



June 24, 2019

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1716-P; 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

Submitted electronically via <http://www.regulations.gov>

Dear Administrator Verma,

Trinity Health appreciates the opportunity to comment on the proposed policy and payment changes set forth in CMS-1716-P. Our comments and recommendations to the Centers for Medicare and Medicaid Services (CMS) reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest multi-institutional Catholic health care delivery systems in the nation, serving diverse communities that include more than 30 million people across 22 states. We are building a People-Centered Health System to put the people we serve at the center of every behavior, action and decision. This brings to life our commitment to be a compassionate, transforming and healing presence in our communities. Trinity Health includes 94 hospitals as well as 109 continuing care locations that include PACE, senior living facilities, and home care and hospice services. Our continuing care programs provide nearly 2.5 million visits annually. Committed to those who are poor and underserved, Trinity Health returns \$1.1 billion to our communities annually in the form of charity care and other community benefit programs. We have 35 teaching hospitals with graduate medical education (GME) programs providing training for more than 2,000 residents and fellows in 184 specialty and subspecialty programs. We employ approximately 133,000 colleagues, including more than 7,800 employed physicians and clinicians, and have more than 15,000 physicians and advanced practice professionals committed to 23 Clinically Integrated Networks (CINs) that are accountable for approximately 1.5 million lives across the country through alternative payment models (APMs).

Proposals to Change the Calculation of the Wage Index

The area wage index is used to adjust Medicare operating and capital payments for geographic variations in labor costs. CMS proposes a number of changes to how it calculates and applies the Medicare wage index to address disparities between low wage and high wage hospitals and improve payment to rural facilities. To mitigate these changes, CMS proposes a 5 percent cap on any decrease from a hospital's wage index in FY2019.

Wage index adjustment

Beginning in FY 2020, CMS proposes to increase the wage index for low wage index hospitals (wage index value below the 25th percentile) and decrease the wage index for high wage index hospitals (wage index value above the 75th percentile) in budget-neutral manner. These adjustments would be effective for four years to allow time for increased wages to be reflected in the wage index calculation.

Trinity Health recognizes the need for policies to help support rural hospitals and the communities they serve and we urge the Department of Health and Human Services and Congress to continue to explore options. However, adjusting the wage indices as proposed by CMS is not the correct way to address the financial sustainability of low-wage hospitals. The proposed rule would inappropriately and arbitrarily shift funding from high wage hospitals to low wage hospitals—the wage index for high wage index hospitals is the result of actual wages and benefits paid to employees, not an arbitrary amount established by hospitals. **Trinity Health opposes this quartile adjustment and does not recommend CMS finalize the policy.**

As disparities among geographic regions and challenges faced by rural hospitals continue to grow, **Trinity Health recommends CMS work with Congress to create a new designated pool of funding for low-wage hospitals that is not subject to budget neutrality as part of a comprehensive, long-term approach to help these facilities.**

Urban to Rural Reclassification

CMS is proposing to remove wage index data from hospitals that undergo urban-to-rural reclassifications from the calculation of the rural floor, such that, beginning in FY2020 the rural floor would be calculated without using the wage data of hospitals that have reclassified.

Hospitals that reclassified did so under allowable HHS authority and as such, should not be penalized through this proposal. As outlined in the proposed rule, this policy creates a funding cliff for impacted hospitals, the extent of which the proposed 5 percent cap on wage index reduction will not mitigate. **Trinity Health recommends CMS does not finalize this proposal. Should CMS move forward with this policy, hospitals negatively impacted should be given a more reasonable phase down, while continuing to maintain a capped wage index reduction, so as not to inflict financial harm on these community hospitals.**

Medicare DSH

For FY 2020, CMS proposes to use FY 2015 Worksheet S-10 data to allocate the nearly \$8.5 billion uncompensated care (UCC) pool—an increase of about 2.6 percent from FY2019. Given changes in reporting instructions that became effective FY2017, CMS seeks feedback on whether the single year of Worksheet S-10 data should come from FY 2017 instead of FY 2015.

Since CMS implemented the DSH formula mandated by the Affordable Care Act in FY 2014, it has mitigated the impact of significant swings year-to-year by using a three-year average. Trinity Health acknowledges the importance of reporting accurate and consistent data on the

Worksheet S-10. **We urge CMS to continue existing policy of using a three year average of data, rather than one year, for allocating the UCC pool. If CMS is looking for an alternative to current policy, Trinity Health recommends CMS calculate the FY 2020 UCC factor 3 for each hospital based on two-thirds of their FY 2019 UCC factor 3 and one-third of their FY 2015 factor 3.**

Direct Graduate Medical Education

CMS proposes to modify the definition of “nonprovider sites” to include critical access hospitals (CAHs) and allow hospitals to claim residents training in a CAH in its FTE count as long as the nonprovider setting requirements are met. In addition, CMS is proposing flexibility that would allow hospitals to choose whether the CAH continues to incur the costs of training residents and receive 101 percent of reasonable training costs, or whether instead an IPPS hospital incurs those training costs and claims resident FTE time.

Under current Medicare policy, a CAH is not considered a “nonprovider setting,” which prohibits IPPS hospitals from claiming on their cost reports any time residents spend at CAHs, even if the IPPS hospitals incur the stipend and benefit costs for residents during their training at the CAH.

This proposal will help support residency training in rural and underserved areas, Trinity Health supports this policy.

Promoting Interoperability Programs (PIPs)

CMS proposes that hospitals report four self-selected electronic clinical quality measures (eCQMs) for one calendar quarter in both the PIPs and the Inpatient Quality Reporting (IQR) Program in 2020 and 2021.

Trinity Health appreciates CMS extending the requirement of 4 self-selected eCQMs for 1 calendar quarter through CY2021, as it has been challenging for EMR vendors and hospitals to respond in an efficient manner due to ongoing CMS maintenance and updates.

CMS proposes to revise the Query of PDMP measure to make it an optional measure worth 5 bonus points in CY 2020, remove the exclusions associated with this measure in CY 2020, require a yes/no response instead of a numerator and denominator for CY 2019 and CY 2020.

Trinity Health supports making this measure a yes/no option. Many of our providers have incorporated this action into their workflows but need more time to build the direct integration into their EHRs. This provides incentive for them to adopt this activity into their workflow now rather than wait for the built integration.

CMS is proposing to remove the Verify Opioid Treatment Agreement measure beginning in CY 2020. **Trinity Health supports this change, as we have not seen adoption of this activity by our providers, even with the optional bonus points.**

Quality

Hospital Acquired Conditions Reduction Program

CMS proposes several changes to HAC Reduction Program policies for FY 2020, although the program measures, data collection processes, scoring methodology, and the policies for review and correction of program data would remain unchanged.

CMS finalized in the FY2019 IPPS rule a HAC Reduction Program data validation process to replace the one used for the IQR Program. Under the policy, the five chart-abstracted NHSN measures will be subject to validation under the HAC Reduction Program. All subsection (d) hospitals are eligible for random selection for the data validation sample because they are subject to the HAC Reduction Program. Sample sizes were continued from the IQR Program: 400 randomly selected hospitals and 200 hospitals selected using targeting criteria.

In this rule, CMS proposes to modify the number of hospitals targeted from exactly 200 hospitals to “up to 200 hospitals,” to provide flexibility to avoid selection of hospitals simply to meet the 200 number. **Trinity Health agrees with this change; however, it is problematic that hospitals can be selected multiple years in a row between the IQR and OQR validations, random and targeted. Trinity Health recommends CMS modify the process of random selection for validation so that a hospital selected for validation (IQR or Outpatient Quality Reporting) would be exempt from random selection of either program in the subsequent year.** We are not opposed to a hospital selected first randomly and then as part of the targeted selection should the hospital fail initial validation, but the same Trinity Health hospital has been randomly selected for validation of abstracted measures (which include core measures and hospital associated infection measures) in three consecutive years.

Validation is a labor-intensive year-long process for the quality and health information management departments, where resources are limited. The same staff are supporting improvement initiatives for abstracted measures, eCQMs, and clinical processes. When resources are repeatedly required for administrative processes involved in validation, their availability for important quality improvement initiatives is reduced. **Trinity Health urges CMS to consider this process recommendation.**

Proposal to adopt the Hybrid Hospital-Wide All-Cause Readmission (HWR) Measure

CMS is proposing to remove claims-based Hospital-Wide All-Cause Readmission measure and replace with the proposed Hybrid Hospital-Wide All-Cause Readmission (Hybrid HWR) Measure, which had a 6-month voluntary reporting period in 2018, beginning with FY 2026.

Trinity Health supports moving away from claims-based data and supports requiring hospitals submit this data to the eCQM platform; however, the platform is unreliable and does not perform well. For the last three years, hospitals have been required to submit one quarter of data to the platform and we have had challenges reporting this data, as the platform is unable to handle the amount of traffic it receives when hospitals report just one quarter of data. As a result, CMS has had to extend the deadline each year for the reporting requirement and hospitals are unable to run real-time reports to confirm whether data has been submitted. **For these reasons, Trinity Health does not believe the platform can handle a complete year of reporting and recommends CMS delay the proposed requirement until CMS can demonstrate better performance and reliability of the eCQM platform.**

New Opioid Clinical Quality Measures

To address the Meaningful Measures priorities regarding prevention and treatment of chronic disease and reducing harm cause in the delivery of care, CMS proposes to adopt two new opioid-related electronic clinical quality measures beginning with the CY 2021 reporting period/FY 2023 payment determination:

1. Safe Use of Opioids—Concurrent prescribing eCQM. This measure calculates the proportion of patients age 18 and older who are prescribed two or more opioids or an opioid and benzodiazepine concurrently at discharge from a hospital-based encounter.
2. Hospital Harm—Opioid Related Adverse Events eCQM. This measure assesses the proportion of an acute care hospital's patients with an opioid-related adverse event during an admission as indicated by the administration of naloxone.

Trinity Health supports the proposed Safe Use of Opioids measure for IQR and PIP, as it will help to focus efforts to address the opioid crisis. The significance of this national crisis justifies implementing the eCQM change in CY2022.

Trinity Health does not support adding the new Hospital Harm measure. We strongly believe the measure will result in clinicians hesitating to use or withholding completely the administration of naloxone or appropriate opioid prescribing in the hospital setting. The immediate use of Naloxone is critical to life saving measures. We believe that this proposal will have the unintended consequence of limiting the use of this life saving medication.

Further, naloxone is not only used in situations where opioids are the known causation of respiratory depression, it is also used when it is unclear why a patient is in respiratory depression or as a first step of action to ensure opioids are not contributing to the condition of a patient. Because naloxone is administered to address respiratory depression caused by reasons other than opioid administration, this measure will not accurately capture adverse events and could unfairly penalize providers when it is used for resuscitation for conditions unrelated to opioids.

Trinity Health supports this measure only if it is used solely for the purposes of gathering statistical information and such information is not be used in any manner to penalize providers or hospitals.

New Hospital Inpatient Quality Reporting Measures

CMS outlined three potential future IQR program measures, all of which are eCQMs also under consideration for future addition to the Promoting Interoperability Program:

1. Hospital Harm-Severe Hypoclycemia. measures the proportion of patients who experienced a severe hypoglycemic event (low glucose test result of <40mg/dL) within 24 hours of the administration of an antihyperglycemic agent
2. Hospital Harm—Pressure Injury. measures the rate at which new hospital-acquired pressure injuries occur during an acute care hospitalization
3. Cesarean Birth—assesses rate of a woman who have never given birth with a term singleton term baby in a vertex position delivered by cesarean birth.

Trinity Health supports the three proposed eCQMs as the information can be easily found within the clinician workflow. Implementation of the measures will reduce patient harm, length of stay and reduce costs.

Proposal of new IQR measures

A large percentage of hospital patients are at risk of malnutrition and malnourished patients experience longer hospital lengths of stay, increased mortality, and increased readmission rates.

Standards of care, tools, and best practices to address malnutrition have not been systematically adopted across care settings, and is challenging to maintain consistent coordination and transitions among care providers to manage patient nutrition needs.

Trinity Health requests that the following malnutrition eCQMs adopted by the National Quality Forum be included in the hospital IQR:

- **NQF #3089/MUC16-372: Nutrition Care Plan for Patients Identified as Malnourished after a Completed Nutrition Assessment**
- **NQF #3090/MUC16-344: Appropriate Documentation of a Malnutrition Diagnosis**

Proposed Changes to the MS-DRG Diagnosis Codes

CMS is proposing to change the severity level designations for 1,492 ICD-10-CM diagnosis codes. **Trinity Health strongly disagrees with many of these changes, as outlined below.**

Malnutrition Diagnostic Codes

Malnutrition in hospitalized patients is associated with longer lengths of stay, higher mortality, higher readmissions, and higher cost. CMS is proposing to downgrade unspecified severe protein-calorie malnutrition (E43) from a major complication or comorbidity (MCC) to a complication or comorbidity (CC) and upgrade moderate protein-calorie malnutrition code (E44.0). Data shows that more Medicare beneficiaries are discharged from the hospital with a diagnosis of E43 compared to a diagnosis of E44.0.

The proposed rule does not include a rationale for the downgrade of this code and the described methodology and data used as a basis for this revision is unclear. **Trinity Health does not support this adjustment and we urge CMS delay making any changes in CC/MCC levels for E43 and E44.0 until other data can be analyzed to support or refute the proposed changes. We recommend CMS obtain data from the Agency for Health Care Research and Quality HCUP 2016 NIS dataset to discern cost differences between these ICD-10 codes.** This data can be filtered by age and payer and thus can be matched to the CMS dataset. In addition to these comments, we support comments submitted by the Academy of Nutrition and Dietetics and the American Society for Parenteral and Enteral Nutrition on this adjustment.

Neoplasm Diagnostic Codes

CMS is proposing to downgrade more than 700 neoplasm codes from a CC to a non-CC.

Patients with active neoplasm require additional resources and metastatic neoplasms have a major bearing on the treatment plans and on-going care of patients, as cancer patients are frequently admitted to hospital due to acute conditions or refractory symptoms. These symptoms revolve around the effects of the secondary tumors (e.g. pain, dyspnea, neurological symptoms due to brain metastases, intestinal obstruction) or effects of chemotherapy (bleeding or infection). **Trinity Health disagrees with these proposed downgrades.**

Sickle Cell Disease and other Anemia/Blood Disorders

Trinity Health disagrees with the proposed 26 downgrades for these codes. The sickle cell disease codes related to acute chest syndrome and splenic sequestration represent more severe forms of sickle cell disease. These patients require extensive monitoring or additional treatment related to shock. **We recommend the acute chest syndrome remain an MCC and the splenic sequestration remain at least a CC.**

Non-sickle cell disease codes within this section should maintain current MCC or CC status. These patients require Oncology/Hematology or other extensive evaluation, supportive treatment and diagnostic workup and are at increased risk of complications.

Other codes

- Type 2 diabetes mellitus with hyperosmolarity without non-ketotic hyperglycemic-hyperosmolar coma (code E1100) should remain an MCC as the coma is not driving the resource consumption, it is the hyperosmolar, hyperglycemic state.
- Diagnosis codes beginning with F related to intellectual disabilities, Autistic disorder, etc, should remain in CC status as these patients require a higher level of nursing care due to communication difficulties.
- STEMI codes (14 codes starting with I21 or I22) should remain an MCC as cardiac arrest and ventricular fibrillation are currently excluded if the patient succumbs.
- Cardiac arrest (codes I46.2, I46.8 and I46.9) should be at least a CC if expired and remain an MCC if patient survives event, as additional diagnostics and treatment modification will be required to determine underlying cause.
- Ventricular fibrillation (I49.01) should remain an MCC as immediate therapy and additional diagnostics are required to prevent death.
- Acute appendicitis with peritonitis codes (K32.20, K35.21, K35.30, K35.31, K35.32 and K35.33) should remain in the current MCC/CC status as a patient with peritonitis will require surgical procedures and additional resources to control infection.
- Crohn's Disease and Colitis (43 codes beginning with K50 or K51) should remain a CC as the condition signifies active disease which would require medications and diagnostics.
- Stage 4 pressure ulcers (L89.__4) should remain MCC status. In comparison to the less severe pressure ulcer stages that reflect superficial skin or subcutaneous tissue damage (CC status), the extent of stage 4 ulcers inherently involves greater resource utilization to include wound care consultation, bedside debridement/procedures, and a higher risk of deep infection.
- ESRD (N18.6) should remain an MCC. Consistent with the clinical severity inherent to organ failure, increased resource consumption (e.g. dialysis, renal consultation), and a greater length of stay, ESRD should retain equal MCC status with the other organ failure codes (that remain MCCs).
- Acute pyelonephritis (N10) should remain a CC. While a urinary tract infection (N39.0) remains a CC, proposed changes suggest downgrading code N10 to a non-CC. Acute pyelonephritis reflects an infection of the urinary tract to involve the kidneys, which can cause long-term organ damage, be life threatening, and take longer to resolve medically than a simple UTI (N39.0).
- Fracture of Pubis (18 codes beginning with S32) should remain a CC, as these require increased resources to complete activities of daily living and often require extensive inpatient therapy.
- Fracture of femur codes (36 codes beginning with S72) should remain an MCC to a CC, as lower limb fractures require increased resources to complete activities of daily living, ex: bathing, dressing, walking.
- BMI above 40 should remain CC with corresponding code for obesity condition and not downgraded. The actual clinical care of the patient with morbid obesity (defined by the Centers for Disease Control and Prevention as a BMI > 40) impacts resource use, health care costs, and needs for care that would not be reflected in the claims data that

serves as the basis for CMS work.

- Transplant Status codes (9 codes beginning with Z94) should remain a CC, as transplants require additional monitoring of organ functioning, often requiring additional in-house management by a consulting physician, treatment modification and anti-rejection drugs. Transplant codes themselves do not indicate that there is an acute condition, such as rejection. If an acute condition is identified, then the code reflecting the acute condition would serve as a CC instead, and would replace the use of the status code.

HL7 Fast Healthcare Interoperability Resources FHIR RFI

CMS is seeking comment on if ONC's proposal for a FHIR-based API certification criteria is finalized, would stakeholders support a possible bonus under the Promoting Interoperability Programs for early adoption of a certified FHIR-based API in the intermediate time before ONC's final rule's compliance date for implementation of a FHIR standard for certified APIs?

Trinity Health would be very supportive of a possible bonus as long as ONC clearly defines what FHIR version and what data information is made available via the FHIR-API to consumers. Our experience to date is that each EMR vendor states that they support FHIR-API however they only enable a minimum data set of information. In regards to FHIR STUv2, example;.

- EMR #1 enabled 19 of 92
- EMR #2 enable 24 of 92
- EMR #3 enabled 32 of 92

FHIR-API STU4 is the current standard and EMR vendors should be held accountable to enable the version within an acceptable timeframe.

General HIT Question

What criteria should CMS employ, such as specific goals or areas of focus, to identify high priority health IT activities for the future of the program?

Trinity Health applauds the direction CMS and ONC are moving toward for interoperability and supports the following CMS projects and goals, some of which were included in the recent proposed ONC and CMS rules:

- Requiring Medicare Advantage, Children's Health Insurance, Medicaid managed care, and QHP plans adopt a standards based API so beneficiaries can connect to an app of their choice and view their claims and aggregated clinical history within one business day of adjudication, this information should include patient costs sharing.
- Require plans to organize all data assembled on members for sharing with organization of the member's choosing. One option for implementation is the CMS "bulk API" standard in beta for Medicare ACOs.
- Requiring Part D health plans to delivery pricing information to physicians at the point of care.

In addition, we recommend CMS work with health plans to improve the accuracy of health plan provider directories.

Promoting Interoperability Program Questions

Proposed EHR reporting period

CMS invites comments on whether they are correct in thinking that there are no hospitals that would be able to receive Medicaid Promoting Interoperability Program payments in 2021. If this is not true, CMS is seeking comment on how they should adjust 2021 reporting periods for Medicaid eligible hospitals in a manner that limits the burden on hospitals and States.

CMS is correct—Trinity Health does have any hospitals eligible in 2021 for Medicaid incentive dollars.

Should CMS post data from PIP Measures on the Hospital Compare website?

Trinity Health supports transparency of measures. However, if this information is posted on the CMS Hospital Compare website, CMS should clarify who the intended audience is and what actions can be taken with this data.

Request for Information on the Provider to patient exchange objective

CMS seeks comment on whether eligible hospitals and CAHs should be required to make patient health information available immediately through the open, standards-based API, no later than one business day after it is available to the eligible hospital or CAH in their CEHRT.

Trinity Health is committed to working across the health care continuum to advance interoperability and to help consumers easily and securely access their electronic health data, direct it to any desired location, and be assured that their health information will be effectively and safely used to benefit their health and the health of their community. **We note the proposal under discussion could potentially delay the timing of providing patient information given the current requirement defines timely access as 36 hours, rather than one business day as noted in the above question.**

Conclusion

We appreciate CMS's ongoing efforts to improve payment systems across the delivery system. If you have any questions on our comments that follow, please feel free to contact me at granttw@trinity-health.org or 734-343-1375.

Sincerely,



Tina Weatherwax Grant, JD
Vice President, Public Policy and Advocacy