June 6, 2023

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-1808-P; Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes

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

Dear Administrator Brooks-LaSure,

Trinity Health appreciates the opportunity to comment on policies set forth in CMS-1808-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 121,000 colleagues and more than 26,000 physicians and clinicians caring for diverse communities across 27 states. Nationally recognized for care and experience, the Trinity Health system includes 101 hospitals, 126 continuing care locations, the second largest PACE program in the country, 136 urgent care locations and many other health and well-being services. Trinity Health has 15 medical groups with 8,200 medical group physicians and providers. Based in Livonia, Michigan, its annual operating revenue is $21.6 billion with $1.5 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 2 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. All of these markets participated in the "enhanced track", which qualifies as an advanced alternative payment model (AAPM). Two of the 14 markets also participate in CPC+. In addition, we have participated since 2014 in the Bundled Payments for Care Improvement Advanced (BPCIA) initiative and the Comprehensive Care for Joint Replacement (CJR) program across 37 hospitals. Our work—and experience in value-based contracting—also extends beyond Medicare as illustrated by our participation in 123 non-CMS APM contracts.

In our detailed comments below, we urge CMS to:

- Revise the inadequate payment update and provide a fair market basket update. Specifically, CMS should:
    - Use its special exceptions and adjustment authority to make a one-time retrospective adjustment of 10-15% to the market basket to account for what hospitals should have received in 2022 when accounting for inflation.
    - Establish a threshold whereby if the payment differential between what was provided and actual costs is greater than 1.5 percentage points, CMS would retroactively adjust payments for that year.
    - Rebase the market baskets more frequently and at least every three years to ensure the market basket reflects the appropriate mix of services provided to Medicare beneficiaries.
- Work with Congress to maintain the COVID-19 DRG add-on payment for inpatient admissions and analyze data to determine what the appropriate payment should be for a permanent DRG.
- Work with Congress to distribute additional GME residency positions.
- Not finalize proposed modifications to the criteria for new residency programs.
- Continue to link payment for social influencers of health to payment in traditional Medicare and explore additional Z codes to add in the future.
- Wait to require reporting on the patient safety structural measure until it is backed by a consensus-based entity and work with the CDC to ensure NHSN can accommodate new measures and data submission.
- Not finalize an increase to the mandatory electronic clinical quality measure (eCQM) reporting requirements under the Hospital Inpatient Quality Reporting (IQR) and Medicare Promoting Interoperability Program and instead continue to work with stakeholders to address persistent challenges with eCQM reporting.
- Make modifications to the Transforming Episode Accountability Model (TEAM) to make it more sustainable and decrease risk and burden for hospitals.

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 2.6% in the FY25 IPPS rule. This woefully inadequate update will result in the fifth consecutive year where the IPPS payment update is not reflective of the actual cost increases hospitals are experiencing. This update, as well as the payment updates for FYs 2021-2024, does not capture the unprecedented increase in the cost of caring for patients and comes at a time when many non-profit health systems are struggling to stay afloat after years of COVID-related financial losses, high inflation, and increased labor expenditures.

According to CMS' latest forecasts, the most recent IPPS payment updates are notably lower than what CMS is estimating based on actual data. Of particular note, CMS now estimates that total hospital costs increased by 5.7 percent in FY 2022, which is *3 percentage points higher* than the market basket update that CMS finalized for that year (2.7 percent). This underpayment is one factor leading to significant financial challenges for Trinity Health and other health systems. In addition to FY 2022, CMS has also underestimated the last several years:

- FY 2021, CMS now estimates 3.0 percent growth (based on actuals), or 0.6 percentage points higher than the final market basket.
- FY 2023, CMS now estimates 4.8 percent growth (based on actuals), or 0.8 percentage points higher than the final market basket.

- FY 2024, CMS now projects 3.5 percent growth, or 0.2 percentage points higher than the final market basket.

We urge CMS to:

- **Use its special exceptions and adjustment authority to make a one-time retrospective adjustment of 10-15% to the market basket to account for what hospitals should have received in 2022 when accounting for inflation.**
- **Establish a threshold whereby if the payment differential between what was provided and actual costs is greater than 1.5 percentage points, CMS would retroactively adjust payments for that year.**
- **Rebase the market baskets more frequently and at least every three years to ensure the market basket reflects the appropriate mix of services provided to Medicare beneficiaries.**

The cost of caring for patients in recent years has been significantly higher than the increase reflected in the Medicare annual payment updates. Since 2019, Medicare rates have increased 6% while Trinity Health's cost per case has increased 14% including:

- 15% increase in labor costs.
- 17% increase in supply costs.
- 24% increase in drug costs.
- 10% increase in implant costs.

This inflation has made it harder for hospitals to maintain access to care and invest in cybersecurity and cutting-edge treatment. To maintain access to quality care for Medicare beneficiaries, reimbursement must cover the cost of delivering care. At Trinity Health, 49% of revenue comes from Medicare. Unfortunately, as noted above, Medicare payment rates have not kept up with the increased costs of delivering care across all settings. With 20% of our revenue also coming from Medicaid and patients who are uninsured, there is little room to cost-shift Medicare losses to other payers.

Rate Setting

CMS proposes to use the usual methodologies of using most recently available claims data (FY2023 claims and FY2022 cost report data) for rate setting.

Trinity Health supports this methodology.

COVID-19 Add-On Payment

Trinity Health urges CMS to work with Congress to maintain the COVID-19 DRG add-on payment for inpatient admissions and analyze data to determine what the appropriate payment should be for a permanent DRG.

WAGE INDEX

Low Wage Index Policy

CMS proposes to continue its policy to increase wage index values for low-wage index hospitals and extend for three years. 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.

The low-wage index policy has been subject to on ongoing litigation (Bridgeport Hospital vs. Becerra), with the D.C. District Court ruling last spring that the Secretary did not have the authority under statute to adopt the low-wage index policy and ordering additional briefing on the appropriate remedy. CMS subsequently appealed the court decision, and that appeal is still pending.

Trinity Health recognizes the need for policies to help support rural hospitals and the communities they serve; however, we continue to not support this policy. We 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 provide funding for low-wage hospitals that is not subject to budget neutrality.**

Rural Floor Calculation
CMS will continue to include urban and rural reclassified hospitals in the rural floor wage index and estimates that 494 hospitals would receive their state's rural floor wage index in FY 2025.

Trinity Health continues to support this policy.

Imputed Floor Calculation
As required by the American Rescue Plan Act, CMS permanently reinstated a minimum area wage index for hospitals in all-urban states ("imputed rural floor)**.** As such, CMS proposes to continue the imputed floor policy for FY 2025.

Trinity Health continues to support this policy.

GRADUATE MEDICAL EDUCATION
Distribution of Additional Residency Positions
Legislation requires an additional 200 residency positions to be distributed for FY 2026, with at least 100 of the positions for psychiatry or psychiatry subspecialty residency training programs. CMS proposes to use the same method finalized in the FY 2022 IPPS rule to distribute these 200 slots and to prioritize the distribution of slots based on HPSA scores. The applications for these new 200 slots are due March 31, 2025.

Trinity Health supports the implementation of section 4122(a) of the Consolidated Appropriations Act, which requires CMS to distribute an additional 200 residency positions. However, we note these 200 positions still do not meet current need/demand and we urge CMS to work with Congress to distribute additional residency positions.

Proposed Modifications to the Criteria for New Residency Programs and Requests for Information (RFI).
CMS proposes that for a residency program to be considered new, at least 90% of the individual resident trainees (not FTEs) must not have previous training in the same specialty as the new program. CMS seeks comments regarding the selection of teaching staff and a program director and their relative experience. CMS also solicits comments on why hospitals might want to train residents in separately accredited programs, but in the same specialty, and the degree to which this happens in general, in both sparsely populated and more densely populated areas.

We are concerned about how these more specific requirements will interact with the rules of the Accreditation Council on Graduation Medical Education (ACGME) for accrediting residency programs.

Of the proposals CMS has made, the one that is most concerning to us is that a residency program director may not have had residency program director experience in the past five or ten years and Trinity Health urges CMS to not finalize this proposal. The ACGME has accreditation requirements for the experience of the Program Director (PD) that may be problematic for some programs if 90% of all roles must be "new". Many programs require the PD to have three years of experience as faculty in a residency or fellowship program prior to becoming the PD. Some sub-specialties such as micrographic surgery and dermatologic oncology, require completion of a rare, and very specialized fellowship or 10 years of PD experience in a different dermatologic surgical fellowship. The ACGME requirements should be taken into consideration prior to this threshold being established at 90%.

HEALTH EQUITY
Last year, CMS changed the severity designation of the three ICD-10-CM diagnosis codes describing homelessness (Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and Z59.02 (Unsheltered homelessness)) from non-complication or comorbidity (NonCC) to complication or comorbidity (CC). Among the factors that may cause increased financial impact to hospitals, CMS noted that patients experiencing homelessness can require longer inpatient stays due to needing a higher level of care and/or difficulty finding discharge destinations to meet these patients' needs.

This year, CMS proposes to build on this policy by changing the severity level designation for an additional seven social determinants of health (SDOH) diagnosis codes describing inadequate housing and housing instability from NonCC to CC, effective FY 2025.

Trinity Health strongly supports health equity and it is critical that CMS continue to link payment for social determinants of health to payment in traditional Medicare. Trinity Health supports the proposed change and urges CMS to finalize this policy and continue to explore additional Z codes to add in the future. In addition, we urge CMS to incentivize the use of Z codes to encourage their use. There are many Z codes (10+ Z codes for housing and transportation alone) and currently there are no additional payments for using these codes and there are no standards on which code to use, both of which impacts consistency.

In addition, we urge CMS to waive beneficiary cost sharing requirements for community health improvement payments. Requiring patients who access these services is a significant barrier to access.

CHANGES TO MS-DRG CLASSIFICATIONS FY 2025 MS-DRG UPDATES
MDC 01 (Diseases and Disorders of the Nervous System): Logic for MS-DRGs 023 through 027
In the FY 2024 inpatient/LTCH PPS final rule (88 FR 58661 through 58667), CMS discussed a request to reassign cases describing the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain from MS-DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) to MS-DRG 021 (Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage with CC) or reassign all cases currently assigned to MS-DRG 023 that involve a craniectomy or a craniotomy with the insertion of device implant and create a new MS-DRG for these cases. CMS continues to seek public comments for consideration in potential restructuring of these MS-DRGs.

CMS should allow providers more time to identify which diagnosis supports this procedure code. As such, we do not agree with moving it to MS- DRG 021.

MDC 05 (Diseases and Disorders of the Circulatory System): Logic for MS-DRG 215+

CMS received a request to review the GROUPER logic for MS-DRG 215 (Other Heart Assist System Implant) in MDC 05 (Diseases and Disorders of the Circulatory System). CMS' analysis indicates that the cases assigned to MS-DRG 215 have much higher average costs than the cases reporting a procedure code describing the open revision of devices in the heart valves, atrial septum or ventricular septum currently assigned to MS-DRGs 228 and 229.Therefore, CMS proposes to maintain the GROUPER logic for MS-DRG 215 for FY 2025.

Trinity Health agrees with CMS and supports this decision.

MDC 06 (Diseases and Disorders of the Digestive System): Excision of Intestinal Body Parts

CMS identified a replication issue from the ICD-9 based MS-DRGs to the ICD-10 based MS-DRGs regarding the assignment of eight ICD-10-PCS codes that describe the excision of intestinal body parts by open, percutaneous or percutaneous endoscopic approach. Because the procedures described by the eight procedure codes are not clinically consistent with procedures on the anus or stoma, CMS believes it is clinically appropriate to reassign these procedures to be consistent with the four other procedure codes that describe excision of intestinal body parts. For FY 2025, CMS proposes the reassignment of the eight procedure codes.

As the highlighted codes do not belong in the DRGs they are currently assigned to, we support the proposed reassignment.

MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue): Logic for MS-DRGs 456, 457, and 458

CMS identified an inconsistency in the GROUPER logic for MS-DRGs 456, 457 and 458 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with MCC, with CC, and without CC/MCC, respectively) related to ICD-10-CM diagnosis codes describing deforming dorsopathies. CMS believes the five diagnosis codes describing deforming dorsopathies of specific anatomic sites to be clinically aligned with the diagnosis codes currently included in the "OR Secondary Diagnosis" logic list. For FY 2025, CMS proposes to add diagnosis codes M43.8X4, M43.8X5, M43.8X6, M43.8X7 and M43.8X8 to the "OR Secondary Diagnosis" logic list for MS-DRGs 456, 457 and 458.

Trinity Health agrees with CMS and supports this change.

MEDICARE PROMOTING INTEROPERABILITY PROGRAM

Antimicrobial Use and Resistance Surveillance Measure

CMS proposes to Split the Antimicrobial Use and Resistance Surveillance measure into two measures starting in CY25.

Trinity Health supports the proposal to separate the AUR Surveillance measure into two measures, adding a new exclusion for AU and AR, and treating these two new measures as new measures with respect to active engagement (beginning with the EHR reporting period in CY 2025).

Increasing Performance-Based Scoring Threshold

The proposed rule would increase the performance-based scoring threshold for eligible hospitals and CAHs reporting to the Medicare Promoting Interoperability Program from 60 points to 80 points beginning with the EHR reporting period in CY 2025.

Trinity Health urges CMS to reconsider raising scoring threshold to 80 points in CY2025 and instead provide a runway for hospitals to meet a higher threshold. The likely pathway for hospitals to increase scores so significantly would be to pursue collection of 30 points via either the Health Information Exchange (HIE) Bi-Directional Exchange measure or Enabling Exchange Under the Trusted Exchange Framework and

Common Agreement (TEFCA) measure in the HIE objective; but those hospitals that do not currently participate in these activities today likely do not due to financial constraints. As such, this increase would require hospitals to establish engagement with an HIE (and/or TEFCA), requiring both time and money. **Thus, we strongly recommend CMS delay to (earliest) CY2026 if finalizing a threshold increase to 80 points.**

Medicare Program Integrity Program Request for Information

The proposed rule includes an RFI on the goals and principles for the Medicare Promoting Interoperability Program's Public Health and Clinical Data Reporting objective and solicits feedback on a series of questions. In response to the RFI question, "what, if any, challenges exist around sharing data with public health agencies (PHAs)?", we have the following feedback:

As a large national healthcare system with many hospitals, we are challenged to data-share with more than 20 PHAs. There is large variation in standards across states – for example, Iowa and Pennsylvania want syndromic surveillance data from inpatient locations and ED whereas majority only want it from ED. This variation requires us to create separate feeds/interfaces from our single EHR that in turn require their own maintenance (creating additional burden). Similarly, some states require we enter into contracts with their HIEs in order to submit the data required under PI. Iowa, for example, requires us to contract with their HIE, CyncHealth, at significant cost to our hospitals. As part of that contract, we were required to also implement additional data feeds to the HIE vendor, costing us significant resources and dollars. Compare this to other states where we send data directly to the state and the cost/time we are required to output are related only to our internal costs. **We appreciate CMS' efforts to reduce burden on providers and would greatly support any additional efforts made on the PHA front to simplify our engagement in data sharing.**

HOSPITAL QUALITY REPORTING AND VALUE PROGRAMS

Hospital Inpatient Quality Reporting (IQR) Program

CMS proposes to add seven new measures to the IQR while removing five other measures. CMS also proposes to increase the total number of eCQMs hospitals are required to report, and to weigh eCQM validation equally with the validation of other IQR measures. Lastly, CMS proposes changes to the HCAHPS survey questions, resulting in changes in the sub-measures used to calculate performance.

Patient Safety Structural Measures

CMS proposes to add an attestation-based measure (yes/no) that would assess whether hospitals are implementing specific polices, processes and practices that are related to safer care in hospitals. The measure includes a total of 25 practices across five separate domains and is all or nothing-- if hospitals can't answer yes to all practices within the domain, hospitals would receive zero points.

Hospitals would report the measure using the CDC National Healthcare Safety Network (NHSN) website.

Trinity Health is concerned with the additional burden of reporting 25 practices across 5 domains, especially because CMS is also proposing new measure reporting for AUR and AU this year as well. **We recommend CMS wait to require reporting on this measure until it is backed by a consensus-based entity. In addition, prior to additional reporting to the NHSN website, we urge CMS to work collaboratively with the CDC to ensure NHSN can accommodate new measures and data submission.** This site goes down periodically—the CMS and CDC should make sure the website function effectively and that it would be able to support new measure reporting.

Age Friendly Structural Measure
CMS proposes an attestation-based measure to assess whether hospitals implement certain policies and practices that CMS believes are linked to better care and outcomes for older adults. It would be an all or nothing measure that includes a total of 10 attestations spread across five domains.

Trinity Health supports the need to consider the aging population and improve geriatric care. However, we do not support adoption of this attestation-based measure which neither measures patient outcomes nor evaluates patient care. It is unclear what additional value this measure would bring to patients, caregivers, hospitals or other stakeholders. **CMS should assess what (if any) gaps in quality measurement exist around geriatric care in the current quality reporting programs and work with the stakeholder community to develop meaningful outcome measures around geriatric care if it is determined that gaps do exist.** We also recommend that the measure receive consensus-based endorsement prior to adoption into the IQR Program.

HAI Measures for Inpatient Oncology Locations
CMS proposes to report hospitals' catheter-associated urinary tract infections (CAUTI) and central-line associated blood stream infections (CLABSI) standardized infection ratios (SIR) stratified for inpatient oncology locations. These new measures would "supplement, not duplicate, the existing hospital CAUTI and CLABSI measures so CMS would continue to report overall hospital SIRs for CAUTI and CLABSI, while also reporting SIRs specific to the hospital's inpatient oncology units.

Trinity Health does not recommend CMS finalize this proposed measure. Our care for this population has an emphasis on ambulatory care and if they require inpatient care, they end up in different units due to staffing and bed availability. **For these reasons, there are no pure oncology units. Thus, mapping or assigning this population to an oncology unit isn't feasible.**

Hospital Harm – Postoperative Respiratory Failure eCQM
This new measure would calculate the risk-adjusted rate of elective inpatient hospitalizations for patients aged 18 years and older without an obstetrical condition who have a procedure resulting in postoperative respiratory failure.

This is a poor measure that will not provide the detail CMS is looking for. Many times, staff will write post-operative respiratory failure but most of the time it is due to an underlying condition and not related to the surgery. **If CMS chooses to finalize the measure, we urge the agency to provide hospitals more time prior to implementation**.

eCQM Reporting Requirements
CMS proposes to require the reporting of all of its previously adopted hospital harm-related eCQMs. For the CY 2026 reporting/FY 2028 payment year, hospitals would report nine eCQMs, three of which would be self-selected from the menu of available eCQMs. For the CY 2027 reporting/FY 2029 payment year, hospitals would be required to report 11 eCQMs, three of which would be self-selected. CMS would continue to align the IQR's eCQM reporting requirements with those in the Promoting Interoperability Program.

Trinity Health is very concerned about the additional required eCQMs. **The proposed rule lists the regular eCQMs but does not acknowledge that hospitals are also required to submit the hybrid measures and the new outpatient eCQM – so the additional burden is not only the addition of the 5 new required measures over 2 years. CMS is not removing anything to ease burden—for example, quality teams must still abstract sepsis, which is very laborious**. We are concerned that our resources will not be able to support

the new requirements, as the submission and validation process is resource-intense. **CMS should not finalize these changes.**

IQR Validation Process

In this rule, CMS proposes to implement eCQM validation scoring based on the accuracy of eCQM data beginning with eCQM data from CY 2025, which affects payments in FY 2028. Under this revised process, CMS would assess the extent to which eCQM data abstracted for validation matches the measure data that hospitals submit in their Quality Reporting Document Architecture-I (QRDA-I) files.

Validation is a significant burden for hospitals and increasing the number of eCQMs from 6 to 11 will only add to this burden. We urge CMS to provide some relief, such as requiring the validation of fewer measures for hospitals selected (instead of all of the measures submitted). Should CMS move forward with finalizing this proposal, the agency should start with a validation lower than 75%.

HCAHPS

CMS proposes to change several of the questions included in the HCAHPS patient experience survey, including adding seven new questions, while removing four others. As a result, CMS would modify the composite sub-measures used to calculate overall HCAHPS performance in both the IQR and the HVBP program. In addition, CMS would add three new sub-measures and modify one existing sub-measure, each of which would reflect new or modified survey questions.

Trinity Health is excited CMS is proposing to modify the care transition questions to be clearer and reworded in a way that patients can understand. **We recommend CMS remove question #3 in the restlessness question that is related to rest. Hospitals provide 24/7 care and providers often need to interrupt patients throughout the night for treatment or to take vitals. We are concerned the wording of this measure could disincentivize practices necessary for safe patient care.**

Hospital Readmissions Reduction Program (HRRP)

As required by the 21st Century Cures Act, CMS implemented a sociodemographic adjustment approach beginning with the FY 2019 HRRP in which CMS places hospitals into one of five peer groups based on the proportion of patients dually eligible for Medicare and Medicaid that they treat. CMS is also seeking feedback on whether measures should be included in value programs that focus on post-discharge interactions with acute care beyond readmissions, such as emergency department (ED) visits and observation stays.

We do not recommend CMS add measures for ED visits; however, we support the inclusion of observation stays and inpatient stays.

Condition of Participation (CoP) for Acute Respiratory Illness Data Reporting

CMS proposes to modify and make permanent its CoP requiring hospitals and CAHs to report certain data on acute respiratory illnesses, including during times outside of a PHE.

To reduce reporting burden, Trinity Health urges CMS to make this an eCQM based on claims data rather than requiring data abstraction. In addition, hospitals should not have to report this information more than once per month.

The proposed rule also includes an RFI asking about the use of the CDC's National Syndromic Surveillance Program (NSSP). The NSSP is most effective for capturing ED encounters, rather than for capturing useful information through inpatient stays or labs, largely because there are too many confounding variables for

inpatient settings and labs don't generally capture syndromic surveillance (labs don't know why physicians order a test). **Should CMS finalize policy around this, we urge you to only focus on ED encounters.**

COVID-19 Vaccination Reporting.

We continue to have concerns with the required COVID-19 vaccine reporting requirements as finalized last year. Currently, our acute care facilities are required to report this data for one week/each month and our SNFs must report every week. **This is a significant burden and demand on our resources and the data is entirely dependent on colleagues reporting if they are up to date with vaccination as defined by CDC (which changes over time – especially when new formulations of vaccine are manufactured).** The frequency with which we must report this data is excessive, as the data changes very little from month to month.

We urge CMS to collaborate with NHSN and transition the frequency to mirror that which has long been in place for the influenza vaccine – a one/year summary report that coincides with a point in time that influenza season has ended. This would reduce burden on providers/hospitals and align COVID-19 vaccination reporting with flu reporting.

TRANSFORMING EPISODE ACCOUNTABILITY MODEL (TEAM)

With our many years of successful participation in BPCI and BPCIA, as well as multiple ACO and primary care models, Trinity Health appreciates the opportunities we have had with CMMI to transform care delivery through alternative, voluntary payment models. We have also participated in the CJR mandatory model in multiple markets, and of course our hospitals have experience in the mandatory Value Based Purchasing model. **As reflected in our comments here, our experience in both voluntary and mandatory models compels us to strongly urge CMMI to set a higher bar in TEAM than has been set in voluntary models, for each model component.**

We have the greatest concerns with the elements of TEAM that do the opposite of what has been done for voluntary models: that create more financial risk, more business risk, and greater administrative burden for hospitals required to participate. TEAM as proposed would add significant risk and burden to some of the most distressed hospitals at time when they – and especially non-profit community hospitals who are mostly serving Medicare and Medicaid beneficiaries—have no capacity to take on new risks and burden. CMMI must make this model, if mandatory, *easier to implement*, *less risky to manage*, and *more aligned* with other work than voluntary models.

To address these risks and burdens of greatest concern:

- ***TEAM must have less risk and more reward.*** As we discuss in more detail below, a 3% discount is too steep for hospitals to earn savings. We recommend CMS move to a shared savings model, where the participant and CMS have shared accountability for earning savings. CMS could ask a participant to choose a shared savings track with up to 75% shared savings similar to the MSSP ACO, or a combination of a 1% discount with less shared savings, similar to the Next Gen ACO model.
- ***TEAM must include two years of no downside risk at a minimum, for all participants.*** As we explain below, a participant will not have enough data on claims and quality performance to make whatever changes are necessary to be successful until part-way through the second year.
- ***TEAM must include a no-downside risk track for the full 5 years of the model.*** This would be for rural, safety-net and/or other financially distressed hospitals. TEAM simply cannot put additional financial burden on these hospitals at this time, but would benefit from the data and participation experience they would bring

to the model. Participants that want to progress to risk after their first two years of experience would have the opportunity to do that, to earn a higher reward.

- ***TEAM must use a retrospective trend which will be more accurate.*** Greater accuracy and statistical significance is critical in a mandatory model, especially at a time when most participants are stressed financially.
- ***Only include hospitals that have a minimum of 50 episodes in the baseline year per episode.*** Again, TEAM as a mandatory model must meet a higher actuarial test and create enough opportunity for participants to succeed.
- ***Provide enough lead time for CMS to give participants a full set of claims and quality data a year prior to launch.*** This will be critical for hospitals to do the care redesign necessary to be successful and a mandatory model should meet this minimum ask.
- ***Provide opportunity for voluntary participation in year 3.***
- ***Do not introduce PROMs without engaging the provider, beneficiary and measure setting community in a full redesign of these measures.*** While the intent of patient-reported outcome measures is excellent, in practice as currently designed and implemented they fail to collect data that can be used at a population or payment level and so should not be included in a mandatory model. In addition, the volume is so small in some of these metrics that the information may be less meaningful to CMS.
- ***CMS should not expand TEAM to medical or chronic conditions.*** These are more appropriately managed by an ACO.
- ***CMS should not include new and untested measures in the TEAM model.*** The measures under consideration may create reporting challenges and benchmark data is not available to support quality improvement efforts. CMS should consider alternatives such as registry-based data, which is available for most of the TEAM clinical episodes, similar to what was done for BPCIA.
- ***In addition, CMS must provide all component data for the Composite Quality Score with frequency and full transparency on how the CQS was calculated.*** Because of the mandatory nature of the model, and the fact that quality performance only reduces payment, CMS must provide monthly reporting in a form that the participant can see the component data and replicate the quality score.
- ***CMS should include additional waivers to allow participants to redesign care and lower cost, with greater latitude for financial arrangement.*** Given the high-stakes nature of this model – mandatory, 30-day only opportunity – CMS needs to make more, not fewer waivers available, especially waiver of home-bound status, waivers for post discharge visits, transportation including alternatives to ambulance, and waivers that are allowed in the MA VBID program. In addition, CMS needs to give participants greater latitude to create new payment and downstream risk arrangements with medical and community-based providers.
- **The definition of safety net should fully account for safety net facilities.** The proposed definition for safety net focuses exclusively on the Medicare population and does not fully capture hospitals that are safety net hospitals and qualify for DSH payment and 340B the 340B program. It is imperative protections are included in TEAM for safety net hospitals, as they care for the most vulnerable patients and receive the lowest reimbursement rates from payers, thereby increasing financial challenges. CMS should use a broader definition of safety net that more closely aligns with community need and is more reflective of high levels of indigent care.

Model Performance Period

CMS proposes a 5 -year performance period Jan 1, 2026- Dec 31, 2030, for the mandatory TEAM model.

In general, Trinity Health supports a calendar year start to the model, as it's how we are set up for reporting and tracking performance in all other Medicare alternative payment models. Population-based quality reporting, including PROMS, are also set up for calendar year reporting. In addition, a calendar performance year would help with the administrative burden of reconciliation and forecasting and could potentially reduce the need for an extensive true-up process.

Because of the lack of alignment in timing with other Medicare programmatic requirements, we would not support an April start date for TEAM. In addition, we support a model length of five years, as that's an appropriate length of time to be able to evaluate a model to determine success.

It is essential that CMS provides participants with sufficient time from when policies are finalized until the launch of the model**. Trinity Health urges CMS to finalize policies and provide additional guidance, including participant selection and available waivers, at least one year prior to the launch of the model.**

Participant Exclusions

The rule proposes to exclude all CBSAs located entirely in the state of MD or are located partially in MD and in which more than 50% of the five episode categories were initiated in MD between Jan 1 2022, and June 30, 2030. CMS does not propose to exclude AHEAD participants.

Trinity Health supports excluding MD and we recommend CMS also exclude states/CBSAs that are participating in the AHEAD model as they will have accountability for total cost of care, including hospital global budgets, and should have the ability to implement their specific state-based approach. CMS should avoid the confusion of having multiple model interactions at the point of an acute care episode. **In addition, we also strongly urge CMS to allow hospitals that are not chosen to participate in TEAM the flexibility to opt *into* the model voluntarily.** For Trinity Health and others who participated in BPCIA, this would support continuing success in those programs on a voluntary basis.

It is also essential that CMS establish appropriate exclusion criteria for low-volume hospitals. Providers who have a low volume of procedures can face significant variability in performance and large losses due to only a handful of patients. **To that end, we also encourage CMS to either exclude low-volume hospitals from participation or allow these facilities to remain in Track 1 for the duration of the model.** In addition, based on our analysis and experience, the low-volume threshold should be 50, not 30 as is being proposed.

Lastly, ACOs that participate in full-risk ACOs, such as the MSSP Enhanced Track or REACH ACOs, should be allowed to have their participating hospitals opt out of TEAM. This would recognize the fact that these ACOs already bear risk for all of the episodes included under TEAM. Allowing the opt-out would both support ACOs already taking on risk, as well as encourage other ACOs to enter full-risk tracks.

Geographic selection

CMS outlines a stratified random sampling method to select 25% of the 803 eligible CBSAs for participation. Stratification will be based on 4 criteria: average historical spending, number of hospitals, number of safety net hospitals and exposure to prior bundled payment models, with CMS proposing to oversample those with high numbers of safety net hospitals and low participation in previous bundled payment models.

The proposed rule uses an existing safety net definition from CMMI's strategy refresh that includes short-term hospitals and critical access hospitals (CAHs) that serve an above-baseline number of beneficiaries with dual eligibility (DE) or Part D Low-Income Subsidy (LIS) (proxies for low-income status). Specifically, under this

definition, hospitals are identified as safety net when their patient mix of beneficiaries with dual eligibility or Part D LIS exceeds the 75th percentile for all congruent facilities who bill Medicare.

CMMI's proposed definition of safety net for TEAM focuses exclusively on the Medicare population. As such, we are concerned this definition is too narrow and doesn't capture all safety net hospitals, including those that serve high numbers of Medicaid and SSI recipients. Safety net facilities are challenged with resources that will be required to succeed in TEAM. **It is important that CMMI properly identify these facilities and it is imperative that protections are included in the model. If finalizing a mandatory model, CMS should use a broader definition of safety net than what is being proposed to capture facilities that serve as safety nets across all populations.**

In addition, reviewing and changing a safety net designation annually would be disruptive. **If deemed a safety net facility at the start of the demonstration, a facility should maintain this designation for the duration of TEAM.**

Selection Strata
CMS proposes to stratify CBSAs into groups based on average historical episode spending, the number of hospitals, the number of safety net hospitals, and the CBSA's exposure to prior CMS bundled payment models. One of CMS' policy objectives is to extend the reach of value-based care to more beneficiaries, including beneficiaries from underserved communities. As such, CMS proposes to oversample CBSAs that have limited previous exposure to CMS' bundled payment models and CBSAs with a higher number of safety net hospitals.

CMS may want to consider a market readiness variable to include in selecting strata. The inclusion of Metropolitan Statistical Areas (MSAs) may pose a risk to success, as some MSAs have only one hospital and may not have the assets in place (e.g. provider network) to be successful. One option may be CMS' market saturation by CBSA to identify how many beneficiaries there are per provider. Lower numbers may reflect the geography is currently not ready and would require investment prior to go-live of TEAM. Given the model is a 5-year plan, adding the needed assets are a multi-year endeavor.

Many safety-net, rural, and CAH hospitals have closed over the years due to financial distress. All bundle models except for EOM began prior to the pandemic and many hospitals have experienced declining margins. If these facilities are to be included and required to participate, a financial health indicator (EBITDA, op margin etc.) may be needed either as a strata selection variable or used to assess hospitals prior to/after CBSA selection. These financial health indicators would also help identify facilities that are most at risk of not being successful in a mandatory model. Facilities with a low financial health metric may not have the ability to prepare for at-risk models and are at a low risk of success. Otherwise, the program may need to be voluntary if the above hospitals are to be included.

Strata percentages are largely based on the number of safety net hospitals and prior model exposure, but not average spend, which is the crux of APMs. CBSAs with a low average spend shouldn't have the same selection percentage as CBSAs with high average spend. **CMS should consider selection percentages among similar strata (e.g. strata 1 vs 3, 2 vs 4, 5 vs 7 etc.) and adjusting Table X.A.-03 to better reflect the selection method is largely based on average spend and past exposure.**

For the reasons outlined above, rural and safety net hospitals should have zero required downside risk for the full 5 years if CMS chooses to include them in the mandatory model. These facilities should be able

to choose to take on downside risk for increased upside opportunity but should not be required to advance in risk.

<u>Participation Tracks</u>
CMS 3 participation tracks with an optional glide path to two-sided risk.

We appreciate that CMS is offering all participants the opportunity to participate in upside-only financial risk for PY1. **However, Trinity Health strongly urges CMS allow all participants to get two years in Track 1, even if they have participated in BPCI/CJR models, to support practice transformation, provide hospitals the time to determine if the work they are doing to manage risk is actually working, understand performance, and ensure all providers can participate in the model**. Our experience with BPCIA is that it took 18 months after the end of an episode to reconcile, further illustrating the need for an additional year in Track 1 than is being proposed.

For reasons outlined in the above section, those entities that CMS have outlined in Track 2 who don't have prior experience with bundled payment models, who have low patient volume, are safety net facilities, and may be financially distressed (ie., safety net hospitals, rural hospitals, sole community hospitals, etc.) should have the option to remain in the upside only Track 1 for all five years of the demonstration with the remaining participants moving to Track 3 beginning in the third year of the demonstration. After the first two years of the demonstration, we recommend a limited and slower glide path to risk (i.e. 10% in year 3, 20% in year 2) with an option for hospitals that want and are able to take on more risk faster to do so. If CMS is unwilling to keep safety net hospitals, rural hospitals, CAHs, etc. in Track 1 (no downside risk) for all 5 years of the demonstration, those facilities should be excluded from TEAM or the model should be voluntary. Pushing these providers to take on two-sided risk, even with the guardrails proposed under Track 2, could further jeopardize access to care in these communities.

CMS has acknowledged the need for up-front investment payments in other models, such as the Medicare Shared Savings Program (MSSP) Advanced Investment Payment. Without up-front investment, rural and safety net providers may be unable to make essential investments in care management, data and analytics infrastructure, and support for patients' health-related social needs—all of which is necessary to succeed in a mandatory bundle model. **Trinity Health encourages CMS to provide up-front investment opportunities for rural and safety net providers, similar to flexibilities offered under the MSSP's Advanced Investment Payment policy. Ideally, these hospitals should not be required to pay back this investment, even from their shared savings.** At minimum, if hospitals would be required to pay back this investment from future shared savings, the hospitals should be held harmless if they do not achieve sufficient savings to pay back the investment during the model performance period.

<u>Definition of Rural Hospital</u>
A rural hospital is defined as an IPPS hospital located in a rural area, in a rural census track, was reclassified as rural hospital or was designated as a rural referral center. CMS proposes rural designations to be reviewed each performance year and hospital would need to notify CMS of a change within 60 days.

Trinity Health strongly advises CMS not to reclassify hospitals as rural/not rural in the middle of the demonstration---this was a challenge with the BCIPA program. CMS should maintain a hospital's status as rural for the purposes of TEAM for the duration of the demonstration.

Episodes of Care

TEAM would include surgical procedure and inpatient/outpatient stays and related care covered under Parts A and B within 30 days of discharge. CMS proposes to start with the following 5 surgical episode categories, with the possibility of adding other episodes in future years:

- Coronary artery bypass graft (CABG)
- Lower extremity joint replacement
- Major bowel procedure
- Surgical hip/femur fracture treatment
- Spinal fusion

Trinity Health supports CMS' proposal to focus on surgical episodes of care that have defined and well-established care practices or medical protocols. The procedures outlined require care for a set-period of time, which will be managed by a specialist in coordination with other providers. In addition, the types of care furnished under these procedures or conditions are also typically well-defined, lending themself to be included in an episode of care**. However, patients admitted from a congregate care setting (i.e. a nursing home) should be excluded from TEAM as the congregate care setting is their home and we do not have the opportunity to discharge them to an alternate site of care, which is where most savings opportunity will be found in 30-day episodes.**

Trinity Health supports the services outlined in the proposed rule, but we urge CMS not to expand to new episodes during the model period so as not to introduce additional burden onto hospitals at a time they are already trying to adapt to the episodes mandated under this model. If CMS ultimately ends up adding additional services during the model, the services should be optional and not mandatory for participants.

The 90-day episodes in BPCIA demonstrated success in reducing post-acute spending and readmissions, most of which occur in the first 30 days post discharge. **We agree that reducing episode duration to 30 days could retain those spending reductions and mitigate some of the challenges in that model with integrating longitudinal care.** The 30-day episode length is appropriate for the objectives to improve efficiency and reduce variation in cost and outcomes. Evidence of this was noted in our experience within the BPCIA program, where readmissions occurring later in the episode (days 45 – 90) were typically unrelated to the reason for episode initiation.

Our support for the episodes of care and the 30-day duration of the model applies only for surgical and procedural episodes; we strongly urge CMS to NOT include chronic or medical episodes that are typically managed by primary care physicians or other specialists long-term in TEAM and allow those to be managed through accountable care relationships.

In addition, among the existing E/M visit services, CMS envisions these services will be most similar to those described by the office and other outpatient E/M codes. As proposed, CMS would structure the new codes similar to the office/ outpatient E/M codes and adjust them to reflect the location as the beneficiary's residence and the virtual presence of the practitioner. Specifically, CMS proposes to create a parallel structure and set of descriptors currently used to report office or other outpatient E/M services. **This would be administratively burdensome to participants; we urge CMS to use existing codes.**

TEAM Overlap with Population-Based Models
CMS proposes to allow overlap between TEAM and population-based models, including both “total cost of care” models that include downside risk all Part A and B spending, as well as other “shared savings models” that may or may not include downside risk.

Trinity Health strongly supports the proposed policy to allow overlap between TEAM and population-based models without recoupment. This policy will incentivize coordination between ACOs and specialists, supporting CMMI’s goals for specialist engagement in value-based care, as well as alignment between episode-based and population-based models. The policy would support TEAM participants, by simplifying the attribution process and increasing episode volume. TEAM participants will know which patients are attributed to the model in real time, without retrospective carve outs due to ACO alignment – which was a key problem under BPCIA and CJR. This policy will also increase TEAM episode volume, which will then provide greater financial predictability for TEAM participants, given that low-volume variation is a key challenge for episode-based models. We recommend CMS allow participants in ACOs the option to voluntarily drop out of TEAM if they are selected.

Transfers
Hospital to hospital transfers would be viewed discretely and could lead to an episode initiated depending on hospital participation and the MS-DRG.

The services selected are surgical and for a patient to be transferred, they would have to have a significant surgical complication. **We recommend CMS remove discharge disposition 02 (transfer to another acute hospital).**

Baseline Period for Benchmarking
Three years of baseline spending data would be used to calculate the target prices for performance years, with annual rebasing. CMS is proposing the three-year window to avoid the ratchet effect and also proposes to weight more recent baseline years more heavily.

Trinity Health recommends CMS implement TEAM with a baseline that is set for three years without rebasing. Should CMS finalize as proposed, the methodology of including three years to avoid the ratchet effect makes sense.

Regional Target Prices
CMS would provide target prices for each MD-DRG/HCPCS and regional based on 100% regional data for all TEAM participants. CMS soliciting feedback on additional options to support safety net hospitals and whether regional target prices at the episode category would be more appropriate.

Trinity Health supports CMS’ proposal to set benchmarks based on regional spending; however, we urge CMS to assess the sustainability of benchmarking in regions where there has been high CJR penetration. In addition, CMS should provide additional information on what benchmarks would be in these regions and work with stakeholders to evaluate the sustainability of continuing to discount these benchmarks year-over-year.

Baseline and Prospective Trend Factor
CMS proposes to use a prospective trend factor to calculate targeted prices updated from baseline data with the percent difference between average regional DRG/HCPCS episode expenditures computed using most recent years of applicable baseline period and the comparison average regional expenditure during first year of that baseline.

While a prospective trend factor provides some stability, it is not the most accurate. Greater accuracy and statistical significance is critical in a mandatory model, especially at a time when most participants are stressed financially. The most accurate target prices would use actual experience and would update for payment system updates. Thus, **Trinity Health recommends CMS use a retrospective trend factor rather than a prospective trend and include payment system updates.**

In addition, we recommend CMS expand the list of excluded drugs to include other high-cost drugs. Consistent with the hemophilia exclusions, CMS should exclude any drugs that have a mean cost of more than $25,000 per episode, including drugs for oncology and other conditions. This exclusion is necessary due to the high cost of these drugs, combined with the large annual price increases that many high-cost drugs experience.

Discount Factor

CMS proposes a 3% discount factor to the target price to serve as Medicare's portion of reduced expenditures from an episode that would then be taken off the top of the target price before shared savings are calculated.

The savings CMS requires off the top is based off of the total cost of the episode, including both the index admission or procedure, as well as the post-discharge spending. Because CMS proposes to reduce the total among of post-discharge spending, the index DRG or procedure becomes an even larger proportion of the total spending – and therefore even more savings must be achieved within the 30-day post-discharge period.

This model will cost money to run effectively and participants will need to invest in order to run TEAM well. Taking 3% off of the top limits the ability of participants to invest in the model (especially participants that will be new to bundled payments).

The proposed discount is too steep for the model. The proposed discount will be most problematic for Clinical Episodes with high-cost index admissions relative to their post-discharge spending, such as CABG and spinal fusion. For spinal fusion, the index admission represented 73% of the total cost of care under a hypothetical 90-day episode. To break even, hospitals would need to reduce post-discharge spending by 11% to break even over 90 days. For 30-day episodes as proposed under TEAM, the required spending reduction rises to 13%. This math is more extreme for CABG, because the index admission would account for 79% of the total cost of care under a hypothetical 90-day episode. As a result, hospitals would have to reduce post-discharge spending by 14% within 90 days – and this rises to 17% under 30-day episodes.

In addition, spinal fusion and joint replacement procedures are primarily done in an outpatient setting. For these services, hospitals receive the most complicated patients, as ASCs don't take patients that have more than one comorbidity. **As such, hospitals get patients with a high likelihood of medical complications and don't have the opportunity to manage less complex cases. CMS needs to account for medical complexity in the discount rate—we urge CMS to move to shared savings approach with TEAM (no discount) for all tracks, or use a combination of no more than 1% discount plus shared savings (similar to the Next Gen model) for those that want more upside opportunities, while adding a track for no downside risk for rural and safety net hospitals as noted above with shared savings only, similar to the original ACO model.**

CMS proposes a mandatory TEAM model with a limited number of episodes. Therefore, the model should have discounts that reflect the opportunity and variation of the specific episode rather than one standard discount rate for all episodes. Moving to shared savings model as above would recognize these differences.

If hospitals that have historically participated in other bundled models are selected for TEAM, the episodes included in those bundles should not be included for these TEAM participants. For example, we

know both from experience in CJR/BPCIA and CMS evaluations that the cost of joints shifted and decreased overall as a result of participating in those prior models. Therefore, CMS should not take a discount and only apply shared savings for those episodes. Alternatively, CMS can remove these episodes from the model for those participants.

Low-Volume Thresholds
If a participant doesn't meet a threshold of 31 total episodes in the baseline period for PY1, then payments would be reconciled, but would be subject to Track 1 stop gains. If a threshold of 31 episodes not met in baseline period for years 2-5, then payments reconciled against track 2 stop loss and stop gain limits.

The proposed low-volume threshold is too low and not sufficient to protect low-volume hospitals from catastrophic losses. In fact, CMS the regulation includes the lowest low-volume threshold that they have ever proposed. In BPCIA, CMS set the low-volume threshold at 41 episodes during the four-year baseline period (averaging at least 10 episodes per year) for a given clinical episode. In contrast, the TEAM threshold is set at fewer than 31 episodes in the baseline aggregated across all Clinical Episodes. With volumes this low, the TEAM participant's results would be driven by low-volume variation, and it would not be possible to meaningfully determine their financial and quality performance.

Providers who have a low volume of procedures can face significant variability in performance and large losses due to only a handful of patients. **Trinity Health recommends that CMS set the low-volume threshold as 50 episodes per episode category during the baseline period. Hospitals that meet the low-volume threshold should either be excluded from the model or be subject to no downside risk with shared savings only (no discount).**

Risk Adjustment and Normalization
CMS proposes to risk adjust episode-level target prices at reconciliation by beneficiary age, the beneficiary's Hierarchical Condition Count (HCC) and social risk. CMS proposes to use a modified version of the risk adjustment methodology used under the CJR model.

CMS would calculate risk adjustment multipliers prospectively for each MS-DRG/HCPCS episode type level based on baseline data, and hold those multipliers fixed for the performance year.

For beneficiary age, CMS proposes to use the same age brackets used in CJR: less than 65 years, 65-75 years, 75-85 years, and 85 years or more, based on the beneficiary's age on the first day of the episode as determined through Medicare enrollment data.

CMS proposes to use a variable to account for social risk composed of three elements:

1. fully dually eligible for Medicare/Medicaid,
2. position on the distribution of the beneficiary's geographic residence on the distribution of Area Deprivation Index (ADI) values (>the 80th percentile for national ADI, and the 8th decile for state ADI), and
3. whether or not the beneficiary qualifies for the Part D Low-Income Subsidy (LIS).

CMS proposes to calculate a prospective normalization factor based on the data used to calculate the risk adjustment multipliers. The prospective normalization factor would be applied, in addition to the prospective trend factor and discount factor described previously, to the benchmark price to calculate the preliminary target price for each MS-DRG/HCPCS episode type and region. The prospective normalization factor would be subject to a

limited adjustment at reconciliation based on TEAM participants' observed performance period case mix, such that the final normalization factor would not exceed +/- 5 percent of the prospective normalization factor.

Trinity Health strongly recommends CMS incorporate normalization retrospectively, rather than prospectively, to increase accuracy.

We also recommend CMS adopt more sophisticated risk adjustment for TEAM, such as the adjustment applied under BPCIA. It is essential that CMS adjust for patient-level factors on clinical and social risk (e.g., patients who live in nursing homes, patients experiencing homelessness), as well as hospital level factors (e.g., safety net status). TEAM should adequately risk adjust for the following characteristics:

- **Patient-level clinical risks:** The CMS proposal does not include numerous relevant variables that are incorporated in the risk adjustment for BPCIA. **One of the most concerning omissions is whether a surgical episode such as CABG was planned or due to an emergency.** This is a meaningful clinical difference that drives patient complexity and the need for more intensive care patterns, which in turn increases cost. **Another significant omission from the proposed risk adjustment is whether a patient lived in a nursing home prior to the episode.** Patients who previously lived in a nursing home will return to a nursing home after discharge, which may be charged to Medicare for up to 60 days – substantially driving up post-episode spending. This care pattern reflects appropriate care delivery for known clinical risks, which are outside the control for TEAM participants. The CMS proposal to omit this relevant clinical data from the risk adjustment would penalize hospitals that care for the sickest patients, potentially leading to unintentional consequences that harm patient access, quality of care, and equity. **Lastly, CMS should account for both HCC weights and counts in the risk adjustment, as well as HCCs captured during the episode, as is done in BPCIA. In addition, there should be a one-year look back for HCCs, comparable to Medicare Advantage risk adjustment methodologies.**

<u>Reconciliation</u>
TEAM participants would reconcile performance year spending against the target price to determine if a hospital is eligible for a reconciliation payment or repayment. Reconciliation performed annually and would be lump sum payments.

It is preferable for participants to pay money back after the reconciliation process rather than having CMS recoup future payments. In addition, we urge CMS to finalize an annual reconciliation process (compared to the quarterly reconciliation process for BPCIA). CMS should also provide participants regular monthly reporting similar to ACO models so they can track how they're doing against both financial and quality outcomes.

<u>Participant Responsibility for Increased Post-Episode Payment</u>
CMS is proposing to calculate 30-day post episode spending to determine if TEAM participants have spending three standard deviations above the regional estimate. If they do, CMS would subtract the amount from the reconciliation/repayments for following year.

Rather than just make an assumption that a participant has withheld care and pull money back, CMS should use a review and finding process and ask participants to submit information about the episode.

Use of Quality Measures in Payment Determination

To be eligible for a reconciliation payment, a hospital must meet or exceed performance thresholds on certain quality measures:

- For all episodes: Hybrid Hospital-wide all cause readmission
- For all episodes: patient safety and adverse events
- For LEJR episodes: total hip and/or total knee arthroplasty PROM

CMS solicits feedback on these proposed measures and whether three additional measures currently on the 2023 measures under consideration list should be included:

- Hospital harm – fall with injury
- 30 day risk standardization death rate among surgical inpatients with complications
- Hospital harm – post operative respiratory failure

We have several concerns about using the Hybrid Hospital-Wide all cause readmission measure for TEAM and recommend this be replaced with a measure that has been submitted for several years and for which CMS has already published benchmarks. Our concerns include:

(1) the measure includes all Medicare cases and are not specific to surgical episodes;

(2) this is a new mandatory measure. The first reporting period is 7/2023-6/2024 and submission is due by 10/1/24. Trinity Health participated in the voluntary submission period but have not received reports from CMS on that submission to determine how we've done. Many hospitals are unable to extract the required data elements from their EHRs.

(3) There are data quality requirements where, if not met, the files will not be accepted and the hospital will fail the measure submission. Hospitals that attempted submission but CMS would not accept due to data quality issues would be subject to a zero score for that measure. Hospitals would need time to update our operations and protocols prior to inclusion.

Patient Safety and Adverse Events Composite (CMS PSI 90) is an appropriate measure for TEAM, as it's not limited to surgical patients. It is a composite score for patient safety indicators and has been in the IQR program for many years.

We do not recommend CMS include the Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure for LEJR due to the following:

(1) This is a new measure and the first submission will be for procedures performed 7/2024-6/2025.

(2) At least 50% of inpatient elective THA/TKA data must be submitted - which means both the pre-procedure PRO data and the post-procedure PRO data. Post-procedure data is collected 300-425 days after surgery so there are many concerns about how successful participants will be with that collection and if hospitals will meet the 50% requirement.

(3) Very few of our hospitals were collecting the data before the EHRs were able to support it.

In lieu of this measure, CMS could consider using the complications measure that has been in the IQR program for several years: COMP-HIP-KNEE Hospital-Level Risk-Standardized Complication Rate Following Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty.

The three proposed MUCs are proposed as new IQR measures in the FY2025 IPPS proposed rule and are not currently in use and are untested. As such, there has been no opportunity to validate the measures. There may be reporting challenges and benchmark data is not available to support quality improvement efforts. **While we**

generally support using quality measures that are reported for IQR; we do not support using measures in payment penalty programs when the measures are new (or are being proposed) as hospitals have not had the ability to validate data or assess measure performance.

Instead of the proposed quality measures, CMS should consider alternatives such as registry-based data, which is available for all TEAM Clinical Episodes except major bowel procedures. CMS should adopt a similar approach to BPCIA, in which participants may select registry-based measures rather than claims-based measures. Registries provide clinical outcome data for patients treated by a given hospital and physician, making it highly specific to the TEAM Clinical Episodes. Even without one-to-one matching between TEAM episodes and the patients in the registry (which represents all patients with a given condition treated by that hospital/physician), using registry data would create a closer link between TEAM clinical outcomes and the proposed claims-based measures. In addition, the registries provide national benchmarks for this outcome data, and many hospitals already report to registries, minimizing any additional burden.

CMS seeks comment on TEAM's proposed methodology at proposed § 512.550(d) to calculate and apply the CQS. We also seek comment on our proposed definition of quality adjusted reconciliation amount at § 512.505.

Trinity Health recommends CMS modify the rule so that TEAM participants can earn a CQS of 100 if they are a top performer overall *or* among Team participants. This would follow how hospitals attain quality performance in the Value Based Purchasing Program which is relative to other VBC participants, for consistency. Given that quality scores only adjust down TEAM financial performance, CMS should take care to create reasonable and attainable goals consistent with other models.

<u>Episodes that Begin in One Performance Year and End in the Subsequent Performance Year</u>
Some TEAM episodes will begin during one performance year and end during the following performance year. CMS proposes that all episodes would receive the target price associated with the date of discharge from the anchor hospitalization or the anchor procedure, as applicable, regardless of the episode end date, which determines the performance year in which the episode would be reconciled.

Trinity Health supports treating episodes that cross a calendar year same as in CJR and BPCIA; however, CMS must confirm which target year will be affected by the performance in the final rule.

<u>Composite Quality Score</u>
CMS proposes to adjust a participant's reconciliation amount by its Composite Quality Score (CQS). CMS is proposing to use three quality measures under the model that are currently collected through existing Medicare hospital quality reporting programs.

To help participants understand how they can improve their performance for these bundles, they need to be able to parse out contributions to the CSQ. We urge CMS to report each part of the CSQ as part of an improved monthly reporting package so that we can see how it is derived for each episode. This is something we have never been able to do in prior models and it made it exceptionally challenging to determine what we should be modifying to make improvements.

In developing the CSQ, CMS proposes a normalized weight would be calculated by dividing the TEAM participant's volume of episodes for a given quality measure by the total volume of all the TEAM participant's episodes. **THA/TKA is an inpatient-only measure and there are very few procedures. The proposed CSQ**

weighting process would be challenging with just three measures. CSQ weighting works well for other quality payment penalty programs because they have more measures.

We seek comment on TEAM's proposed methodology at proposed § 512.550(d) to calculate and apply the CQS. We also seek comment on our proposed definition of quality adjusted reconciliation amount at § 512.505.

We have concerns regarding the proposed composite quality score:

1. A weighting process using only 3 measures does not align with other CMS quality program scoring methodologies. For example, Hospital Value-Based Purchasing uses 4 domains with multiple measures in each domain, which is conducive to a weighted score.
2. Two of the measures are new and the first mandatory submission has not yet occurred. We cannot yet anticipate hospital performance, and we cannot yet anticipate how many hospitals will experience failed submissions or rejected files.
3. To align with the Hospital Value-Based Purchasing approach, TEAM participants should earn 100 points if they are a top performer in comparison with other TEAM participants. Given that quality scores only adjust down TEAM financial performance, CMS should take care to create reasonable and attainable goals consistent with other models.

Participant Responsibility for Increased Post-Episode Payments

CMS seeks comment to make TEAM participants responsible for making repayments to Medicare based on high spending in the 30 days after the end of the episode and for our proposed methodology to calculate the threshold for high post-episode spend.

Rather than what is proposed, we urge CMS to monitor the model for the first year to determine if this is even necessary.

Considerations for Notification Process for Shared Savings or Total Cost of Care Model

CMS considered, but is not proposing, a notification process required of the TEAM participant to ensure they are alerting the total cost of care participant of their aligned beneficiary's episode during the anchor hospitalization or anchor procedure.

CMS was right not to propose the TEAM participant take on this responsibility—CMS has all of the information and as such, this burden should not be on the TEAM participant but rather with CMS.

CMS seeks comment on ways to implement a notification process for shared savings or total cost of care participants that would be used to alert a shared savings or total cost of care participant that one of their aligned beneficiaries has initiated an episode in TEAM.

We support CMS notifying ACOs when a patient who could be eligible for inclusion in TEAM is admitted to a participating hospital, since CMS receives that notification from hospitals as part of standard process eligibility checks today. CMS can share that information from the admitting hospital to ACOs directly or by sharing with third party notification systems (e.g. Patient Ping).

HEALTH EQUITY REQUIREMENTS

Health Equity Plan

Participants will be required to submit a health equity plan to CMS starting in PY2 that would include identification of health disparities within the beneficiary population, health equity goals, intervention strategies and performance measures.

All licensed hospitals are currently required by the Joint Commission and by CMS to submit a health equity plan that focuses on the lager systemic issues that the hospitals and communities need to work on. CMS should not require a separate, standalone health equity plan for TEAM and should accept—without review—the health equity plans that are already required.

Demographic Data Reporting

To align with other CMS efforts, CMS proposes TEAM participants voluntarily report to CMS demographic data of TEAM beneficiaries in PY1. Beginning in PY2 and all subsequent performance years, TEAM participants would be required to report demographic data of beneficiaries to CMS in a form and manner and by a date specified by CMS. The demographic data would also be required to conform to USCDI version 2 data standards, at a minimum.

In general, we urge CMS to ensure it is not requiring participants to submit data that CMS already has. Hospitals are early in the process of collecting the proposed expanded demographic data—including data on race, ethnicity, language, disability, sexual orientation, gender identity, sex characteristics, and other demographics. **As such, we urge CMS not to apply penalties for errors and/or incompleteness. While we support participants collecting this important information, it may not be meaningful to CMS given the early stages of reportability. Collecting this data should be voluntary until it can be reported in an automatic fashion similar to dQM. CMS could encourage this voluntary reporting through financially incenting TEAM participants to report by providing upfront investment payments.**

Health Related Social Needs (HRSN)

Participants will be required to screen TEAM beneficiaries for HRSN across for domains starting in PY1:

- Food insecurity
- Housing instability
- Transportation needs and
- Utility difficulties.

CMS seeks comment on the potential use of the Hospital Inpatient Quality Report Program (IQRP) measures related to HRSN screening.

Trinity Health agrees that using the IQRP measures makes the most sense for IPPS hospitals.

CMS seeks comment on possibly providing upfront infrastructure payments to qualified safety net hospital participants to further support safety net hospitals in the transformation of care delivery.

There is likely going to be a gap in reporting capacity for HRSN data. Trinity Health urges CMS to provide all TEAM participants upfront payment for the HRSN screening as well as infrastructure payments to enhance closed loop referral infrastructure. In addition, CMS infrastructure payments could help TEAM participants ensure there is Wi-Fi/internet access in safety net facilities and neighborhoods - we can't provide the care if access doesn't exist.

Trinity Health supports HRSN screening but recommends that CMS streamline reporting requirements for TEAM participants. Beginning in 2024, CMS requires all hospitals – not just TEAM participants – to report on all five HRSN domains (housing, food, transportation, utilities, interpersonal violence) as part of IQR. Under TEAM, CMS proposes that TEAM participants report on four of the five domains, which is redundant with the IPPS reporting requirements. Instead, CMS should align the TEAM requirements with the IQR and use the IQR data to obtain this information from TEAM participants.

WAIVERS

CMS proposes to use its authority to waive certain Medicare program rules for providers and suppliers furnishing services to TEAM beneficiaries.

In general, we encourage CMS to establish a standard set of waivers across all APMs to streamline requirements across models. CMS could still vary which waivers are offered under each model based on the design and goals of the model. However, establishing a standard set of waivers and standard requirements for those waivers would reduce administrative burden on participants who may be engaged in multiple APMs and increase the likelihood of participants utilizing waivers.

<u>SNF Three-Day Rule</u>

The rule proposed to waive the SNF three-day rule for discharges to SNFs with at least a three-star rating.

We support a waiver of the SNF three-day rule; however, we urge CMS to use the same guidelines as is currently used for the MSSP SNF three-day wavier. As outlined in the rule, it differs from MSSP and TEAM participants would benefit from consistency.

Regarding the concern that there may be scenarios where a beneficiary could be charged for non-covered SNF services, **we recommend a SNF affiliate agreement that details out the responsibility of the parties and for participants to include a beneficiary notice that they would not be responsible for SNF stays that don't meet the quality requirements of 3 stars or higher.**

<u>Post-Discharge Home Visits and Telehealth Visits</u>

CMS should waive the homebound requirements under TEAM, as this would allow beneficiaries to receive home health care services in their home/place of residence and expand TEAM participants options for management. In addition, we support CMS waiving geographic site requirements and originating site requirements for telehealth.

<u>Incident-to Rule</u>

Changing this bundle to 30-days from 90 days compared to CJR could definitely impact focus areas for management of costs. As such, we think an "incident to" waiver remains appropriate for TEAM and encourage CMS to provide this waiver.

<u>Additional Waivers</u>

Additional waivers not outlined in the proposed rule would benefit TEAM participants. For example, we recommend CMS provide a waiver that would allow participants to provide non-medical transportation services to a physician's office (similar to what was allowed early in the BPCIA program). For purposes of the model, we also ask CMS to broaden the transportation waiver to add non-medical transportation services to the list of TEAM collaborators. Such waiver would also allow participants to use ride sharing as a means for ensuring beneficiaries receive transport as well as arrange wheelchair vans as an alternative to ambulance.

In addition, providers in Medicare Advantage are able to coordinate post discharge meal services similar to what is allowed under Medicare Advantage VBID program. This flexibility would be helpful in that it would allow TEAM participants to coordinate this service without the beneficiary having to go to a SNF or to social services to receive necessary nutrition.

In addition, we urge CMS to provide the following waivers:

- **Patient cost-sharing waivers:** Allow providers to waive patient cost-sharing for select services or patient populations, as allowed under ACO REACH. This is especially important for patients with HRSNs, and the services designed to address these needs, such as community health integration services.

- **Post-discharge home visit waivers:** ACOs have experience home-visit waivers available and have noted the importance of making post-discharge home visits available to many high-risk patients, not only those that are homebound, as allowed under the waiver for the homebound requirement. In addition, the ACOs also used team-based care approaches to allow non-physician clinicians to deliver home-based assessments, as allowed under the incident-to billing waiver. In addition, CMS should offer the Care Management Home Visit waiver offered under the Next Generation ACO Model, which allowed paramedics and community health workers to deliver home-based services. While these waivers may not be used by all participants, their inclusion would support TEAM participants in the delivery of team-based care, to increase patient access, quality, and equity.

- **Beneficiary inducement rules for home visits:** Home visits prior to surgery may qualify as beneficiary inducements. From a clinical perspective, however, home safety checks or structural modifications prior to surgery could foster a prompter and safer return home, which would be responsive to patient preferences and reduce avoidable spending. CMS should offer a waiver of beneficiary inducements in these cases to allow APM participants to proactively access a patient's home environment prior to surgery and help ensure that the patient has the best chance of being able to recover at home. Without these waivers, APM participants must continue to rely on inpatient or SNF settings, where costs are higher and there is an increased risk of facility acquired infections.

- **Flexibility in PAC payments:** In cases where patients need care in SNFs, inpatient rehab or other PAC facilities, APM participants should be offered the flexibility to negotiate rates and payment structures. This would allow APM participants to create partnerships with PAC providers to deliver high-quality, seamless care to patients within innovative value-based care arrangements. Home health services are currently paid as an all or nothing benefit; a waiver in this case would allow providers participating in an APM to negotiate different rates for home care – such as smaller payments for shorter/more frequent home health visits – that better address patient needs. In addition, explicitly allowing PAC providers to accept less than the Medicare fee-for-service payment rates in APM arrangements would add flexibility that fosters clinical decision making that is less affected by cost considerations. This flexibility is similar to what was allowed in the Next Gen ACO model.

- **ACO shared savings distribution waiver**: to ensure participants are allowed to enter into gainsharing arrangements across the full spectrum of collaborators, we urge CMS to provide more

flexibility on the distribution and uses of gainshare funds consistent the ACO shared savings distribution waiver. This waiver of the physician self-referral law (Stark) and Antikickback statute also provides broader options and protections than the gainsharing payment and quality requirements for selecting collaborators that are outlined in the proposed rule.

FINANCIAL ARRANGEMENTS

CMS acknowledges that it is necessary to provide participants with flexibilities that would support their performance in TEAM and allow for greater support for the needs of beneficiaries, including the ability to engage with other providers and suppliers and engage in gainsharing arrangements. To this end, CMS proposes several policies to help facilitate downstream financial arrangements and would determine that the anti-kickback statute safe harbor for CMS-sponsored model arrangements is available to protect certain remuneration with eligible providers and suppliers.

We urge CMS and OIG to provide greater clarity and educate providers on the types of arrangements and flexibilities that are allowed under these exceptions and safe harbors to reduce uncertainty about whether arrangements are protected. Such uncertainly leaves providers less likely to utilize flexibilities given the risk of non-compliance with Stark Law or AKS, which can result in civil monetary penalties, criminal charges or exclusion from federal health programs. In addition, CMS should ensure that they provide participants the flexibility to be able to gainshare with CBOs.

In addition, Trinity Health is concerned that the proposed policy would not allow gainsharing contracts to take volume of services into account. Without tying gainsharing agreements to volume, it would not be possible to link the size of the gainsharing payment to the partnering organizations' level of involvement in TEAM. Further, TEAM participates should have the ability to prioritize collaborators that can have the largest impact.

BENEFICIARY CONSIDERATIONS

Beneficiary Notification

CMS proposes requiring hospitals to notify beneficiaries of the model upon discharge and require all providers and suppliers with whom it executes a sharing arrangement with send beneficiaries certain notification materials.

We are concerned about the requirements for collaborators to send notification to beneficiaries as this could cause confusion for the beneficiary and could be burdensome enough that it could be a disincentive for collaborators to participate. We recommend only requiring participants to notify beneficiaries at discharge. In addition, Trinity Health recommends that CMS allow TEAM participants to edit the standard notification templates to customize it to the specific hospital, provided that all required core elements are included. The hospital should also provide information to the beneficiary about any down-stream contracts.

Beneficiary Incentives

CMS proposes to allow TEAM participants to provide in-kind incentives that are directly linked to the patient's clinical care or disease prevention, documented and collectively worth under $1,000 per patient. CMS proposes a documentation requirement to apply to any item or service worth at least $25, including recording the patient, date, and the item or service. In addition, CMS proposes that TEAM participants must retrieve any item worth more than $75 and document efforts to retrieve the item. As with gainsharing, CMS explicitly stated that APM safe harbor laws apply.

Trinity Health supports beneficiary incentives as a means of improving patient care, particularly for historically underserved populations. However, we recommend CMS streamline the documentation

requirements by increasing the $25 price point that requires documentation to $100. In addition, we recommend CMS eliminate documentation requirements that place added burden directly on patients, such as the requirement that patients return any item over $75.

Monitoring Access and Quality
CMS proposes to require that TEAM participants must, as part of discharge planning, account for potential financial bias by providing TEAM beneficiaries with a complete list of all available post-acute care options in the Medicare program, including HHAs, SNFs, IRFs, or LTCHs, in the service area consistent with medical need, including beneficiary cost-sharing and quality information (where available and when applicable). This list should also indicate whether the TEAM participant has a sharing arrangement with the post-acute care provider.

It isn't realistic to expect TEAM participants to know or publish cost-sharing information, especially since most beneficiaries have supplemental/gap insurance that TEAM participants would not have insight into, and that can change. Instead, we recommend CMS revise the requirement to require participants provide beneficiaries access to a comprehensive resource of post-acute care providers in the Medicare program in the service area.

AAPM Considerations
CMS proposes to adopt two different APM options for TEAM—an AAPM option in which TEAM participants would attest to meeting the CEHRT standards and in which the TEAM participant's eligible clinicians may be assessed for QP determinations (to the extent TEAM is determined to be an Advanced APM for Track 2 and Track 3), and a non-AAPM option in which TEAM participants would not meet CEHRT or financial risk standards and in which the TEAM participant's MIPS eligible clinicians may be assessed for reporting and scoring through the APM Performance Pathway (APP) (to the extent the TEAM is determined to be a MIPS APM for all tracks).

A two-track option that allows entities chosen to not have to attest to CERHT requirements would be preferred. The entities in this MIPs APM should be allowed to take on risk in this program if they so choose, even without receiving QP status through being in a non AAPM option.

CMS proposes that each TEAM participant with eligible clinicians or MIPS eligible clinicians must submit to CMS a financial arrangements list in a form and manner and by the date specified by CMS on a quarterly basis during each performance year or attest that there are no individuals to report on the financial arrangements list.

CMS should ensure the timeline for the financial arrangement lists align with model reconciliation periods.

Interoperability
CMS notes that given the existing federal interoperability initiatives, they do not want to create duplicate efforts or create unnecessary burden on TEAM participants and are seeking comment on how CMS can promote interoperability in the proposed TEAM, in particular, to what extent TEAM participants are planning on participating in TEFCA in the next 1-2 years, as well as other means by which interoperability may support care coordination for an episode. Any further proposals related to interoperability included in TEAM would be done in future notice and comment rulemaking.

Trinity Health is planning to participate in TEFCA in the next 1-2 years via our standard EHR platform. To enhance data exchange that might benefit these patient populations, CMS could:

1) Enhance the current ADT requirement (hospitals must send ADT event notifications to a patients primary care provider and care team as part of CMS CoPs, to include Patient's name, Treating practitioner name, and Sending institution name) to specify a standard for the content, format, or delivery of these notifications – and any additional required data that would enhance the value of these notifications.
2) Further specify data to be exchanged as part of the "health information exchange" interoperability measures. For example, the traditional HIE measures (send/receive and reconcile) require hospitals conduct clinical information reconciliation for medication, medication allergy, and current problem list. The TEFCA measure does not specify data to be exchanged but rather requires participation in TEFCA and the use of it to support bi-directional exchange of patient information.

Appeal Procedures

The proposed rules outlines a process for appealing payment and reconciliation determinations.

Trinity Health asks CMS to clarify whether the 30-day timelines are business days or calendar days.

Referral to Primary Care

CMS proposes that participating hospitals would be required to include a referral to a supplier of primary care services as part of hospital discharge planning on or prior to discharge from an anchor hospitalization or anchor procedure.

Trinity Health supports, as it is reasonable to provide patients a referral to primary care if they don't already have a relationship with a primary care provider.

Voluntary decarbonization and Resilience Initiative

CMS proposes a voluntary Decarbonization and Resilience Initiative within TEAM to assist hospitals in addressing the threats to the nation's health and its healthcare system presented by climate change and the effects of hospital carbon emissions on health outcomes, healthcare costs and quality of care. The voluntary initiative would have two elements:

(1) technical assistance for all interested TEAM participants
(2) voluntary reporting option to capture information related to Scope 1 and Scope 2 emissions as defined by the Greenhouse Gas Protocol (GHGP) framework, with the potential to add Scope 3 in future years

Trinity Health supports CMS including a voluntary mechanism for TEAM participants to engage in these activities with support and guidance from CMS. **To incentivize participants to take advantage of this opportunity, we recommend:**

- CMS provide upfront funding/incentives for this reporting to help offset the cost to health care organizations that invest into platforms and consulting.
- CMS ensure that reporting leverages the least burdensome approach for hospitals. Reporting requirements should be streamlined, easy to understand, and automated to the extent possible to reduce administrative burden. In addition, CMS should work with federal partners to ensure that similar reporting for all federal agencies align so there aren't different measures for different programs or settings.
- CMS provide additional leniency in reporting of Scope 3 emissions due to the complexity of these emissions in large healthcare systems.

CONCLUSION

We appreciate CMS' ongoing efforts to improve payment systems across the delivery system. We welcome the opportunity to inform any future Medicare and are happy to partner with CMS. If you have any questions on our comments, please feel free to contact me at jennifer.nading@trinity-health.org.

Sincerely,

/s/

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