June 17, 2022

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

Re: CMS-1771-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 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation

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

Dear Administrator Brooks-LaSure,

Trinity Health appreciates the opportunity to comment on policies set forth in CMS-1771-P. Our comments and recommendations 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 not-for-profit, Catholic health care systems in the nation. It is a family of 115,000 colleagues and nearly 26,000 physicians and clinicians caring for diverse communities across 25 states. Nationally recognized for care and experience, the Trinity Health system includes 88 hospitals, 131 continuing care locations, the second largest PACE program in the country, 125 urgent care locations and many other health and well-being services. Based in Livonia, Michigan, its annual operating revenue is $20.2 billion with $1.2 billion returned to its communities in the form of charity care and other community benefit programs.

Trinity Health has 17 Clinically Integrated Networks (CINs) that are accountable for approximately 1.5 million lives across the country through alternative payment models.  Our health care system participates in 14 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes eleven markets partnering in one national MSSP Enhanced Track ACO, Trinity Health Integrated Care.  Two of the 14 markets also participate in CPC+. In addition, we have 33 hospitals participating in the Bundled Payments for Care Improvement Advanced (BPCIA) initiative, and three hospitals in the Comprehensive Care for Joint Replacement (CJR) program. Our work—and experience in value-based contracting—also extends beyond Medicare as illustrated by our participation in 123 non-CMS APM contracts.

**Hospital Financials and Market Basket update**
Given the extraordinary inflationary environment and continued labor and supply cost pressures hospitals face, Trinity Health is deeply concerned with the proposed net operating payment increase of 3.2% in the

FY23 IPPS rule.  This update, as well as the FY 2022 payment update of 2.7%, are woefully inadequate and do not capture the unprecedented inflationary environment. The proposed increase does not come close to reflecting the increased costs experienced by hospitals—including the incredibly high labor costs, which make up 53% of the market basket calculation. Further, hospitals would actually see a net decrease of 0.3% compared to FY22 due to proposed cuts in DSH and other payments.

Delta and Omicron surges have created a one-two punch that has crippled our health system.   The recent surge in cases that fueled new Omicron variants is a warning that this public health emergency is not over.  Unlike other industries, hospitals lack price elasticity and cannot simply increase prices to compensate for lost revenue and increased expenses. Not-for-profit health systems like us across the industry are in deep financial straits, as indicated by the number of bond downgrades that are occurring almost daily.  Lower patient volumes and escalating labor costs due to the nursing shortage and use of expensive contract labor, combined with skyrocketing pharmaceuticals and supply expenses, have created significant financial strain on our health system. Trinity Health's cost per COVID-19 case has increased 17%, including 20% increase in labor costs from pre-pandemic levels. On a per-case basis, supply costs have increased 16%, including: Drugs 24%, Implants 6%, Other supplies 17%. There are no signs that any of these costs are returning to a lower level.

The current high rate of inflation—which hit a new 40-year high in May[1]--is not projected to abate in the near term, and inflationary pressures will, without question, continue to be part of wage expectations. It is critical to account for these challenges when considering hospital and health system financial stability in FY 2023 and beyond.

When historical data is no longer a good predictor of future changes, the market basket becomes inadequate. Yet, this is essentially what has been done when forecasting the FY 2022 and 2023 market basket and productivity adjustments.  The market basket is a time-lagged estimate that uses historical data to forecast into the future.  With more recent data[2], the market basket for FY 2022 is trending toward 4.0%, well above the 2.7% CMS actually implemented last year.  In addition, CMS updates labor costs using data from the U.S. Bureau of Labor Statistics' (BLS) Employment Cost Index (ECI).  The ECI survey of hospital employment costs only includes employed hospital workers, not contracted employees, and hospitals have seen a surge in labor costs as a result of contracted employment. Contract labor as a percentage of total hours and contract labor as a percentage of total labor expenses both increased five-fold between 2019 and 2020.  As of March 2022, the median wage rate for contract nurses was four times higher than the wage rate for employed nurses. [3]

**Trinity Health urges CMS to revise the FY23 IPPS payment update to reflect the increased financial demands that have been placed on hospitals, including increased labor costs (and ensuring the calculations specifically account for contract labor costs) and the impact of inflation.  CMS should implement a one-time retrospective adjustment for FY23 to account for the difference between the market basket update that was implemented for FY22. Further, CMS should use alternative sources of**

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[1] Smialek, J., Consumer Prices Rose Rapidly in May, *The New York Times,* June 10, 2022.
[2] IHS Global, Inc.'s (IGI's) forecast of the IPPS market basket increase, which uses historical data through third quarter 2021 and fourth quarter 2021 forecast.
[3] Kaufman Hall, The Financial Effects of Hospital Workforce Dislocation, May 2022.

**information that better account for rising costs as they update the market basket to ensure it reflects costs fairly**.

**Rate Setting and Outlier Threshold**
CMS proposes to resume normal policy of using most recently available data for rate setting and modifying the payment calculation to account for COVID hospitalizations. In general, Trinity Health supports this policy.

However, we are concerned about the dramatic scale of the proposed increase in the high-cost outlier threshold—a 39% increase from the FY 2022 threshold—that would significantly decrease the number of cases that qualify for an outlier payment. If finalized, the rule would increase the outlier threshold from $30,988 to $43,214 but if CMS used the latest charge inflation and changes to the cost to charge ratio, the outlier threshold would be significantly higher. **We ask CMS to examine its outlier threshold methodology more closely and consider making additional, temporary changes to help mitigate the substantial increases that are still occurring in the outlier threshold. At minimum, CMS should finalize a policy that transitions the rate in a way that fairly accounts for the increased outlier threshold.**

**Medicare DSH**
CMS estimates DSH payments of $6.5 billion in 2023, a decrease of $654 million that is driven in part by a lower expected uninsured rate. We are concerned that the proposed uninsured estimate does not fully account for the end of PHE and the expiration of two critical pieces of legislation that will likely increase the rate of uninsured.

Under the Families First Coronavirus Response Act, state Medicaid programs are prohibited from disenrolling individuals during the PHE. With the PHE expected to end in 2022, more than 14 million people could lose Medicaid coverage, according to an Urban Institute study.[4] While some of these individuals could be eligible for other coverage, such as through the Marketplace, several factors (including state policies) could impact whether individuals receive alternative coverage.

The American Rescue Plan (ARP) also included two provisions that improved the affordability of obtaining coverage through the Marketplace that are only available through coverage year 2022 and will expire in 2023. An estimated 3 million people are expected to become uninsured when the premium tax credits expire, according to a recent study by HHS' Assistant Secretary for Planning and Evaluation (ASPE).[5]

**We urge CMS to take the expiration of these provisions into account when updating its estimate of uninsured in the final rule. At a minimum, CMS should provide additional detail on how it accounted for the expiration of these policies in its analysis.**

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[4] Buettgens, Matthew and Jessica Banthin, "Estimating Health Coverage in 2023," Urban Institute, May 10, 2022, https://www.urban.org/research/publication/estimating-health-coverage-2023
[5] Branham, D. Keith et al, "Projected Coverage and Subsidy Impacts If the American Rescue Plan's Marketplace Provisions Sunset in 2023," Department of Health and Human Services, Assistant Secretary for Planning and Evaluation (ASPE), Office of Health Policy, March 23, 2022, https://aspe.hhs.gov/sites/default/files/documents/1647ad29528ee85a48d6ffa9e7bfbc8f/arp-ptc-sunset-impacts-03-22-22%20Final.pdf

<u>Uncompensated Care Distributions</u>
CMS proposes to use multiple years of audited cost report data.  For FY23 CMS would use an average of two years of audited data (FY18 and FY19) and for FY24 forward, CMS will use the average of uncompensated care data from the three most recent audited cost reports.

**Trinity Health supports this policy, as it aligns with recommendations we made in past comment letters on the IPPS regulation.** Using a three-year average mitigates the impact of significant swings from year to year and help ensure predictability for CMS rate setting and provider budget planning by providing more predictability and less variance.

<u>Medicaid Fraction of Medicaid DSH Calculation</u>
Due to a number of court decisions regarding the inclusion of certain patient days in the numerator of the Medicaid fraction when calculating a hospitals disproportionate patient percentage, CMS is proposing that for a section 1115 demonstration patient day to be included in the numerator, that patient must be eligible for essential health benefits (EHB) under an approved state Medicaid plan (section 1115 demonstration itself or insurance purchased with the use of premium assistance equal to at least 90% of the cost of the health insurance provided by a section 1115 demonstration) that includes coverage for EHBs on that day or directly receives EHBs on that day under an authorized waiver.  If finalized, the FY23 IPPS regulation would revise policy related to the calculation of the Medicaid fraction of the Medicare DSH calculation.

Last year, CMS proposed to exclude people who are in low-income pools or get premium assistance through Medicaid 1115 waivers.  **The ruling from recent litigation, Bethesda Health, Inc. vs. Alex Azar, (D.D.C, 11/13/20) interpreted the regulation as requiring CMS to include patient days from those sources, in particular in that case, the Florida Low Income Pool for uninsured/underinsured patients.  Trinity Health urges CMS not to overrule the courts with revised regulations, but to align with the rulings to the fullest extent possible and recognize patient days under the approved Section 1115 waiver demonstrations.**

**Wage Index**
CMS proposes to continue its policy to increase wage index values for low-wage index hospitals.  For hospitals with a wage index value below the 25th percentile, the agency would increase the hospital's wage index in a budget neutral manner by adjusting the national standardized amount for all hospitals.

Trinity Health recognizes the need for policies to help support rural hospitals and the communities they serve. We continue to urge HHS and Congress to develop a comprehensive, long-term approach to help these facilities. As disparities among geographic regions and challenges faced by rural hospitals continue to grow, **HHS should work with Congress to create a new designated pool of funding for low-wage hospitals that is not subject to budget neutrality.**

Last year, Trinity Health urged CMS to consider establishing a permanent 5% floor on wage index decreases to reduce volatility in the wage index.  We were pleased to see this is being proposed as a permanent policy.

<u>Labor-Related Share</u>
For FY 2022, CMS rebased and revised the hospital market basket and finalized a labor-related share of 67.6% using the 2018- based IPPS market basket. For FY 2023, CMS is proposing to continue the use of a labor-related share of 67.6%

Trinity Health and other health systems have experienced an exponential increase in the cost of labor as a result of the COVID-19 pandemic and labor shortages----Trinity Health's labor costs have increased 20% from pre-pandemic levels (February '22 over Feb '20). **We urge CMS to evaluate the impact of rising labor costs on wage indices.**

**Graduate Medical Education**
In light of recent court decisions (Hershey v. Becerra), CMS proposes to modify the methodology for all teaching hospitals beginning October 1 when determining full time equivalent caps. **Trinity Health supports these changes.**

**Expiring programs**
<u>Low-Volume Hospital Payment Policy</u>
The BBA of 2018 modified the definition of a low volume hospital and the methodology for calculating the payment adjust. Per statute, the low-volume hospital policy is set to revert to requirements and prior payment adjustment methodology as implemented in FY2005. **Trinity Health urges CMS to work with Congress to keep the criteria in place by extending the authority, along with the Medicare Dependent, Small Rural Hospital Program.** As outlined above, hospitals are struggling financially due to financial pressures from the COVID-19 pandemic, inflation, and increased labor and supply costs. Allowing this provision to expire will add undue financial strain to hospitals.

**New Treatment Add on Payments (NTAPS)**
CMS proposes a transition to NDC codes for the purposes of NTAP drug reporting instead of the long-established use of ICD-10-PCS codes.

**Trinity Health recommends CMS retain the long-established ICD-10-PCS coding for NTAPs rather than switching to NDCs for the NTAP drugs.** CMS does not currently require National Drug Code (NDC) reporting except in rare cases of previous NTAPs so this is outside of normal CMS reporting requirements. Reporting NDCs for only the occasional drug, and on an inpatient claim, would be difficult to operationalize and doesn't align with NDC reporting requirements for Medicaid and other payers. Further, NDC reporting impacts more than just the NDC code, there is also the NDC unit of measure and NDC quantity that would need to be determined and included on the claim. If finalized, the policy would create new operational burdens.

**COVID and Influenza Data Reporting**
During the PHE, CMS has required hospitals to report daily on certain COVID-19 related information, such as number of staffed and occupied beds, information about its supplies, count of COVID-19 cases, and current inventory and usage of COVID-19-related therapeutics. These reporting requirements are currently in place for the duration of the PHE.

CMS proposes to modify its Medicare conditions of participation (CoPs) to require that, beginning at the conclusion of the PHE and continuing until April 30, 2024, a hospital must electronically report information about COVID-19 and seasonal influenza in a standardized format specified by the Secretary. Additionally, to respond to future crises more effectively, CMS proposes a framework for hospitals to report requested data in the event of a future local, state, and national PHEs specific to an infectious disease or pathogen. If finalized, hospitals would be required to report requested data through the CDC NHSN or other surveillance system, as determined by the Secretary. As part of this proposal, CMS could require hospitals to report person-level

information, including medical record identifier, race, ethnicity, age, and relevant comorbidities of infected patients.

**Trinity Health does not support creating a new CoP for reporting data beyond the PHE and is concerned broadening these requirements will lead to an increased reporting burden as this reporting is resource intensive**. **We urge CMS to maintain the reporting requirement while under the PHE and then return to reliance on state public health agency reporting, while evaluating other data sources that can be used to obtain critical data.** In addition, CMS proposes to require reporting of influenza detected among patients and personnel. **Trinity Health does not support adding an influenza reporting requirement in the IPPS regulation, as hospitals are already required to follow state reporting requirements for influenza infection.** Further, Trinity Health does not routinely test colleagues for influenza as they go to their primary care provider for this and there isn't a reliable way to track influenza among our personnel. **We urge CMS to follow existing reporting requirements for communicable diseases. Person-level information is more burdensome than aggregate reporting. Should CMS finalize the proposed policies, we ask CMS to use enforcement discretion and to ensure that there is ample time for hospitals to come into compliance.**

### Hospital Quality Reporting and Value Programs
*Cross Program Measure Suppression Policy*
CMS proposes to continue to suppress the use of quality measures in certain programs if determined COVID-19 has had a significant impact on measures and calculations. Where measures aren't suppressed for certain programs, CMS will adopt a covariate adjustment for patient history of COVID-19 in the 12 months prior to admission.

**Trinity Health applauds CMS for recognizing the impact COVID-19 has had on these programs and supports these policies including the outlined suppression factors.**

Hospital Readmissions Reduction Program (HRRP)
For 2024, CMS will not suppress any readmission measure but would modify specification to exclude patients with a primary or secondary COVID 19 diagnosis and would apply the covariate adjustment to patients with COVID-19 history in last 12 months. For program scoring, CMS is proposing to exclude data from the first half of 2020. **Trinity Health supports these policies and appreciates CMS' continued evaluation of the impact COVID-19 is having on the program.**

Hospital Value Based Purchasing (HVP) Program
For HCAPS and patient safety measures, CMS proposes to set the baseline for 2023 performance using CY19 rather than CY21 data. Trinity Health supports this policy and notes it may take hospitals some time to get back to this baseline (or exceed it) given the impact of COVID-19. **Trinity Health made a lot of progress prior to pandemic that has been greatly impacted by staffing shortages and the ongoing pandemic. We urge CMS to continue to evaluate this as they set future policy. Further, it will be important for CMS to communicate any reset of baselines to providers and we do not feel restoration of performance gains prior to the pandemic can be accomplished in a short time frame. Improvements in patient safety measures aimed at mitigating incidence of HACs requires considerable coordination by the patient's care team which have been disrupted throughout pandemic response.**

Hospital Acquired Condition Reduction (HAC) Program
**Trinity Health supports the changes proposed for the HAC Program, including the measure suppression for PSI 90 and HAI, and the proposed scoring policies.**

Hospital inpatient Quality Reporting (IQR) Program
CMS proposed to adopt 10 new measures, refine two existing measures, and update reporting and submission requirements for Electronic clinical quality measures (eCQMs).

Trinity Health understands that the long-term goal of eCQMs was to replace manually abstracted measures, therefore reducing the abstraction burden and promoting reassignment of staff from abstracting data to implementing quality improvement initiatives. The proposed increase to six eCQMs is a substantial impact on hospital resources to establish the measures (IT), validate and educate (health informatics), and incorporate into workflows (quality teams). **We urge CMS to introduce the increased requirements over a longer timeframe, as the impact is significant. Additionally, we urge CMS to match actions to the original goal and reduce manually abstracted measures as electronic measure requirements are increased.**

*Hospital Commitment to Health Equity Measure*
CMS is proposing to add a new structural measure including five domains of hospital commitment to health equity: equity is a strategy priority; data collection; data analysis; quality improvement; and leadership engagement.

CMS and the Administration's emphasis on addressing disparities and advancing health equity aligns with work we have been doing internally as well as across our footprint. In the summer of 2020 as the impacts of COVID-19 on minority and unreserved communities became clearer, Trinity Health initiated a systemwide effort led by our senior leadership, including our system CEO, to examine our role as a health system in advancing equity across all of our communities. As part of this effort, we have developed a set of principles to guide our journey to health equity, which can be found here. We have engaged representatives from all of our regional health ministries to both develop our guiding principles and to implement these principles locally to reflect each community's unique strengths, challenges, and needs. We believe our experience can provide an example of how health systems can commit to health equity from the very top to all parts of the organization – and work with the communities we serve to shape these efforts.

**While Trinity Health supports the emphasis CMS is placing on strategic commitment to addressing disparities, we are concerned that the proposed measure is too prescriptive and may not reflect the diversity of approaches needed at the community level.** Furthermore, taken together, the five domains of this measure represent a significant level of effort to implement. We also note that the proposed measure is not aligned with the Disparities Toolkit recently released by the AHA Health Research and Educational Trust, which may result in confusion and place undue burden on health systems. **We encourage CMS to further evaluate the use of this newly developed measure through field testing and other means and base its inclusion in the IQR in a future year on the results of that evaluation. We also recommend CMS consider opportunities for alignment with the AHA tool.**

*Screening for Social Drivers of Health Measure*
CMS proposes to add an eCQM measure with voluntary reporting in the 2023 and mandatory reporting in 2024. CMS notes that to collect this data, providers could use a range of tools (e.g., 10-item AHC Health-Related Social Needs Screening Tool) but would report on the share of inpatients admitted to the hospital who

are 18 years or older at time of admission and who are screened for each of the five health-related social needs: food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

Trinity Health has prioritized collected information on social needs and invested considerable technical, financial and staff resources to ensure that we have the best information to support our patients and communities. **We support CMS in promoting the collection of this data and agree with the approach of limiting this data collection to patients who are adults.** However, based on our experience, we present the following questions and concerns.

First, **Trinity Health recommends that CMS not specify the specific domains for data collection at this time.** Hospitals and health systems are at varying stages of collecting this data and will need to build experience and invest in staff training to ensure that these sensitive data are collected in appropriate ways that provide individuals with an understanding of why it is being gathered. In addition, we recommend that CMS refrain from including the domain of interpersonal safety, given that this area interacts with a range of state and local laws.

Second, **we are concerned that the inpatient setting may not be the most appropriate place for collecting this information.** Trinity Health has adopted an approach of collecting this information on all individuals treated across our health system. In many instances, the ambulatory care setting, and particularly the primary care setting, is best suited for engaging in the type of conversation needed to collect this sensitive information. Further, it may not be appropriate – or even possible – to collect these data from individuals admitted for acute conditions such as a heart attack or stroke. In some cases, these data could be collected as part of the discharge process.

Third, **we ask that CMS clarify whether data previously collected about an individual could be used to satisfy this measure.** Our current practice is to consider information collected during encounters across our system to be accurate for 365 days. That means, for example, that if social needs data were collected by a primary care physician in January, we would not seek to update that information during a hospital stay in July.

Finally, CMS has not specified the specific instruments to be used to collect this information, although the proposed rule references a number of options. We support this flexibility given that hospitals and health systems may serve different populations and have varying levels of experience in collecting these data. **However, we encourage CMS to work with stakeholders to move toward more standardized instruments so comparable data may be collected.**

*Screen Positive Rate for SDOH Measure*
CMS proposes to add an eCQM measure with voluntary reporting in 2023 and mandatory reporting in 2024 that would build on the proposed Screening for Social Drivers of Health process measure and entail reporting of the resulting screen positive rates for each domain (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety).

Trinity Health believes that the results of the screening for social drivers of health will be important for hospitals to identify community needs and develop strategies to address them. **While we are committed to the collection and use of these data at the local level, it is unclear why this data would be reported to CMS as part of a quality reporting program**. Given that hospitals have flexibility in the use of instruments to capture this information, it seems clear that the resulting data will not be comparable across facilities. Further,

we believe that the lack of experience across the field in collecting these data and variability in the data that will be collected limits its usefulness for quality measure stratification or other purposes. **Therefore, we believe it is premature for CMS to include this measure in the IQR and urge CMS to not move forward with this measure until its utility is clearer.**

*Patient-reported outcomes measure following elective THA/TKA*
Trinity Health has concerns with the adoption of the hospital-level, risk standardized patient-reported outcomes measure following elective primary total hip arthroplasty and/or total knee arthroplasty. Given the problematic and burdensome experience participants in the Comprehensive Care for Joint Replacement Model have had with this measure, **Trinity Health does not recommend CMS finalize for mandatory reporting until they can evaluate and provide information on the voluntary reporting experience**.

*Medicare Spending Per Beneficiary Hospital*
CMS proposes to refine the Medicare spending per beneficiary measure, which is currently in the VBP Program. Changes to this measure could be confusing for hospitals and beneficiaries, **Trinity Health recommends CMS work to ensure clarity as we would be reporting for two separate quality programs.**

*Severe obstetric complication eCQM*
CMS is proposing a new severe obstetric complication eCQM to assess the proportion of patients with complications that occur during delivery. **Prior to finalizing this measure for inclusion, it should undergo endorsement by the National Quality Forum (NQF) to review concerns of validity, feasibility, risk adjustment and clinical appropriateness.**

*Excess days in acute care after acute myocardial infarction*
The proposed rule would increase the minimum case count for reporting for the excess days in acute care after hospitalization for acute myocardial infarction measure. **This measure should be removed, as it does not add value to the IQR program.**

*Birthing Friendly Hospital Designation*
If finalized, the IPPS rule would create a new hospital quality designation of a birthing friendly hospital that would award hospitals this designation based on their ability to attest affirmatively to the maternal morbidity structural measures that were adopted in the IPPS rule last year. **Trinity Health supports this designation and applauds CMS for working to address maternal health outcomes.**

Potential Future Measures for IQR
*Clostridioides difficile CDC NHSN Health-Associated Infection (HA-CDI) Outcome Measure*
CMS is considering a HA-CDI dQM to track the development of new *C. difficile* infections among hospital inpatients, using algorithmic determinations based on EHR data.

**While this is a measure under consideration, we do not support proceeding with this potential future measure until it receives NQF endorsement as wells as voluntary assessment of the value of the measure compared to existing hospital onset C. difficile infection (HO-CDI) measure. Further, collation of numerator and denominator will likely require more detailed review of patient EHR to extract these. There is a need to objectively evaluate this measure in terms of value it adds to not only internal trending but also inter-facility comparison.**

*CDC NHSN Hospital-Onset Bacteremia and Fungemia Outcome Measure*
This measure would This measure captures the development of new bacteremia and fungemia among patients already admitted to acute care hospitals, using algorithmic determinations from data sources widely available in EHRs.

**Trinity Health does not support proceeding with this measure under consideration until it receives NQF endorsement and there is a voluntary assessment of the value of this newly proposed measure. We also are concerned that hospital onset bacteremia and fungemia may be disproportionately more frequent at facilities that care for a higher proportion of immunocompromised patients. In addition, those cases who meet criteria for this measure will require considerable assessment for preventability. A notable proportion of hospital onset bacteremia and fungemia represent translocation of inherent microbial flora and we therefore question the preventability as compared to CLABSI. More voluntary investigation and testing of this measure is needed prior to widespread adoption.**

Promoting Interoperability Program
*Query of Prescription Drug Monitoring Program (PDMP)*
The rule would change this e-prescribing measure from voluntary to mandatory and expand to include Schedule II, III, and IV drugs. **In general, Trinity Health supports these changes but recommends CMS delay finalizing this policy by one year as we continue to operate in a PHE and this would require significant work.** The documentation burden for this requirement is high if not included as part of the vendor report package (which it isn't currently). **In addition, Trinity Health requests guidance on how to document for audit purposes.**

*Health Information Exchange*
If finalized, the FY23 rule would add a new Enabling Exchange under Trusted Exchange Framework and Common Agreement (TEFCA) measure under the Health Information Exchange (HIE) Objective as a yes/no attestation measure.

The wording outlined in the proposed rule is vague regarding what is expected and leaves hospitals at risk for not meeting this measure. **We request CMS provide more clarity on the proposal prior to implementation**; for example,
- What are we supposed to exchange?
- Are we expected to incorporate any of this exchanged information into the patient chart like we are with the current HIE measure 'sending health information'?
- How do we document we meet this measure?

*Public Health and Clinical Data Exchange*
CMS propose to add a new Antimicrobial Use and Resistance (AUR) Surveillance measure and require its reporting under the Public Health and Clinical Data Exchange Objective. **Trinity anticipates challenges for some of our hospitals that are dependent on external lab information systems since although our EHR may be able to report this data if it has it, we may have challenges with functionality of laboratory information systems (LIS) providing data in a way that is reportable (for example, we currently have hospitals in our system that use external Clinical Lab where results are transmitted into the patient's EHR however the elements of the report are not discrete and therefore can't be submitted electronically into NHSN AUR module in HL7 compatible format.** As this is not something hospitals have

control over, particularly if we are in contract with a vendor, we recommend CMS allow an additional exclusion for infrastructure with electronic resistance lab information is not in a reportable format.

CMS proposes to reduce the active engagement options for the Public Health and Clinical Data Exchange Objective from three to two options. In addition, CMS proposes hospitals may spend only one EHR reporting period at the proposed option 1 (pre-production and validation) level of active engagement per measure and must progress to the option 2 (validated data production) level for the next EHR reporting period for which they report a particular measure. **Trinity Health does not support these changes**. How a hospital advances through the three definitions of active engagement is not generally in the hospital's control. It is often the partner a hospital is trying to exchange data with, e.g., the public health agency (PHA), that is the barrier to moving forward with the sending of production data and the proposal, as outlined, would create significant additional burden on hospitals, particularly as CMS proposes to add a new measure to this objective. Additionally, if a hospital switches EHRs, then we need to re-establish the production feed which would place us back in previous active engagement status(es). The current active engagement options appropriately incentivize hospitals towards the sending of production data – particularly since once hospitals receive requests from the PHA, there are explicit timelines they must follow to remain in active engagement status, but also allows for flexibility in situations where hospitals switch EHRs or switch to a different PHA.

CMS would require submission of the level of active engagement, in addition to submitting the measures for the Public Health and Clinical Data Exchange Objective. Public health agency (PHA)-provided documentation is not always accurate with regard to level of active engagement, and hospitals rely on this documentation to support their attestations. Thus, reporting the level of active engagement would increase our documentation burden. **Trinity Health recommends CMS does not finalize this policy. As an alternative, CMS could incentivize PHAs to offer accurate documentation on a hospital's level of active engagement in a timely manner.**

*Public Reporting*
The rule would require public reporting of certain Medicare Promoting Interoperability Program data, including hospital total score and ERH certification ID. As proposed, this is not information that would be valuable to our patients, nor does it appropriately represent our support of patient access to their information or the care we provide. **A more helpful alternative would be whether a hospital *meets* program requirements vs. *does not meet, though this is already publicly reported today*.**

**Changes to Medicare DRG Classifications**
*Creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup*
CMS uses specific criteria to determine if the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS-DRG is warranted. This year, CMS analyzed how applying this criteria would affect the MS-DRG structure beginning in FY 2023 and given the significant number of modifications that would result, CMS is not proposing to make any changes at this time.

**Trinity Health supports this decision and appreciates CMS evaluating the impact the volume of DRG changes would have on hospitals during the COVID-19 PHE.** If implemented, the policy would result in the deletion of 123 MS-DRGs and the creation of 75 new MS-DRGs—which would be a considerable amount of changes. In addition, we not that as CMS considers these changes for future rulemaking, stakeholders would need to know the proposed weights for impact adjustments.

**Request for Information: Overarching Principles for Measuring Healthcare Quality Disparities Across CMS Quality Programs**

Trinity Health supports CMS' goal of using measurement and stratification as tools to address healthcare disparities and advance health equity across quality programs. Below, we offer more detailed comments related to the five areas CMS lays out in the proposed rule, which could inform its approach to disparity measurement or stratification guidelines.

*Identification of goals and approaches for measuring health care disparities and using measure stratification across CMS quality programs*

**Trinity Health supports the stratification of quality measures as part of the goal of identifying and measuring health disparities and believes that this is the right direction for CMS to take.** As noted by CMS, a variety of demographic and social needs data could be relevant to stratification efforts. Trinity Health is committed to addressing disparities and has invested significantly in tools, workflows and staff training to capture information on race, ethnicity, gender, age, and social needs. Specifically, through Epic/TogetherCare, we currently collect data on 10 social related health needs.  We do not yet collect data on sexual orientation or gender identity.

We caution, however, that complete collection of demographic and social needs data may not yet be attainable and the validity of the data collected is not yet known. Furthermore, collecting these data requires significant staff education and outreach to patients so that they understand why the data are being collected and how they will be used. Before using these data to stratify quality measures, **CMS should work with health care organizations to establish valid, reliable and complete collection of standardized data.** After establishing that data are complete and comparable, stratified quality measures results should be presented alongside overall performance. We welcome the opportunity to partner with CMS on working towards this goal.

*Guiding principles for selecting and prioritizing measures for disparity reporting across CMS quality programs*

**As noted above, Trinity Health recommends that CMS focus first on the collection of valid, reliable and comparable data before selecting specific measures that may be stratified for disparity reporting.** The collection of an expanded set of information and data can inform the assessment and identification of measures that are important to stratify. **We urge CMS to ensure that any stratification of quality measures uses accurate and complete data and that these measures are not publicly reported or used for payment purposes until this can be achieved.**

*Principles for social risk factor and demographic data selection and use*

Trinity Health agrees with CMS that the use of self-reported data is preferred to ensure accuracy and to eliminate the potential for any bias on the part of those collecting data. However, other sources of information may be needed as we build our data collection capabilities.

In the proposed rule, CMS asks for feedback on the appropriate use of administrative data, area-based indicators, and imputed sources for social risk and patient demographics. We do not believe that one of these approaches is more appropriate than the others as they all present some challenges. For example, we caution that the use of ICD-10 "Z codes" to report social risks on claims is not widely done and requires a high level of sophistication to implement. **As a result, we encourage CMS to pursue multiple strategies to inform our understanding of social risk factors and associated demographics and conduct studies to**

**understand their validity, reliability, and limitations. However, we discourage the use of indirectly estimated data for any reporting or payment purposes given it may not yield accurate data.**

*Identification of meaningful performance differences*
**Trinity Health believes it is premature to consider how to identify meaningful performance differences with respect to disparities given the current limitations of the data being collected.** As discussed above, data collection and completeness needs to be standardized and validated as a first step.

*Guiding principles for reporting disparity results*
Given the current challenges with data collection, standardization and validity**, we urge CMS to limit the reporting of disparity results to confidential reporting until accurate and complete data are available and validated.**

**Request for Information: Additional Activities to Advance Maternal Health Equity**
Like CMS, Trinity Health is committed to advancing equity for all and we have been working across our footprint to develop [recommendations](#) and advance policies that support access to coverage and care and improve the health of our patients and communities. Paramount to this is improving and addressing disparities in maternal health outcomes.

To this end, we strongly urge CMS and states continue to advance policies and programs that support access to coverage including expanding post-partum Medicaid coverage to 12 months, instituting presumptive eligibility to allow qualified entities to screen pregnant women for Medicaid eligibility and expanding access to marketplace coverage (e.g., through permanently expanding temporary marketplace subsidies). We also recommend expanding coverage for services that would support access and improve outcomes, such as covering maternal telehealth care (e.g., virtual prenatal care) and coverage for doula services.

To address maternal health disparities and improve outcomes, Trinity Health believes the maternal care workforce must be expanded and diversified to ensure individuals have access to culturally appropriate care and support. CMS and its partners should consider opportunities to fund and expand education and training to support more diversity in the workforce (e.g., loan pay-downs, grants for cultural competency training, reimbursement for services provided by community health workers). We also believe that coordinated care across provider teams can support patient experience, care and outcomes and recommend CMS consider incentives for maternal health providers to practice in collaborative, team-based approaches that include a range of members such as social workers, patient navigators and community health workers (CHWs).

Further, we believe that to improve patient health and outcomes, patients must have access to whole person care that entails addressing social influencers of health (SIOH). We recommend CMS continue to work with states and other partners to expand investment in initiatives and programs that support access to services that address SIOH (e.g., transportation, childcare, housing, food). We also support expanding Medicaid coverage for education and outreach to address social and health needs, and support community partners in maternal health activities.

***CMS outlines best practices in the memorandum to state survey agencies entitled "[Evidence-Based Best Practices for Hospitals in Managing Obstetric emergencies and Other Key Contributors to Maternal Health Disparities](#)." What other additional effective best practices or quality improvement***

***initiatives are currently being utilized by hospitals? How else can hospitals improve maternal health outcomes, enhance their quality of maternity care, and reduce maternal health disparities?***
Trinity Health supports the Alliance for Innovation on Maternal health (AIM) program and urges continued funding for this program and other state-based perinatal quality collaboratives. Trinity Health also supported the proposed Maternal Morbidity Structural Measure and recommended CMS broaden its definition of a structured state or national perinatal QI collaborative to also include quality initiatives with patient safety organizing or insurers.

***What are the best practices that hospitals are utilizing to educate and conduct outreach to patients in underserved communities to increase access to timely maternity care?***
Trinity Health has implemented initiatives across our footprint to support prenatal, pregnancy and post-partum care. This includes Holy Cross Health's Maternity Partnership Program, which is a collaborative partnership with the Montgomery County Department of Health that provides prenatal and post-delivery education and care to women, regardless of their insurance or financial status. Program staff are bilingual and trained to provide culturally competent care. Additionally, the program—which has served more than 23,000 women, including patients with diabetes, hypertension and a history of pre-term labor—supports pregnancy, delivery and postpartum care as well as supports access point for underserved communities.

More broadly, we believe that eliminating disparities and addressing the needs of underserved communities requires cross-stakeholder collaboration and addressing drivers influencing poor outcomes and disparities—including those related to maternal health. We believe that meaningful community engagement is supported by a health care workforce that is diverse and understands the needs of the communities they serve, which enables relationships and trust to be built across providers, patients, organizations and communities.

***Do hospitals provide prevention-related education and community outreach on the specific maternal health conditions that have the greatest impact on disadvantaged and underserved communities?***
Trinity Health has implemented a number of initiatives across our footprint to support maternal care. For example, Mount Carmel Health System's Welcome Home Program has provided visits to over 20,000 mothers and babies who are discharged at one of the three birthing hospitals. The program targets first time moms, single moms, teen moms, moms with concerns identified by a hospital social worker and moms who request a visit.  During the visit, physical, psychological and social issues that can interfere with the health and welfare of the mother or child are monitored and nurses offer education and support related to breastfeeding, safe sleep, maternal and newborn health related questions and concerns and referrals as needed.

Additionally, Trinity Health of New England's Breastfeeding Heritage & Pride Program involves peer counselors who provide prenatal breastfeeding education, in-hospital, immediate hands-on support postpartum and continued breastfeeding education and hands-on support through home visits and phone calls for 12 months postpartum.

***How can hospitals review and monitor aggregate data on the maternal health risks of the patient population that they serve? What data should hospitals review related to the maternal health risks of the patient population they serve? What data sharing best practices are required for hospitals to share data with external entities, including local and state health departments, community-based organizations, or other health care providers? How can hospitals connect data collected for mothers***

***and their babies after delivery to support research and evaluation of maternal health care after delivery?***

Trinity Health is committed to reducing health inequities and eliminating health disparities. It is not possible to reduce or eliminate an inequity or a disparity without first knowing which populations are disproportionately impacted. To improve maternal health outcomes and address disparities, certain quality improvement strategies and safeguards should be in place such as ensuring collection and reporting of standardized and valid data that includes race and ethnicity, language preference and other social influencers of health (SIOH).

Addressing maternal health disparities requires reporting and sharing of data between health systems, other clinical providers, public health departments and government. However, outdated data systems prevent interoperability and fail to produce data-driven strategies. Trinity Health recommends policies to build and strengthen the nation's data infrastructure to create a robust, interoperative system across public health, health care providers, states and the federal government.

It is important to note that collecting these data at point of admission within a health system will require significant training of staff to ensure standardization and accuracy. Our hospital in New York, for example, is participating in a CMS pilot, which includes screening for SIOH. They have used and integrated an abbreviated eight-question tool but have found that it has been difficult to integrate even a short questionnaire into staff workflow at point of care. From our experience, there is a hesitancy among the workforce to ask about these social and demographic aspects of public health data.

***What challenges are there to collecting data on patients with specific maternal health risks? Can these data be stratified by demographics (for example, race and ethnicity)? In addition, how can these data be used in a hospital's quality improvement efforts, and specifically, in their quality assurance and performance improvement (QAPI) program, to improve maternal health outcomes and advance health equity and reduce disparities within their facility? How can maternity care be incorporated into an ongoing QAPI program?***

There must be consistent data collection and effective evaluation to improve outcomes and quality. States, municipalities and hospitals have different terminology for determining maternal morbidities, such as hemorrhage. We would encourage CMS to use its existing mechanisms, such as the National Quality Forum and Core Measure Quality Collaborative, to promote standardized definitions. The implementation of MMRCs in all states also should help standardize data collection and the dissemination of strategies to reduce pregnancy- related morbidities and eliminate mortality.

Trinity Health has historically reported data to regulatory agencies on births and birth outcomes, however there is not consistent collection and reporting of data that indicates good maternal and infant outcomes (such as initiation of prenatal care, delivery method, delivery date, infant weight and breastfeeding initiation). This is often because Trinity Health does not have access to data from external providers whose patients deliver at one of our facilities. Additionally, adverse events are typically reported post-discharge and different data systems are used to maintain those reports.

***Are hospitals currently utilizing community health needs assessments to determine the specific maternity care needs and social determinants of health of the patient population that they serve? For those hospitals that are utilizing community health needs assessments, are there certain best practices or examples of ways that this assessment can be used to reduce disparities in maternal outcomes?***

Trinity Health recommends CMS partner with health systems and incentivize more community collaboration that is done in line with community health needs assessments (CHNA). Federal funding streams should encourage public health, health care and payers to work together on conducting CHNAs, greater availability of collaborative funding pools to support addressing identified needs, and increased evaluation to allow for a better understanding of what works and the sharing of best practices widely. We also recommend that CMS consider the role of hospitals in conducting CHNAs that would support health equity interventions and initiatives. We believe that aligning hospital CHNAs and Public Health Accreditation standards would facilitate more collaboration and less duplication of efforts among the different entities within communities.

***Do hospitals have readily available referral relationships and points of contact with community resources or community-based organizations to address additional services that a postpartum patient may need upon discharge? This could include the consideration of behavioral and mental health services or resources to address health-related social needs, such as food insecurity, housing instability, and transportation challenges. If hospitals do not have readily available referral relationships and points of contact within the community, what barriers and facilitators impact hospital relationships with community resources or community-based organizations?***
In Spring 2020, Trinity Health launched the [Community Resource Directory](#), powered by Aunt Bertha--an online portal for colleagues, patients and community members to anonymously search for free or reduced-cost social services. To date, food, housing and access to health care have consistently been the top searched needs across all our communities. There are not enough social services to address these unmet needs.

Trinity Health has also standardized an annual social needs screening assessment for all patients via our electronic medical record (EMR). We were the first among EPIC users—our EMR—to launch a Social Care application integrating social and clinical care. Social Care addresses patients', colleagues and community members' social needs and promotes healthy behaviors by facilitating connections between health care providers and community partners.

Trinity Health is building Community Health Worker (CHW) Hubs in each of our local health systems. These hubs are staffed by trained and certified CHWs, collaborating with both clinical care teams and local community-based organizations (CBOs) to receive referrals of patients with positive social needs screenings and use the Community Resource Directory to work to meet these needs.

Providers across Trinity Health are utilizing best practices to screen our obstetrics patients early in their pregnancy and refer them to needed services. Completion of the social needs screening can help ensure that eligible moms are being referred to home visiting programs, as available. Providers are also empowering moms with the Community Resource Directory so they can better find resources needed based on where they live. Through Mount Carmel's Welcome Home program, at each home visit they give moms the Community Resource Directory cards so they can scan the QR code. This tool has been beneficial to link postpartum moms to other resources. In addition, the Welcome Home program can refer postpartum moms to our Community Health Worker Hub for additional support.

A barrier we have encountered in using our EMR—along with the Community Resource Directory—to their maximum capacity has been the lack of trained professionals (Social Workers and CHWs) to screen patients for social needs and then refer and follow-up on referrals to CBOs. Given the wide adoption of Epic, we believe that implementation of the Social Care application by more users will lessen burden on CBOs and better support coordination between health systems and their community partners.

***What best practices exist for ensuring systemic racism and biases, including implicit bias are not perpetuated in maternity care?***

Trinity Health believes that racism is a public health crisis and we acknowledge that racism exists in both health care delivery and financing and that it is a root cause of health inequities. This lack of equity is reflected in limited access to care, restricted affordability, and exacerbated biases that impact health care decision-making and health outcomes.

Trinity Health is committed to be an anti-racist organization. Our Mission and Core Values compel us to advocate for health equity including addressing disparities in maternal health outcomes. We have undertaken systemwide efforts led by our senior leadership to examine our role as a health system in advancing equity in every community we serve. As part of this effort, we have developed a set of principles to guide our journey to health equity, which can be found here.

Trinity Health has instituted a number of efforts to eliminate systemic racism across our organization, including:

- Advocating for racial justice through declaring racism a public health crisis, addressing the racial inequities of COVID-19, and advancing comprehensive health care for all.
- Supporting equitable compensation and talent management processes, including reviewing and updating all human resources policies and practices to reinforce and promote equity, and mitigate the impact of systemic racism.
- Reinforcing a culture of inclusion through mandatory annual cultural proficiency training for employees and de-escalation training for all security (employed or contracted).
- Supporting through stewardship by setting the goal of a 50 percent increase in diverse supplier spend over next three years.

**Conclusion**

We appreciate CMS's ongoing efforts to improve payment systems across the delivery system and efforts made to provide relief to providers during the COVID-19 pandemic. If you have any questions on our comments, please feel free to contact me at jennifer.nading@trinity-health.org or 202-909-0390.

Sincerely,

/s/

Jennifer Nading
Director, Medicare and Medicaid Policy and Regulatory Affairs
Trinity Health