



June 25, 2018

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

Re: CMS-1694-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 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

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-1694-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. This includes our comments on CMS's requests for information (RFIs) on Price Transparency and Interoperability.

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. 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 that are accountable for 1.4 million lives across the country.

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 wellstk@trinity-health.org or 734-343-0824.

Sincerely,

A handwritten signature in black ink that reads "Tonya K. Wells".

Tonya K. Wells
Vice President, Public Policy & Federal Advocacy
Trinity Health

Hospital Requirements to Publicly List Standard Charges and Request for Information (RFI) on Price Transparency

The Affordable Care Act established section 2718(e) of the Public Health Service Act. This provision requires each hospital operating within the United States to make public a list of its standard charges for items and services including for diagnosis-related groups according to guidelines established by the Secretary. In the FY 2015 IPPS/LTCH rule (79 FR 50146), CMS reminded hospitals of their obligation to be in compliance with this provision by making public a list of their standard charges (whether that be the chargemaster itself or in another form of their choice) or their policies for allowing the public to view a list of those charges in response to an inquiry. The proposed rule describes CMS' concern that challenges continue to exist for patients due to insufficient price transparency. CMS cites challenges such as out-of-network bills for physicians, for example anesthesiologists and radiologists. CMS also acknowledges that chargemaster data are not helpful to patients for determining what they are likely to pay for a particular service or hospital stay.

Trinity Health strongly agrees with CMS that charge data is not helpful to consumers. It does not solve the price transparency challenge. Very few patients pay the charge regardless of their insurance status; and, therefore, this data is not meaningful to consumers and serves to only further confuse patients as a result. Trinity Health has considered the opportunity to adjust the chargemaster to make it more relevant and rational. However, because charges have been used for years as the basis of payment for single and multi-year contracts with public (including cost-report reconciliations) and commercial payers, the chargemaster is inextricably linked to reimbursement. In order to rationalize the chargemaster, Trinity Health (and all other providers) would have to renegotiate the majority of their contracts and this could have significant implications on the revenue stream.

Trinity Health is committed to working with consumers, payers and policymakers on developing the best solutions for achieving price transparency goals. Delivering people-centered care requires consumers have access to meaningful information about the price and quality of their care in order to foster personal engagement that promotes self-management and shared decision-making. Trinity Health hospitals are regularly working with patients to provide a deeper understanding of their potential out-of-pocket costs. Depending on the hospital across our 22 state footprint this is either done via an online price estimator or via a call-center utilizing a patient payment estimation tool to aid patients in better understanding their financial responsibility. This assistance is extremely meaningful to patients compared to the confusion created by reviewing charge data. Trinity Health hospitals also post important policies online, including financial assistance and charity care policies. It is our belief that consumers desire transparency to determine two key aspects of price. First, what is my out-of-pocket cost for this procedure/treatment for this provider? And, second, how does this provider's price compare to other providers that I could choose?

When asked by patients about what a specific procedure/treatment will cost, it can be difficult for providers to fully estimate exactly what that procedure/treatment will entail for any given patient. For example, a basic knee replacement can vary greatly dependent on the patient's age and the existence of any chronic conditions. Patients have also expressed their desire in knowing the total cost of care for specific procedures – i.e., all costs associated with that knee replacement including consults, tests, and post-operative visits required as part of the total care experience. **In order to mitigate this variance and to ensure that comparability between providers does exist, Trinity Health recommends that CMS—working with provider groups and payer stakeholders—develops a bundle of the most common—perhaps the top 25-50 inpatient and top 100 outpatient—procedures as a reasonable starting point. This would create some standardization of typical procedures towards accomplishing the goal of comparison shopping. After identification of these "shoppable" services by population, payers should provide hospitals and health systems with accurate information for their enrollees.**

It is critically important that patients understand the basic components of their insurance plan coverage to be well-informed consumers. Consumers first need an understanding of in-network providers, including physicians, hospitals and outpatient centers. They also need an understanding that the price of patient care can vary, including out-of-pocket costs; and that out-of-network cost sharing is higher. **Payers best know the plan benefits for individual patients, and, therefore, should be held accountable to providing the information and tools to providers so that we can better assist our patients in receiving an accurate estimate of out-of-pocket costs.** The payers—whether Medicare, Medicaid or a private insurance plan—establish cost-sharing obligations, which takes into account whether the plan covers the service, whether the provider is in the plan's network, the plan's cost-sharing requirements, and, if applicable, where the individual is in their deductible. Providers, today, do not have access to this information. **Trinity Health recommends that payers provide this information to hospitals and health systems via a web-based portal that providers can use to respond to patient inquires. Ideally, the portal would contain information on where the patient is within their deductible so that the provider can relay cost estimates that are accurate and most relevant for that particular consumer based on their insurance coverage.**

Understanding health care terminology around price poses significant challenges for consumers. If you ask a group of people to define what "price" is, it is likely you will get a variety of answers. **Trinity Health urges CMS to consider the below definitions to help frame understanding on this issue and inform policymaking on price transparency:**

- **Charge:** The dollar amount assigned to specific medical services before negotiating any discounts from payers or providing discounts to uninsured patients. The charge is different from the price. As stated earlier very few patients pay the charge regardless of their insurance status; and, therefore, this data is not meaningful to consumers.
- **Price:** The negotiated and contracted amount to be paid to providers by payers (also called the "allowed amount") or the discounted amount for uninsured patients. An insured patient's out-of-pocket liability for health care services is based on this allowed amount. Note that the price for a given service varies by insurance plan as these are separately negotiated by plan/employer.
- **Cost:** The definition of cost depends on the cost being referenced:
 - **Patient Cost** is the **out-of-pocket cost** to the patient, which includes the portion of payment for medical services and treatment for which the patient is responsible. This includes copayments, coinsurance, and deductibles.
 - Provider cost is the expense incurred to provide health care services to patients.
 - Employer cost is the expense related to insuring its employees, and this will depend on whether the employer is paying premiums to insure its employees or if it self-insured and paying claims for health care services.
 - Insurance plan cost take two forms, allowed and paid costs. The allowed cost is total price allowed by the contract. The paid costs is the portion paid by the insurer.

The above definition of price should guide policymaking on transparency so that data is meaningful to patients. To the extent that CMS is interested in price comparison tools, Trinity Health reiterates that only payers, including CMS for the Medicare population, have complete information about what their enrollees may pay for the same service at different in-network providers. **Payers need to work with providers to ensure meaningful disclosure of pricing information that is relevant to patients.** This should include consistent, standard, accurate and reliable information about plan options; including, covered benefits, prescription drug formularies, provider networks, and out-of-pocket patient liabilities. Also, as CMS notes, patients receive bills from the hospital facility and from the physician. It is not reasonable to hold hospitals accountable for physician bills. It is also important to note that multiple providers may provide services and bills to

the patient, so it is likely that the patient will still need to go to more than one source to get all the information.

Given the challenges associated with making price information more easily accessible, Trinity Health discourages CMS from taking a punitive approach against providers who cannot meet all patient expectations for price transparency. **Instead, Trinity Health encourages CMS to convene hospitals, physicians, payers, consumers and employers to explore ways to increase consumer health care literacy, especially around their health plan benefit design, and develop the best framework for this sharing of out-of-pocket costs from payers to providers.**

Request for Information (RFI) on Interoperability

Interoperability is a key strategic imperative for Trinity Health. 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. We believe that interoperability is essential to a high-performing People-Centered Health System because it allows the widespread exchange of structured and standardized health information through interoperable health information technology (health IT). This makes it simpler to place the patient at the center of an interconnected system of his/her own medical data and helps care providers meet a patient's needs in a more comprehensive and concise manner by eliminating barriers to data sharing and care coordination.

Trinity Health appreciates the commitment of CMS and the Administration to advancing interoperability, and we would be pleased to be a partner in that effort. We appreciate and agree with the efforts to improve the Meaningful Use program that were included in the IPPS rule, as included in our below comments. We recognize the laudable goals driving CMS's efforts to look for additional, and potentially streamlined, levers with which to accelerate the pace of progress toward our shared goal of interoperability.

In this spirit, Trinity Health supports requiring all acute care, post-acute care and skilled nursing facilities to attest that they are regularly transmitting Admit, Discharge and Transfer (ADT) HL7 compliant transactions to established community-wide, regional or state-wide health information exchanges (HIEs) or similar repository that act as vehicles for disseminating information, when such vehicles are available. We believe requiring such transmission is reasonable when a community resource is available and capable of receiving the transmissions. This is a reasonable and achievable expectation with the existing technology and market maturity. Everyday Trinity Health facilities are transmitting more than 200,000 ADTs. We believe that sharing of such data is essential for care coordination, particularly as it pertains to handoffs.

We strongly urge that facilities be accountable for transmission only, as it is not realistic to hold facilities responsible for assuring receipt of such transmissions, nor to hold them accountable to transmit to specific providers. Trinity Health believes that care coordination for patients is most effective when community-wide capabilities are available to all providers. Lastly, we do not support requiring transmissions to individual providers; investing to create a community information exchange is more efficient, effective and smarter spending of the health care dollar.

It is also our recommendation that regulatory guidance require that all participating providers attest annually that they are transmitting ADT notifications. This attestation requirement could be effectuated through the anticipated information blocking rulemaking or any other appropriate vehicle. Based upon review of industry compliance and adherence to an attestation standard, CMS can determine if more extensive regulatory requirements—such as tying this to Conditions of Participation, Conditions for Coverage or Requirements for Participation for long-term care facilities (CoPs, CfCs and RfPs)—is necessary.

Trinity Health believes strongly that federal leadership and action steps are needed to move the nation more expeditiously to interoperability. While the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program (now the Promoting Interoperability Program) did successfully drive adoption of EHRs, the program remains largely government-driven rather than patient-centered, which has led to “tick the box” government requirements that have failed to advance patient care, improve clinician workflow, or make the substantial progress toward interoperability that was envisioned when the program was enacted. Following are our specific recommendations on which the Department of Health and Human Services (HHS) and the Administration can provide leadership, in concert with the private sector, to advance progress toward interoperability:

1. **Accelerate public and private sector efforts toward the consistent implementation of uniform national standards for health information technology.** Adherence to open-source, consensus-based, transparent standards that are sufficiently mature should be a priority, and should be an essential aspect of certification of electronic health record technology. While great progress has been made on standards, there is significant additional work to be done; for example, existing standards in areas such as lab, vital signs, and clinical documents need to be deepened. New areas such as scheduling, pathology reports and patient-reported data are needed. That said, it is important that we make use of existing standards whenever possible; we should not start over. Health IT vendors often provide tools designed to help with interoperability but too often providers are required to develop new workflows that add time without patient or other benefit. Vendors should be required to build new tools within existing workflows. Vendors should also be required to have easily available metrics to measure outcomes. Certification should test EHRs for usability in a broad array of settings, from complex academic medical centers to rural critical access hospitals. Post-installation testing should confirm that installed systems work as intended.
2. **Align Promoting Interoperability Program requirements (previously Meaningful Use and Advancing Care Information requirements) for physicians and hospitals.** Parity in program requirements is essential, and we appreciate CMS proposing steps in that direction in the FY 2019 IPPS proposed rule. Although Trinity Health physicians and hospitals have enjoyed significant success in the Meaningful Use program, the tremendous effort required to meet established Meaningful Use goals has diverted clinician and staff attention as well as considerable resources away from activities with greater direct patient benefit, away from activities with more significant clinician benefit, and away from efforts to advance interoperability.
3. **Accelerate movement toward value-based care, which would provide additional incentives for care coordination and data exchange.**
4. **Promote an effective national strategy for accurately matching patients to their data.** One of the primary challenges impeding the safe and secure electronic exchange of health information is the lack of a consistent patient data matching strategy. Consistency in patient data matching is foundational to interoperability and remains conspicuously absent. Consistency in patient matching is also essential to patient safety and to ensuring that the information in a patient’s EMR actually belongs to that patient and includes all available information.
5. **Establish common national standards for privacy and security.** This will improve the appropriate and secure flow of health data. The current patchwork of state laws impedes information flow.
6. **Require consumer interoperability standards so that it is easy for consumers to access all their information, free of charge, and incorporate it into any certified tool they wish to use.** Make it easy for patients to collate data from multiple sources, creating useful information which is easy to understand and share with their care team. Consumer interoperability standards must be prioritized, and they should be a part of the government’s certification program.

Improvement in authentication standards for consumer applications is needed; for example, consumers should not be forced to sign in each and every time they access information.

7. **Work in cooperation with providers on health care cybersecurity, an essential public health concern.** Insist on greater security and resilience in medical devices. Take steps to assist and incentivize providers, particularly smaller providers, in developing and maintaining good cyber hygiene and in learning about and addressing current and emerging cybersecurity threats. Insist that device manufacturers incorporate patient safety into product design and work in partnership with providers and patients to make transparent a device's cybersecurity capabilities. Make certain that device security is a shared responsibility of manufacturers and providers.
8. **Create a trigger mechanism for ending the Promoting Interoperability program for hospitals.** This is important because the program currently has no sunset date. While physicians have been moved into the MIPS program, which provides opportunity for bonuses and penalties, hospitals remain in the original Meaningful Use program (renamed the Promoting Interoperability Program), which now has only penalties. Consider the development of a mechanism that would trigger the sunset of the program once a sufficient number of Medicare hospitals successfully attest to Stage 3.

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. As Trinity Health works toward a People-Centered Health System, we are also working to provide appropriate opportunities for patients to capture, use and share their health data electronically with providers through the use of personal health devices, personal health tracking tools and more traditional medical devices for remote monitoring. This is part of our commitment to putting the people we serve at the center of every behavior, action and decision.

Thank you, again, for the opportunity to submit our views on this topic. Without interoperability, the potential of health IT will not be fully realized and patients will continue to be stymied in their efforts to access their own electronic medical records.

Promoting Interoperability Program – Formerly the Medicare and Medicaid EHR Incentive Program

Renaming the Medicare and Medicaid EHR Incentive Programs

CMS is renaming the Medicare and Medicaid EHR Incentive Programs as the Medicare and Medicaid Promoting Interoperability Programs. **Trinity Health supports changing the name to focus on interoperability.**

Certification Requirements Beginning in 2019

CMS proposes no changes to its previously finalized policy for 2019 under which eligible hospitals and CAHs must use EHR technology certified to the 2015 Edition of Certified EHR Technology (CEHRT). **Trinity Health supports the use of the 2015 Edition of CEHRT, and encourages CMS to employ flexibility in CEHRT requirements.** We are concerned that some providers' migration to the 2015 Edition may be slowed due to vendor backlogs in updating their technology. **CMS should not penalize providers who are prohibited by their vendor from using the 2015 Edition by allowing a hardship exemption.**

Reporting Periods for 2019 and 2020

CMS proposes that for 2019 and 2020, Medicare and Medicaid Promoting Interoperability Program participants would attest to meaningful use to CMS or to the state for a minimum reporting period of any continuous 90-day period during the calendar year (2019 or 2020, respectively). **Trinity Health supports the proposed reporting period of any continuous 90-day period during the calendar year for 2019 and 2020. Furthermore, we believe that CMS should consider establishing a continuous 90-day reporting period for years 2021 and beyond,** given the uncertainty surrounding several anticipated rules (i.e, APIs and information blocking) along with the yet-to-be determined timelines for the Trusted Exchange Framework and Common Agreement (TEFCA) and USCDI implementation.

CEHRT

Trinity Health believes that CEHRT products should be recertified to a new version of CEHRT shortly after the new version is available; for example, within 12 to 18 months depending upon the complexity of the new CEHRT requirements. Ensuring CEHRT is up to date will enable providers to meet reporting requirements. We caution that new CEHRT versions should be major revisions that address overarching health IT goals and impact storing, collecting and transferring data. Requiring vendors to regularly recertify to new CEHRT versions with minor changes will be a significant financial burden to providers as vendors often pass on recertification costs to providers. CMS and ONC should impose fines on vendors who attest to the update and then are not able to meet the requirements; providers using vendors unable to meet new requirements should be allowed hardship exemptions from the reporting requirements. **Prior to implementing new or revised PI objectives/measures, CMS should ensure that the measures are field tested and are feasible in all applicable reporting methods.** This will help determine if the measure specifications are precise or open to interpretation. CMS should strengthen oversight of certified technologies' ability to calculate and validate data fidelity with regard to data, place, format and level of attribution. The CEHRT requirements should ensure that standardized data elements are implemented and supported to populate measures for all the federal reporting programs; ideally we believe it is essential for the certified technology be able to calculate the measures; at a minimum they should be able to seamlessly and reliably produce the required data elements. Certification should promote high fidelity data to reduce variability across EHRs, bi-directional exchange of information using Application Programming Interfaces (API) and timely data to enable interoperability

Scoring Methodology for Eligible Hospitals and CAHs

CMS proposes major changes to the scoring system used to determine whether an eligible hospital or CAH has met the meaningful use requirements beginning with the 2019 reporting period. The proposed new scoring system relies on fewer measures and eliminates the threshold-based methodology currently used. **Trinity Health appreciates CMS' efforts to reduce burden and increase reporting flexibility for hospitals.** We are supportive of CMS' proposals to reduce the number of measures to be reported, allow exclusions and award bonus points in 2019. However, as we note in our comments above about specific proposed measures changes, we are concerned that the proposed measures and scoring system do not adequately relieve providers of significant documentation and reporting burdens.

Trinity Health is generally supportive of the change away from threshold reporting. However, we believe that the proposed change from a threshold to a performance based scoring methodology would be a major change for providers. **Trinity Health asks that CMS not make any more changes to the objectives and measures finalized for FY 19 reporting for at least two years, allowing hospitals to acclimate to the new scoring method. Similarly, CMS should allow a two-year period of voluntary reporting, with bonus points awarded, for any new measures finalized for FY 19.** Given the number of proposed removed measures, along with the proposed new scoring methodology, it is not possible to comment broadly about the potential ramifications for

individual hospitals, groups of providers, or to the system overall. Trinity Health is concerned that CMS has not provided sufficient information about the proposed new scoring methodology to allow a full evaluation. Trinity Health is concerned that without data we are unable to adequately assess measure weights. CMS should provide complete descriptive statistics reflecting hospitals' performance on each measure with the new methodology and scoring before proceeding with any future measure changes or revisions. CMS needs to provide data to realistically evaluate potential impact of the proposed new measures and the impact of the proposed new scoring methodology. **CMS should provide detailed information on all hospital performance, monitor performance over time and provide this information prior to any future proposed changes.**

Measure Scoring

Trinity Health recommends that **CMS consider alternative scoring methods that would provide hospitals and CAHs even greater reporting flexibility, such as allowing eligible hospitals and CAHs to select among measures within an objective.** CMS employed a similar approach in the Merit-Based Incentive Program Advancing Care Information category. We believe this approach will allow hospitals the opportunity to choose which measures best fit their approaches to advancing interoperability.

Additionally, we are concerned that the proposed performance score methodology is empirically assessed, that is, the performance rate is directly translated into points (i.e., 80 percent is awarded 8.0 points). This method assumes that it is feasible to achieve 100 percent on any of the measures. We are concerned about providers' ability to control performance on these measures and the lack of available data on how providers will perform on the new/revised measures. **Trinity Health suggests that CMS establish benchmarks and award points on decile breaks rather than using empirical scoring.**

Use of Health IT Activities

Trinity Health supports CMS' effort to encourage the use of health IT and suggests that at a minimum, CMS provide bonus points for activities that require health IT use, rather than only recognize the use of CEHRT. We believe this approach will encourage more innovative approaches for using health IT to improve quality of care and ultimately to achieve interoperability.

Implementation of CMS's "Meaningful Measures" Framework and Overall Quality Program Comments

Trinity Health expresses appreciation for CMS' proposed implementation of its "Meaningful Measures" framework across the hospital quality reporting and value programs. Trinity Health has long encouraged CMS to remove redundancy when selecting measures across programs, evolve all quality reporting to focus on outcome rather than process measures, and ensure harmonization across quality reporting programs, including utilization of the same definitions. **Trinity Health strongly believes that quality measurement should be focused on a small number of metrics that emphasize patient-reported and patient-generated data and urges CMS to continue this path of focusing on outcomes-based measures that are meaningful to patients and reflect successful performance toward improving care and outcomes and reducing costs.**

Trinity Health also expresses appreciation that CMS is exploring how to accurately measure and incorporate social risk factors into multiple quality and payment programs. Trinity Health takes a holistic view to caring for each patient – we are not only assessing the disease process but working diligently to understand the role that each patient's environment and social determinants play in his or her health status. We believe this is essential to delivering people-centered care. **Trinity Health continues to urge that quality measure data be risk-adjusted for sociodemographic factors. Significant factors include: income, education, race (including ethnic background), payer type, patient travel distance (derived from their zip code), homelessness and language**

proficiency, all of which have been shown to have a significant relationship to a person's health outcomes.

Hospital Inpatient Quality Reporting (IQR) Program

Trinity Health supports the proposed removal of the list of structural and chart abstracted measures. Trinity Health very much supports the use of quality metrics that can be derived from electronic health records (EHRs) and submitted to CMS electronically, but we also want to ensure these electronic measures are accurate and reliable, the timeline for submission is realistic, and that the CMS submission portal is effectively operating for hospitals and vendors to be able to reliably submit and fulfill requirements in a timely manner. **We continue to urge CMS to: develop a long-term eCQM strategy that focuses on metrics that emphasize patient outcomes and patient-generated data; articulate that strategy in a step-wise process; and build that timeline to include performance measurement in future years so vendors and hospitals can begin planning now.**

Beginning with calendar year 2020, CMS is proposing removal of seven Electronic Clinical Quality Measures or eCQMs from IQR and eight for Promoting Interoperability (MU). **Trinity Health recommends that the eCQM measure removal occur for calendar year 2019 rather than 2020. This would prevent additional work for vendors and hospitals to update internal reporting to the new measure specifications/value sets anticipated in late calendar year 2018.**

CMS is seeking comment on adopting a hospital-wide mortality measure; specifically whether to adopt a claims-only measure; an all-cause risk-standardized measure; or a hybrid risk-standardized measure (incorporating claims and EHR data). **Due to the industry's lack of validated experience working with a hybrid measure, Trinity Health—at this time—supports a claims-based hospital-wide mortality measure.** CMS is also seeking comment on adopting the Opioid eCQM; specifically, whether to introduce it as voluntary; incorporate into eCQM measure set where hospitals can select 4; or adopt as mandatory for all hospitals to report. Trinity Health recommends that CMS incorporate this into the eCQM measure set where hospitals can select four measures. Since CMS is removing eCQMs from the measure set, this would provide an additional measure to choose and would allow hospitals to measure system-wide.

Trinity Health encourages CMS to extend the calendar year 2017 and 2018 process for eCQM validation through calendar year 2019; specifically, Trinity Health asks that hospitals selected for validation are not evaluated based on eCQM accuracy as CMS validation has not yet occurred and therefore the results of eCQM validation for calendar year 2017 are not yet available. The Joint Commission published an assessment of comparative information between chart abstracted and eCQM data; however the eCQM sample included hospitals that voluntarily submitted for 2015 and was very small (<50 hospitals), and the analysis was not a matched pair analysis. Hospitals should not be subject to penalty at this time based on eCQM accuracy since a valid assessment is not yet available.

Lastly, Trinity Health asks that CMS consider modifying 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. Trinity Health is 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 hospitals have been randomly selected for validation of abstracted measures (which include core measures and hospital associated infection measures) in two 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.

Hospital Value-Based Purchasing (VBP)

CMS has proposed that the Hospital VBP Program should focus on measurement priorities that are not covered by the HRRP or the HAC Reduction Program. As such, CMS proposes select metrics that track patient safety measures, including five measures reported through the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) be removed from VBP and IQR (effective for FY 2021) as they already are part of the HAC Reduction Program and will continue to be reported on Hospital Compare. **Trinity Health agrees with and supports this proposal as it will eliminate duplication of the NHSN metrics from multiple IPPS programs.**

HOSPITAL-ACQUIRED CONDITIONS (HAC) Reduction Program

Data Collection

CMS proposes to adopt IQR Program data collection processes for the HAC Reduction Program. All reporting requirements, including quarterly frequency, CDC collection system, and deadlines would remain unchanged from current Hospital IQR Program requirements to ensure there are clear and consistent requirements for hospital reporting. The program would begin receiving NHSN measure data beginning with January 1, 2019 infection events. **Trinity Health supports this proposed transition and its elements of performance.**

Data Validation

Currently, a hospital that fails to meet any part of the validation process receives a full payment reduction. CMS proposes that a hospital that fails validation would be assigned the maximum Winsorized z-score only for the set of measures that CMS validated rather than an “all or nothing” assignment of maximum scores for the entire domain. **Trinity Health supports and appreciates CMS’s efforts to identify an approach that is a more precise and focused validation.**

Supporting Documentation Required for Submission of an Acceptable Medicare Cost Report

Each cost report submission requires the supporting documentation specified in § 413.24(f)(5)(i). A cost report submitted without the required supporting documentation is rejected under § 413.24(f)(5)(i). Under § 413.24(f)(5)(iii), when the cost report is rejected, it is deemed an unacceptable submission and treated as if it had never been filed. CMS is proposing several changes to the supporting documentation requirements, with rejection of the cost report being the penalty for non-compliance. **Trinity Health recommends, alternatively, that should a discrepancy be noted, since several of these proposals relate to agreement of dollar totals of long detailed listings of patients or interns and residents, that the provider (i.e. hospital) be notified by the Medicare Administrative Contractors or MACs upon discovery and given a reasonable time frame (i.e. thirty days) to address and reconcile the discrepancy. The immediate rejection of the cost report and cessation of all Medicare payments would be too harsh and disproportionate a penalty for addition errors or transpositions of numbers.**

The following provides comments to each of the areas addressed in the proposed rule under this section:

For most cost report types, the CMS Form 339 Questionnaire has been incorporated as a worksheet, except for the CMS-216. CMS proposes to incorporate the 339 Questionnaire into the CMS-216, and therefore officially eliminate the requirement to file the 339 Questionnaire as supporting documentation for the cost report. **Trinity Health supports this proposal to eliminate the CMS Form 339 Questionnaire filing requirement.**

CMS already requires submission of the Intern and Resident Information System (IRIS) for teaching hospitals as part of the acceptable cost report supporting documentation. CMS is proposing that both the unweighted and weighted GME FTE and IME FTE resident counts agree between the IRIS

and the respective cost report schedules. However, Trinity Health points out that the IRIS program itself does not provide the FTE count totals. The user must have the knowledge and ability to import the IRIS report details into another propriety program, such as Microsoft Excel, and run their own totals to determine the IRIS report FTE totals. If CMS is going to require—for cost report acceptance—that the IRIS FTE totals and cost report FTE totals agree, then the IRIS program must be able to easily provide those totals without having to import that data into another software program. **Providers should be able to transcribe the FTE totals directly from the IRIS program reports to the cost report schedules. Until providers can view and confirm the FTE totals in the IRIS program itself, this proposal should not be finalized.**

CMS already requires submission of the Medicare bad debt listing as a supporting documentation requirement. **The proposal that the bad debt listing total correspond to the amount claimed on the cost report is a logical requirement, and Trinity Health agrees with this proposal.**

CMS does not currently require a listing of the Medicaid eligible days for use in the Disproportionate Share Hospital (DSH) calculation upon filing of the cost report; but rather, the auditor requests the listing, and typically any updated listings, when beginning to scope their desk review and audit. **CMS is proposing to require—as cost report supporting documentation—a detailed listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed on the hospital's cost report. Trinity Health urges against this as a filing requirement.** As pointed out in Provider Reimbursement Review Board (PRRB) Alert 10 and *Danbury Hospital v. Blue Cross Blue Shield Ass'n*, not all Medicaid eligible Medicaid days are documented as such in time for the cost report filing. Medicaid Pending accounts, in some cases, can take several months to finalize. The total Medicaid eligible days documented through a State Medicaid days eligibility analysis, which is run in time for cost report filing, can be much lower than one run several months later. While many providers file the Medicaid days based on their latest Medicaid eligibility reports, some providers may choose to use their in-house census reports or summaries to report the Medicaid and Total Patient Days on their original submitted cost report, and not have the full support for Medicaid eligibility from the State for their entire Medicaid population at hand when completing the cost report, due to outstanding Medicaid Pending cases.

With respect to the DSH Uncompensated Care Pool (UCP) allocation, CMS has begun the transition from using the proxy data of SSI and Medicaid days to the S-10 reported charity care and bad debt amounts. CMS is therefore proposing to require, effective for cost reporting periods beginning on or after October 1, 2018, for DSH eligible hospitals reporting charity care and/or uninsured discounts, a detailed listing of charity care and/or uninsured discounts that correspond to the amounts claimed on the cost report. To obtain detailed patient level listings in a usable format may present a challenge for hospitals to obtain from various patient accounting systems, and involve manual processes and manipulation, which could be a burden during the timeframes allotted for timely filing of the cost report. **Trinity Health recommends that CMS provide a transition period of two to three years to allow for providers and patient accounting system vendors to develop processes and procedures that would allow for the efficient, automated gathering of this documentation in a format that would allow for easy submission with the cost reporting package.**

CMS already requires submission of the home office cost statement by providers claiming home office cost allocations. CMS is now proposing that the home office cost statement that is submitted corresponds to the amounts allocated in the provider's cost report. **Trinity Health, again, recommends that additional time for submission and reconciliation be provided, as this would be a better remedy than rejection of a provider's cost report.** The current filing deadline time allotted to both providers and home offices is five months from the end of the fiscal year, therefore, in many cases both the provider and the home office have the same filing due date. With the due dates of home office and provider cost reports coinciding, many providers use the prior year home office numbers for the original cost report submission; and update it after the submission when the actual home office cost statement for the fiscal year has been completed and distributed to the providers. If a corresponding home office cost statement is to be required for the cost report to be

accepted, allowance should be made for the use of the prior home office cost statement for an original provider submission, and subsequent update. Another instance where allowing for the interim use of the prior year home office cost statement could be useful is when the home office and the providers have different fiscal year ends, as several states require providers to use a particular year end for cost reporting, i.e. 6/30, 9/30, and 12/31, while the remainder of the multi-state health system is on another fiscal year end.

Wage Index—Application of the Imputed Rural Floor

In FY 2005, CMS temporarily adopted an “imputed” rural floor policy by establishing a wage index floor for those states that did not have rural hospitals. CMS has subsequently extended this policy through FY 2018. However, CMS does not propose to extend the policy again. Trinity Health is disappointed that CMS is not extending the imputed rural floor in the absence of more comprehensive area wage index reform. As the country moves to payment for value and alternative payment models (APMs) the importance of these policies will be lessened; but, currently the wage index remains an important component of fee-for-service payments.

The imputed rural floor is an equitable measure established by CMS which provides relief to hospitals in all-urban states. This long-standing policy has reduced volatility and increased the equitability of the wage index system. We do not believe that CMS should remove the imputed rural floor from all-urban states. Regarding CMS’ concern with the payment impact from the existing imputed floor policy to states with rural hospitals which do not have urban hospitals that benefit from a rural floor, we believe this should be reviewed as part of a comprehensive review of the Medicare wage index system rather than an isolated component. **Trinity Health recommends that the industry consider all recommended changes to area wage index reform and have a chance to provide input to CMS prior to finalizing any decisions regarding elimination of the imputed rural floor. This elimination would greatly impact our Trinity Health safety-net hospitals in Trenton and Camden, New Jersey. If there is a decision made to eliminate the imputed rural floor, that decision should include a two year notification period to allow impacted hospitals appropriate planning time.**

Furthermore, CMS has also disadvantaged providers in all-urban states through its refusal to recognize rural census tracts in all-urban states as a rural area. This occurs via application of Sec. 412.103 which states “Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of 42 CFR 412.103.” This Section clearly identifies rural census tracts within urban areas as a rural area for purposes of applying Section 412.103. **CMS should allow providers in all-urban states, which have rural census tracts in urban areas, to utilize Section 412.103.** New Jersey, for example, has multiple rural census tracts spread over 5 counties and comprising over 100,000 in population. These federally identified rural areas and classifications are not insignificant in either area or population and should be recognized by CMS for purposes of applying Section 412.103. This suggested handling would be congruent with current law, congruent with other federal programs recognizing these areas as rural, create a more equitable wage index system, and provide a potential relief mechanism to those providers disadvantaged by the removal of the imputed rural floor.

DSH Uncompensated Care Pool – Statistical Trims to Anomalous CCRs

Within the computation of the DSH Uncompensated Care Pool (UCP), utilizing S-10 data is the application of the hospital cost-to-charge ratio (CCR). CMS is proposing to continue to apply statistical trims to anomalous hospital CCRs using the method adopted in the FY 2018 IPPS final rule, just as they apply trims to hospitals' CCRs to eliminate anomalies when calculating outlier payments. **Trinity Health recommends that CMS publish, or individually notify, which hospital's CCRs were deemed anomalous and afford the hospitals a chance to support the CCR prior to it being adjusted.** No hospital should have its data adjusted or eliminated without being notified and afforded the opportunity to respond. CMS noted that application of the trims to the

S-10 data for UCP purposes is similar to how they apply trims to CCRs in the calculation of outlier payments. However, the outlier CCR trim is part of the calculation of a national threshold amount, which is applied to all hospitals equally. The UCP CCR trim is being applied to a specific hospital's reimbursement determination, and is therefore not the same, and the hospital should have the opportunity to be notified and to provide additional data and documentation to support the CCR and contest the trim adjustment.

Reclassification Requirements for a Provider That Is the Sole Hospital in the MSA

CMS is proposing to address a problem faced by hospitals which are the sole hospital in their Metropolitan Statistical Area or MSA. In cases in which a hospital wishing to reclassify is the only hospital in its MSA, that hospital is unable to satisfy the 108/106 percent average hourly wage standards criterion because it cannot demonstrate that its average hourly wage is higher than that of the other hospitals in the area in which the hospital is located because there are no other hospitals in the area. CMS is proposing that, for reclassification applications for FY 2021 and subsequent fiscal years, a hospital would provide the wage index data from the current year's IPPS final rule to demonstrate that it is the only hospital in its labor market area with wage data listed within the 3-year period. **Trinity Health supports this CMS proposal, which would decrease unnecessary burdens on such hospitals.**

Codifying Policies Regarding Multicampus Hospitals

CMS has received an increasing number of inquiries regarding the treatment of multicampus hospitals. Current regulations do not directly address multicampus hospitals, therefore CMS is proposing to codify the policies they developed in response to recent questions. CMS is proposing that the main campus of a hospital cannot obtain a Sole Community Hospital (SCH), Rural Referral Center (RRC), or Medicare Dependent Hospital (MDH) status or rural reclassification independently or separately from its remote location, and vice versa. CMS proposes to require that each location independently meets all criteria. CMS states that reasoning for this proposal includes that it would not be administratively feasible for CMS and the MACs to track every hospital with remote locations within the same core based statistical area or CBSA, as CMS only requires hospitals to report multicampus locations on the cost report when they are in separate CBSAs. For similar reasons, Trinity Health believes that it is not feasible for providers to calculate distances between themselves and another provider's remote campus, as only the main campus address is included in Healthcare Provider Cost Reporting Information System (HCRIS) cost report data, and even where the other hospitals may report multicampus hospitals in different CBSAs on their cost report, the remote campus data only includes the hospital name, county, state, zip, and CBSA, meaning there is no street address for actual distance calculations to another hospital's remote location. **Trinity Health recommends that CMS not implement this proposal until such time that CMS changes the cost report S-2 questions (i.e. 165 and 166 of the 2552-10) to include the street address of all remote locations (including those in the same CBSA), and that cost report information becomes available in the published HCRIS data, so that hospitals can properly research and identify both main campus and remote locations of other hospitals which may fall within the distance requirement radius.**

Changes to Medicare GME Affiliated Groups for New Urban Teaching Hospitals

Currently, "new" teaching hospitals can only participate in affiliation agreements where the new hospital increases its FTE cap. CMS is proposing to revise the regulation to specify that new urban teaching hospitals (i.e. hospitals that first began training residents on or after January 1, 1995) may form a Medicare GME affiliated group and therefore be eligible to receive both decreases and increases to their FTE caps only if the decrease results from being part of the Medicare GME affiliated group. **Trinity Health supports this CMS proposal, which allows flexibility in FTE caps for new hospitals (albeit only with other new hospitals), similar to the flexibility available to old hospitals.**

FY 2019 Applications for New Technology Add-On Payments

Using CMS criteria for add-on payments – i.e. 1) new agent or device; 2) cost of same is such that the DRG reimbursement rate is determined to be inadequate; and 3) demonstrate a substantial clinical improvement over existing services or technologies. Trinity Health offers the following from a number of clinicians with subject matter expertise in use of anti-infectives and other modalities for treatment of infections:

VABOMERE™ (meropenem-vaborbactam)

CMS states “improved outcomes in some trials may not be statistically significant, the small number of patients, and the lack of a comparison to other antibiotic treatments of cUTIs known to be effective against uropathogens. “ **Trinity Health agrees with this assessment.**

Plazomicin

CMS states “results of the CARE study indicating reduced mortality and a treatment advantage for Plazomicin compared to standard of care are not statistically significant due to the small sample size (29 patients). CMS is concerned that the results from the EPIC clinical trial are predominately based on patients enrolled in trials in Eastern Europe and it is not clear how generalizable their results would be to patients in the US.” **Trinity Health agrees with CMS assessment.**

Bezlotozumab (ZINPLAVA™)

Because the 3-year anniversary date of the entry of ZINPLAVA™ on the United States market will occur after FY 2019 (February 10, 2020), CMS proposes to continue the new technology add-on payments for FY 2019. **Trinity Health agrees and supports continuing inclusion of bezlotozumab under the add-on payment program.**