated care is a result of higher estimates of the number of individuals that will be uninsured in FY 2019 compared to FY 2018.

From FY 2014 through FY 2017, CMS has 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 (SSI) 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. Under this transition, CMS used two years of low income patient days data (Medicaid inpatient days from FY 2012 and FY 2013 and SSI Medicare inpatient days from FY 2015 and FY 2016) and one year of Worksheet S-10 data (FY 2014) to distribute FY 2018 uncompensated care payments. For FY 2019, CMS proposes to use one year of low income patient days data (FY 2013 Medicaid inpatient days and FY 2016, SSI Medicare inpatient days) and two years of Worksheet S-10 data (FY 2014 and FY 2015) to distribute uncompensated care payments. For FY 2020, CMS would use three years of Worksheet S-10 data (FY 2014, FY 2015 and FY 2016) to distribute uncompensated care payments.

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. CMS also provided a limited window of opportunity for hospitals to resubmit their FY 2014 and FY 2015 cost reports to reflect those revised Worksheet S-10 instructions. **CHA thanks CMS for being responsive to hospital concerns on these issues and for allowing hospitals time to revise and resubmit cost reports to improve Worksheet S-10 data.**

In the FY 2018 IPPS rule, CMS made some modest edits to eliminate clearly aberrant Worksheet S-10 data from the distribution of uncompensated care payments. However, CMS did not adopt any policies to audit Worksheet S-10 data that it will use to distribute uncompensated care payments for FY 2018 – FY 2020. Cost reports beginning in FY 2017 will be the first cost reports for which the Worksheet S–10 data will be subject to a desk review. The FY 2017 Worksheet S-10 will not be used to distribute uncompensated care payments until FY 2021. **CHA continues to urge CMS to only use desk reviewed Worksheet S-10 data to distribute uncompensated payments.**

CHA believes that a longer phase-in period would allow CMS to continue to fine-tune the accuracy, consistency and completeness of the S-10 data before relying solely on that data. CMS is distributing more than $8 billion in uncompensated care payments. To ensure these payments are distributed consistent with government auditing protocols, **CHA recommends CMS develop a desk audit process analogous to the hospital wage index.**

CHA believes in giving hospitals more time to ensure accurate reporting based on CMS’ revised instructions along with a desk audit program. A longer phase-in with desk review audits would also allow for improvements in reporting of data as CMS and hospitals have more experience with these data. **CHA recommends a longer phase-in of the use of S-10 cost report data than the 3-year transition period proposed by CMS and would instead suggest a 5-year transition period to mitigate wide swings in hospital payments from year-to-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.

### Cost Report Information Submission

In the FY 2019 IPPS proposed rule, CMS proposes revisions in six different areas to the requirements for submitting a Medicare cost report. Each of these proposals would be effective for cost reporting periods beginning on or after October 1, 2018. CMS’ rationale for each of the proposed additions of supporting documentation to the Medicare cost report is that requiring this information would facilitate the contractor’s review and verification of the cost report without the need to request additional data from the provider.

CMS believes these requirements would impose no additional burden because cost report regulations already require hospitals to collect, maintain, and submit this data when requested. CHA is concerned however that complying will impose additional burdens on hospitals particularly with respect to the Home Office Cost Statement and Intern and Resident Information System Data. We urge CMS not to implement those two proposals.

CMS’ proposal also indicates the cost report will be rejected if the supporting documentation does not support the amounts claimed for each of the items. This raises a question as to whether Medicare contractors will be doing full audits of the supporting documentation submitted with the Medicare cost report and rejecting the cost report if there is not a match. Such a proposal seems impractical as Publication 15-02 (the Provider Reimbursement Manual, Part II), Chapter 1, section 140 requires the contractor to make a decision regarding acceptability of a provider’s cost report within 30 days of receipt. The responsibility to furnish data that corresponds or matches data claimed in the cost report is one that is more appropriately part of the interactions that will occur between a hospital and a contractor during the audit process rather than through the cost report submission process. Should CMS finalize its proposal to reject cost reports over supporting documentation discrepancies, CHA strongly urges CMS to allow a reasonable time frame, at least 30 days, after a discrepancy is discovered for it to be corrected.
Inpatient Admission Orders

CMS proposes to revise the regulations at 42 CFR §412.3(a) to remove the language stating that a physician order must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital inpatient services under Medicare Part A. According to the proposed rule, CMS is proposing to eliminate the requirement for the inpatient admission order because of inpatient denials due to technical discrepancies such as missing practitioner admission signatures, missing co-signatures or authentication signatures, and signatures occurring after discharge that have led to denial of Part A inpatient hospital payment. CMS indicates that if the hospital is operating in accordance with the hospital conditions of participation, medical reviews should primarily focus on whether the inpatient admission was medically reasonable and necessary rather than occasional inadvertent signature documentation issues unrelated to the medical necessity of the inpatient stay.

CHA appreciates CMS’ interest in reducing burden on hospitals and agrees with CMS’ proposal but believes further clarification is needed in CMS’ policy. While the proposed rule eliminates the requirement for an inpatient admission order, it also states that the proposal does not change the requirement that an individual is considered an inpatient if formally admitted as an inpatient under an order for an inpatient admission. CMS proposed rule appears to include statements that are in direct conflict with each other. Further, CHA believes that CMS needs to clarify how its policy, if finalized, will affect CMS’ sub regulatory guidance on admission order requirements most recently updated on January 30, 2014 and found at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/IP-Certification-and-Order-01-30-14.pdf.

Accounting for Social Risk Factors in the Hospital Quality Reporting and Pay-for Performance Programs

CHA has ongoing concerns about the impact of health disparities and has long urged that quality outcome measures be risk-adjusted for sociodemographic factors (such as income, education, race, homelessness and language proficiency) which have been shown to have a significant relationship to health outcomes. The result of known links between social risk factors and poor outcomes is that providers serving a high percentage of disadvantaged patients can be subject to unnecessary payment reductions if appropriate adjustments for social risk factors are not made in performance-based payment incentive programs.

FY 2019 will be the initial implementation year for changes to the Hospital Readmission Reduction Program required by the 21st Century Cures Act, under which readmission scores will be calculated by stratifying hospitals into five peer groups based on the percentage of patients who are dually eligible for the Medicare and Medicaid programs. Stratification is a good first step in accounting for social risk factors when assessing hospital performance on readmissions measures. However, we believe that more work needs to be done to better understand health
disparities, how they affect health outcomes, and what are the best methods for risk adjusting outcome measures to account for social risk factors.

We are pleased that CMS reports continuing efforts to further consider accounting for social risk factors, including an upcoming Technical Expert Panel that will consider stratification of IQR Program measures. Importantly, as noted in the proposed rule, the National Quality National Quality Forum (NQF) has extended its trial examining social risk factors in outcome measures.

CHA continues to believe that more could be done to use performance measurement systems to identify and eliminate health disparities. Enhanced data collection on social risk factors, along with improved statistical techniques as recommended by the Assistant Secretary for Planning and Evaluation, would allow better measurement of performance and outcomes with respect to individuals with social risk factors.

Regardless of future steps taken toward stratification and social risk factor adjustment, CMS should continue to monitor the effect of the hospital quality programs on vulnerable and disadvantaged populations and the providers that serve them in order to ensure they are not being harmed by the choice of measures and adjustments in these programs.

Hospital Value-Based Purchasing Program

CHA supports the proposed addition of an eighth factor for consideration in removing measures from the Hospital VBP Program and the associated proposed removal of ten measures. Proposed Factor 8 would allow CMS to consider removal of a measure when the costs associated with the measure outweigh the benefits of its continued use in the program. Consideration of costs should include not just the data submission requirements but all the resources required for providers to perform well on the measure, such as monitoring performance and developing strategies for performance improvement. Through its Meaningful Measures initiative CMS is giving weight to measures that offer opportunity for improvement of outcomes that are meaningful to patients while minimizing provider burden. The proposed new removal factor will provide opportunity for CMS to streamline measures to meet these goals.

All ten of the measures proposed for removal would continue in either the Hospital Acquired Condition (HAC) Reduction Program or the Hospital Inpatient Quality Reporting (IQR) Program, so public reporting of hospital performance on these measures would continue. The measures proposed for removal are all seven measures in the VBP Program Safety Domain along with three condition-specific episode payment measures which have not yet been implemented in the Hospital VBP Program, and which are encompassed in the overall Medicare spending per beneficiary measure. We agree with CMS that duplication of measures across programs is unnecessary and adds to hospital burden in tracking performance when the program reporting periods are not identical.
With complete removal of the Safety Domain, CMS proposes to reweight the outcome domain score to count for 50% of a hospital’s total performance score under the VBP Program. CHA agrees with this proposal because the outcome domain includes more measures and because an emphasis on patient outcomes is appropriate for the Hospital VBP Program.

■ Inpatient Quality Reporting Program

CHA supports the proposal to remove 39 measures from the Hospital IQR Program. Performance metrics on about half of the measures proposed for removal will remain on the Hospital Compare website because they are included in other Medicare hospital quality programs. For the measures that would be removed completely from Hospital Compare, we agree with the rationales offered by CMS, which are consistent with the goal of streamlining the measure set to focus on those that will best promote improved patient outcomes.

Four of the 39 measures proposed for removal are chart-abstracted measures. While CHA agrees with the removal of these specific four measures, we are not automatically opposed to the use of chart abstraction to gather data when it is necessary to achieve quality improvement goals, even though this data collection method represents the greatest reporting burden for hospitals. CHA further agrees with the removal of six condition-specific episode payment measures because these conditions have no related quality metrics and reviewing data on payments only is not useful to Medicare beneficiaries and other consumers. Collection of data on the two structural measures proposed for removal no longer has value. Finally, removing the seven electronic clinical quality measures (eCQMs) as proposed will still allow hospitals a choice in reporting while reducing burden on electronic health record vendors in maintaining measure specifications.

■ Reporting of Electronic Clinical Quality Measures (eCQMs)

The proposed rule would extend the current reporting period for eCQMs in the IQR Program. For the 2019 reporting period (FY 2021 payment determination) hospitals would submit one, self-selected calendar quarter of data on four self-selected eCQMs. CHA welcomes this proposal and encourages CMS to also finalize this policy for FY 2020, to be consistent with other requirements in the Promoting Interoperability Program. Giving hospitals some predictability and certainty about future eCQM reporting requirements will help them focus on refinements and best uses for electronic health records.

■ Promoting Interoperability Program

CHA appreciates that CMS is proposing changes to the Promoting Interoperability Program (formerly the Medicare and Medicaid EHR Incentive Program), such as a revised scoring system and streamlined objectives and measures that address concerns raised by providers in the past. We support the proposal to continue for 2019 and 2020 the current reporting period (any continuous 90-day period in the calendar year) to which eligible hospitals and critical
access hospitals (CAHs) must attest to meaningful use of certified electronic health record technology (CEHRT). Instead of moving to a one-year reporting period as would otherwise occur for 2019, this would continue a 90-day period for meeting meaningful use objectives and measures. CHA also supports the move from threshold reporting to a performance based methodology.

CHA has concerns with the mandatory use of Stage 3 requirements in 2019. There are still unresolved issue about data sources and technology functionality with some of the measures. We also believe that hospitals and CAHs would benefit from additional time to implement the 2015 edition CEHRT. If the 2015 edition CEHRT is required for 2019, we urge CMS to incorporate flexibility into the requirements. For example, vendor issues may prevent some providers from updating their technology. CMS should exempt providers in that situation from being penalized.

CHA supports the move to providing patients and consumers with enhanced access to their personal medical data and health records. But we also have significant privacy and safety concerns, from the perspectives of both individuals and providers, about how that information will be accessed. Significant consumer education is needed to ensure that individuals understand that the privacy protections of the Health Insurance Portability and Accountability Act (HIPAA) may not apply to third-party commercial apps. Individuals requesting to access their data through these apps may not realize they lose HIPAA protection of their data and that the apps may have inadequate or no privacy policies of their own.

In this age of cyber-attacks against hospitals, CHA is also concerned about hospitals being asked to have their information systems communicate with outside apps and technology in the absence of strong security standards and technology. Without these protections, hospital systems could be vulnerable to malware attacks and other security breaches. Hospitals must have the ability to deny access to suspect commercial apps. But doing so could have implications under the information blocking provisions in the 21st Century Cures Act. CHA urges CMS to consider these concerns as it develops regulations for that Act, and to work with the Office of the National Coordinator ONC and the Office of the Inspector General (OIG) to make sure that reasonable efforts by hospitals to secure their systems are not considered information blocking which would then trigger payment penalties for non-compliance.

We urge CMS to proceed with great care as it moves toward giving individuals easy access to their personal data, a move CHA supports. CMS should work closely with stakeholders and relevant agencies such as the ONC, the OIG and the Federal Trade Commission to ensure that consumers are able to have genuinely secure access to their data in a manner that protects both their privacy and the security of hospitals’ and health systems’ electronic data systems.
Request for Information on Promoting Electronic Interoperability

CMS seeks comment on whether conditions of participation for hospitals and other facilities should be modified to advance electronic exchange of health information in support of care transitions. **While CHA supports the goal of promoting electronic interoperability, we do not believe that the conditions of participation are an appropriate tool for advancing this goal.** Hospitals already have a very strong financial incentive to participate in health data exchange under the Medicare and Medicaid Promoting Interoperability Program: A hospital that fails to meet the requirements for meaningful use of CEHRT, which include healthcare information exchange loses three quarters of the market basket update factor under the IPPS. Smaller, low-volume facilities that may be lagging in meeting meaningful use requirements may be forced to close if interoperability becomes a condition of participation in the Medicare program. That outcome would not be in the best interest of Medicare beneficiaries and would not result in greater interoperability.

In closing, thank you for the opportunity to share these comments in regard to the proposed FY 2019 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,

Michael Rodgers
Senior Vice President
Public Policy and Advocacy