Trinity Health

September 4, 2024

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-1807-P; Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments
Submitted electronically via http://www.regulations.gov

Dear Administrator Brooks-LaSure,

Trinity Health appreciates the opportunity to comment on policies set forth in CMS-1807-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 participated for many years 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.

The proposed cuts to the conversion factor will negatively impact patient care and increase burnout and turnover. We urge CMS to work with Congress to develop a permanent solution to physician payment. In addition, we urge CMS to:

- Work with Congress to *permanently* extend telehealth flexibilities by year end and finalize the policy that would permit distant site providers to use the currently enrolled practice instead of home address when providing telehealth services from their home through CY25.

- Provide additional guidance and clarification on documentation requirements for the new proposed codes for E/M complexity, add on for infectious disease, and caregiving services.
- Not finalize the proposed enhanced case management and work with stakeholders to identify way to continue to promote and incentivize participation in total cost of care arrangements.
- Finalize the Atherosclerotic Cardiovascular Disease Risk Assessment and create distinct codes that address the management of uncontrolled high blood pressure.
- Finalize the proposed policies on behavioral health and colorectal cancer screening.
- Make certain clarifications for the Medicare Diabetes Prevention Program.
- Implement the proposed policy to permit a signed and dated therapy order to serve as the physician or NPP's initial certification of the plan of care.
- Finalize the QPS calculation methodology without the requirement of the two additional measures in the proposed APP Plus Quality Measure Set, as well as finalize the addition of the Complex Organization Adjustment and the extension of the eCQM reporting incentive.
- Delay the adoption of the APP Plus Quality Measure Set until 2026 and extend the Web Interface as a reporting option in 2025.
- Repeal the CEHRT and mandatory MIPS Promoting Interoperability requirement for Advanced APMs that is set to begin in 2025.

Below are additional comments.

I. MEDICARE REIMBURSEMENT

Physician Payment Cuts

The proposed conversion factor for 2025 is $32.3562, a whopping 2.8% reduction from 2024. Trinity Health is deeply concerned with how these cuts will impact access and patient care, especially as we face critical workforce shortages and inflationary increases in wages, pharmaceuticals and medical supplies.

In 2020, the conversion factor was $36.0896. **These annual cuts are not sustainable for the mission of our health care system and each year, we have been asked to do more with less. These continued cuts create long wait times for patients, lead to staff burnout and turnover, and increase the dissatisfaction of patients and providers.**

The proposed cuts will not occur in isolation and will exacerbate the financial pressures facing Trinity Health and similar providers. We continue to grapple with the extraordinary inflationary environment and continued labor and supply cost pressures.

The proposed cut is a critical reminder that patients and physicians desperately need Congress to develop a *permanent* solution that addresses the financial instability and threatens access to care. **Physician payment must increase via an inflation-based payment update based on the full Medicare Economic Index.**

We urge CMS to use any and all available authorities to eliminate payment cuts and work with Congress to find a permanent solution for these cuts. Trinity Health supports the Strengthening Medicare for Patients and Providers Act (H.R. 2474) that would update the conversion factor by an amount equal to the annual percentage increase in the Medicare Economic Index. Trinity Health understands the conversation factor cuts are a statutory requirement of the Physician Fee Schedule as it was implemented, but the Physician Fee Schedule is the only component of the CMS payment structure that doesn't have an appropriate inflationary factor built into base rates as they are created year after year. As a result of the continued inflationary pressure and this

approach to the Physician Fee Schedule, payments for professional services lag inflation by 29% dating back to 2001. However, it is important that CMS explain to Congress the ramifications that the cut will have on the ability of healthcare providers to offer meaningful access to care for their Medicare beneficiaries and serve their communities.

Telehealth

The telehealth flexibilities provided since the COVID-19 pandemic have greatly benefited patients, caregivers, and providers. Telehealth must become a routine part of patient care to maintain access and meet consumer expectations for convenient, person-centered, technology-supported care. Trinity Health is committed to ensuring that all patients have the ability to use telehealth services when needed, including the most disadvantaged. We urge CMS to work with Congress to implement policy changes that support the permanent continuation of telehealth flexibilities to enable an efficient and equitable health care system.

Trinity Health urges CMS to work with Congress to *permanently* extend telehealth flexibilities by year end, including:

- Allow all telehealth visits to be reimbursed when originated within the patient's home or location of their choosing.
- Allow all Medicare patients access to telehealth, regardless of geographic location.
- Allow clinicians to furnish and bill with parity of payment for in-office visits across all payers and settings.
- Ensure audio-only remains a reimbursable option for physicians to care for patients who do not have audio and visual technology or capability.
- Allow coverage of the facility component of telehealth offered in a provider-based clinic.
- Reimburse providers for telehealth services in home health benefits.
- Include attribution to an ACO as evidence of an existing provider/patient relationship.
- Maintain flexibility for remote-patient monitoring and reimburse for this service, including when provided through home health.
- Allow clinicians to be reimbursed for telehealth when seeing new patients or a patient not previously seen at their practice.
- Remove limitations on frequency of services.
- Advance policies that ensure access to affordable broadband, technology resources, and telehealth services for communities of color and other underserved populations.
- Allow providers to practice across states lines and at the top of their license, including medication prescription and flexibility to allow physicians to treat their patients while in a state where they may be temporarily located.

The rule would permit distant site providers to use the currently enrolled practice instead of home address when providing telehealth services from their home through CY25. This is a policy Trinity Health has advocated for and we urge CMS to make this authority permanent.

In addition, we support the proposal to remove the frequency limitations for subsequent inpatient visit (CPT codes 99231-99233), subsequent nursing facility (CPT codes 99307-99310), and **critical care consultation services** (HCPCs codes G0508 and G0509).

Virtual Presence

During PHE, CMS changed the definition of direct supervision to allow a supervising professional to be immediately available through virtual presence using real time audio video for diagnostic tests, physician services

and some outpatient services. The proposed rule would temporarily extend this flexibility through CY25 and permanently allow for direct supervision to be met through a virtual presence for some services that are often performed by auxiliary personnel.

Trinity Health supports this provision.

Proposed New Codes

E/M complexity code

In CY 2024, CMS implemented a new E/M add-on code (G2211) to account for intensity and clinical complexity. This was intended to account for additional costs in treating a patient's condition. For CY 2025, CMS proposes to refine guidance to allow payment of the complexity add-on code when the base code is reported by the same practitioner on the same day as an annual wellness visit, vaccine administration or any Medicare Part B preventive service furnished in the office or outpatient setting.

Hospital inpatient or Observation (I/O) E/M add on for infectious disease

This add-on payment would describe the intensity/complexity of care associated with a confirmed or suspected infectious disease performed by a physician with specialized training and would include: disease transmission/mitigation, public health investigation, analysis and testing, and antimicrobial therapy, counseling and treatment.

Payment for care giving services

CMS proposes to establish new coding and payment for caregiver training for direct care services to support focus on specific clinical skills aimed at the caregiver effectuating hands-on treatment, reducing complications and monitoring the patient. In addition, the rule would implement new coding and payment caregiver behavior management and modification training that could be furnished to the caregivers of an individual patient.

We appreciate these new codes; however, we urge CMS to provide additional guidance and clarification on documentation requirements for each. Vague documentation for new codes makes it difficult to get reimbursed, as MACs interpret requirements differently. In addition, we have been waiting on additional guidance on documentation requirements for the new E/M add-on code G2211 that was finalized last year.

Advanced Primary Care Management Proposal

The Advanced Primary Care Management Proposal as outlined, does pave the way for primary care providers to focus on the PCP relationship and primary care management services for FFS Medicare beneficiaries outside of an ACO model. **The challenge with the APCM services is the potential overlap with services provided to beneficiaries in the ACO model.**

Trinity Health

- **Supports the recommendation of removal of the time-based CM codes (e.g., PCM, CCM).**
- **Requests CMS provide clarification on the concurrent billing rules (e.g., PCM, CCM, CoCM, TCM).**
- **Asks CMS to consider adding a modifier to Level 2 codes to reflect social complexity and/or additional medical complexity for non-Qualified Medicare Beneficiary.**
- **Asks CMS to evaluate RVU and compensation to ensure reimbursement supports the resources required to provide these services and oversight in primary care.**
- **Asks CMS to allow services to also be billed by specialty providers meeting the requirements of care management (e.g. cardiology, pulmonary, endocrinology).**

Enhanced Case Management

CMS proposes to incorporate key payment and service delivery models from CMMI, including the Comprehensive Primary Care (CPC) and the Primary Care First (PCF) models, into permanent coding and payment under the PFS for "advanced primary care".

As one of the leading health systems that participates in value-based care and alternative payment models, Trinity Health has found that models such as CPC and PFC work inside total cost of care accountability, but not on their own, and CMS' evaluations illustrate this. **As proposed, the enhanced primary care policy would be confusing for providers that are in an ACO model.**

If the model were to move forward, Trinity Health requests adding a payment waiver to allow for the waiver of co-pay for these services for MSSP ACO beneficiaries to ensure beneficiaries do not decline much need CM resources and coordination of care.

Cardiovascular Risk assessment and Risk Management

CMMI's Million Hearts® Cardiovascular Disease Model that was intended to reduce first time incidence of heart attacks and strokes among medium- and high-risk beneficiaries and reduce spending on cardiovascular events. The model included screening assessments and subsequent lifestyle recommendations. Overall, CMS found the model resulted in decreased mortality rates and risk of mortality from cardiovascular events. Based on these findings, CMS proposes to incorporate a separate billing code for the administration of a standardized, evidence-based Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment.

Trinity Health supports reimbursement for ASCVD risk assessment and management. Further, we urge CMS to create distinct codes that address the management of uncontrolled high blood pressure since it is the leading modifiable risk factor for ASCVD deaths, the main cause of death in the United States, but is poorly managed in this country, with adequate control in only about 47% of hypertensive individuals.

Request for Information on Health-Related Social Needs

In the CY 2024 PFS final rule, CMS finalized G-codes to reflect new coding and payment for Community Health Integration; Principal Illness Navigation (and social determinants of health Risk Assessment.

The rule includes a broad RFI on these newly implemented HPCCS codes, seeking comments about additional policy refinements for CMS to consider in future rulemaking as well as any related services that may not be described by the current coding.

Barriers to furnishing services:

- *Cost-sharing:* CHI and PIN services are initiated when a patients' unmet health-related social needs are interfering with diagnosis or treatment of their health conditions. Unmet social needs are often analogous with basic needs, such as adequate food and stable shelter, which can at times be urgent. We applaud CMS's efforts to reimburse for the services that directly address these health-related social needs and feel the definitions are broad enough to encompass the relevant services. However, the cost-sharing provision means that many patients must be prepared to pay out of pocket prior to accepting the help of a Community Health Worker or other auxiliary personnel. This creates an additional financial burden for patients for whom a significant lack of resources is already the problem at hand. While it is only a few dollars, we believe it will disincentivize patients from accepting the CHI and PIN services that could help

them access the resources available to improve both their health and social situations. We recommend CMS make these services exempt from cost-sharing.

- *30-minute time increment for G0022:* Flexibility is key when working with both patient populations and community-based organizations (CBOs) that are resource limited. 60 minutes feels like a fair time increment for the initial CHI/PIN services encounter, particularly if it is conducted as a home visit. However, follow-up work often comprises important communication with patients and CBOs that can come up unexpectedly (for example, if the patient has reached the top of a resource wait list and must claim their spot, or is missing documentation for a program application with a deadline). Patient engagement cannot always wait to be consolidated with other activity into a billable 30-minute session. Trinity Health's regional health system in Michigan had an easier time transitioning their services into billable units in part because Michigan Medicaid selected a 15-minute time increment for CHW billing. In contrast, our system in California has had to make more operational changes to align services with the 30-minute billing increment reimbursed by MediCal, and does more work that ultimately ends up unbillable. A shorter time increment, such as 15 minutes, will allow us to capture revenue for more of the work that legitimately meets the definition of CHI & PIN services and lower operational barriers to implementation.

- *Compliance obligations secondary to Medicare billing:* The services that constitute CHI & PIN were previously unbillable for most if not all patients, making scaling and sustainability difficult. Making such services Part B benefits is a huge step forward in systematizing and sustaining work to address health-related social needs. Maximizing this opportunity means adding billing-related documentation and workflows and financial conversations with patients where there previously were none. Community-based organizations have a much bigger learning curve, but even within a large health system like Trinity Health this transition has led to many compliance questions and concerns. Specifically, determining the breadth of our obligation to begin generating charges for non-Medicare patients receiving similar services in order to remain compliant as a Medicare supplier entity, and how to avoid creating a financial burden for patients whose health insurance does not cover such services, and even more, those who are uninsured. Greater clarity from CMS around the compliance implications of initiating this billing in both health system/provider organizations and community-based organizations would be useful.

- *Provider documentation of medical necessity:* All unmet social needs affect health and well-being so it is not difficult to demonstrate how they impact the management of specific conditions. Clarity on the type of provider documentation that would adequately demonstrate the medical necessity of CHI and PIN services would be helpful.

- *Fair compensation for Community Health Workers:* health care entities value academic degrees government licensures, and certifications from authoritative bodies but are not accustomed to valuing the lived experience of staff members. Community Health Workers should ideally come from the community they are serving and have lived experience that allows them to relate to vulnerable patient populations in a way that many health care professionals may not. However, the absence of a bachelor's degree often puts the pay rates of CHWs similar to those of call center and front desk employees – important jobs, but not at the same level of responsibility or creative problem-solving required of CHWs.

Training and certification for unlicensed auxiliary personnel

- *Training and certification:* Trinity Health agrees with the expectations for training and certification of the auxiliary personnel furnishing CHI & PIN services. Further, we advocate for such training and certification to be the responsibility of the employer to facilitate and fund. The alternative means that community members who would make excellent Community Health Workers (or other types of peer-related roles) but who cannot afford the fees and time away from work to undergo the required training on their own would face significant barriers to entering this line of work.

SDOH Risk Assessment

- *"Screening" vs "Risk Assessment":* The SDOH Risk Assessment benefit caused confusion among our regional health systems. They had been scaling primary care screening workflows in relation to internal key performance indicators, then launched similar work for the inpatient setting in compliance with the new CMS IQRS and Joint Commission hospital accreditation requirements. Many assumed that this SDOH Risk Assessment benefit would fund the screening work already underway even though CMS FAQs released in April 2024 specified that Risk Assessment for patients with a known social need is not the same as screening entire populations. This appeared to be largely due to the fact that CMS suggested the use of tools that refer to themselves as "screenings" – e.g. PRAPARE and the AHC tool. Both of these tools are much too long for routine screening in a clinical setting and are often not used for actual "screening" of entire patient populations. Also, the recent emphasis on screening led to assumptions about the benefit. We recommend CMS consider reimbursing for social needs screening of all Medicare beneficiaries without cost-sharing.

  In addition, many of our clinical settings had set up follow-up workflows based on social needs screening results. The addition of a second, more in-depth formal assessment for which patients must share the cost does not appear to meaningfully change the follow-up action to be taken, and so its utility is limited.

- *Suggested tools:* In addition to confusion around "screening" vs "risk assessment", many of our regional health systems have asked whether the entirety of a validated tool must be used for SDOH Risk Assessment, or if a subset of questions could be selected. Clarification is sought on CMS expectations for use of validated tools. Also, it could be beneficial for CMS to select a tool or short list of tools to recommend be used, rather than require; this would aid in decision-making about which tools to build into EMRs and other systems used by health care providers and staff.

- *Cost-Sharing:* As with CHI and PIN services, it causes moral distress to request additional out-of-pocket payment from patients with known health-related social needs for the act of further assessing their needs, which often times are financial.

Use of Z codes:

- Z code application is much talked about but not always widely practiced as there are no immediate, unique benefits to healthcare providers (assuming there are other sources of aggregate information on patient social needs, such as screening results). The role of Z codes in the industry remains unclear, and this makes it difficult to invest the time and resources needed for EMR builds that facilitate code use and

related training of providers and staff. As CMS sets the tone for the industry, having clear guidance on the use of Z codes specifically (as opposed to e.g. LOINC codes) could be useful to direct infrastructure investments and hopefully bring other payors and accrediting bodies in line with this expectation.

Behavioral Health Policies

CMS proposes several updates regarding mental illness and substance use disorder services, including new payments for practitioners assisting people at high risk for suicide or overdose as well as for post-discharge follow-up, digital treatment, and interprofessional consultations.

The policies support CMS' commitment to behavioral health and patients and we support the proposals. Regarding the provision of opioid agonist and antagonist medication, we recommend this flexibility only be provided as part of an established, longitudinal patient-provider relationship.

Updates to Colorectal Cancer Screening Policies

The rule would remove coverage of barium enemas as a colorectal cancer screening test; add CTC as a covered colorectal cancer screening test; and revise regulations to state that colorectal cancer screening tests includes a follow-up screening colonoscopy after a Medicare covered non-invasive stool-based screening test or a Medicare covered blood-based biomarker screen test returns a positive result.

Trinity Health applauds these expansions for colorectal cancer screening policies.

Certification of Therapy Plans of Care with a Physician or NPP Order

CMS proposes to carve out an exception to the physician signature requirement for purposes of an initial certification in cases where a signed and dated order/referral from a physician, NP, PA, or CNS is on file and therapist has documented evidence that the plan of treatment has been delivered to the physicians, NP, PA, or CNS withing 30 days of completion of the initial evaluation. CMS also seeks additional feedback on addressing the amount of time for changes to plan of treatment for future rulemaking.

Trinity Health supports the policy to permit a signed and dated therapy order to serve as the physician or NPP's initial certification of the plan of care. Any delay in care is a disservice to our patients. Requiring an additional signature beyond the initial order is cumbersome not only to the therapy office, but also to the physician office. The extra time spent in this administrative task could be better used for patient care.

When a physician or NPP refers a patient to physical/occupational/speech therapy, they are relying on the expertise of that therapist to establish a plan of care that is conducive to their medical condition and rehabilitative needs. When the physician wants something specifically done in therapy, it is our experience that they include it on the order or attach their protocol with the referral. It is very rare that we experience a physician or NPP changing the therapist's plan of care. Allowing the physician 10 days to make a modification to the plan of care is also too long. Within 10 days, healing can be delayed, the patient will not receive pain relief or improvements in mobility they are seeking, and it could also result in the patient not being able to schedule therapy on a day that works for them and their caregiver. Payment for therapy services rendered prior to a physician's modification of the plan of care should be guaranteed, and not conditional upon the provider's approval.

It is also not sustainable for a therapy office to absorb the costs of care for a patient because we were not able to obtain a signature on the plan of care. We have some physician offices that are very good at returning the plan

of care right away and others that require multiple reminders. We need to do what is right for the patient AND we need to be properly reimbursed for the services rendered.

Drugs, Biologicals, and Radiopharmaceuticals Blood Clotting Factors.
Blood clotting factor treatments are covered under Medicare Part B, whether the treatment is self-infused or provided in the physician office setting. In contrast, when clotting factor is administered in health care settings, administration fees are paid, reflecting the resources involved in administering the product. To ensure that double payment of administration fees does not occur, CMS proposes to clarify that that blood clotting factors must be self-administered to qualify for the furnishing fee under existing CMS policy.

Trinity Health recommends CMS clarify that there is an exception for when a patient needs a blood clotting factor for hemophilia and surgery while in the hospital. Many of the blood clotting factors are incredibly expensive and the cost of reimbursing the drug while a patient is in the hospital would not be reimbursed if finalized as proposed by CMS. Absent the recommended clarification, there could be a significant negative impact on hospitals due to lack of reimbursement.

Medicare Prescription Drug Inflation Rebate Program
In calculating inflation rebates, the law requires CMS to exclude billing units of Part B and Part D drugs purchased under the 340B drug pricing program. To determine units of Part B drugs purchased under the 340B program, CMS proposes using a claims modifier that it established in the CY 2024 outpatient prospective payment system. For Part D, CMS proposes to estimate the total number of Part D drug units purchased under the 340B program using the total number of units purchased by covered entities under the 340B program for each drug, as defined by the drug's NDC, divided by the total units sold of that drug. CMS would work with the Health Resources and Services Administration and its prime vendor, Apexus, to obtain 340B purchasing data at the NDC level and leverage existing manufacturer-reported data under the Medicaid drug rebate program to determine total drug units for each drug at the NDC level.

Trinity Health agrees with CMS' approach of developing an estimation percentage, especially considering other options could include having a covered entity do a retrospective review, which would increase burden. **Using Apexus as a proxy is fine; however, we caution that Apexus does not include direct purchases and it is possible this could deflate the true number of purchased under 340B.**

Medicare Diabetes Prevention Program
CMS proposes several changes to the DPP program, including changes to conditions of coverage to add flexibility for virtual and distance learning sessions, eliminating bridge payments, and allowing for payment of same-day make-up sessions.

Trinity Health supports the addition of the new MDPP term for "in-person with a distance learning component" so there is alignment with the new standards. When finalizing CMS should clarify if a current MDPP supplier pivots to apply for the new org code "in person with a distance learning component," whether there will there be a period of MDPP billing ineligibility while the new org code is in pending status.

Trinity Health also supports the addition to add a HCPC modifier for reporting a make-up session, as these are aligned with the new standards.

Trinity Health recommends the following changes to the policy:

- **Health Equity concerns with Self – Reporting Weight for distance learning**
    - **Not all members have access to smart phone(s) to accurately take 2 photos according to requirement.**
    - **Recommending possibility of using Bluetooth scales**
- **Clarification on the rule language pertaining to MDPP terminology, payment structure, and requirements. What is being referenced specifically?**

II. MEDICARE SHARED SAVINGS PROGRAM

Trinity Health is pleased that CMS continues to work to improve and enhance MSSP, and while we align with many of the proposed changes, there is still significant opportunity through policy changes that could advance the program and achieve the goal of having all Medicare beneficiaries in an accountable care relationship by 2030.

Quality

New MSSP Quality Measure Set, APP Plus

Trinity understands CMS's desire to better align with the Universal Foundation measure set, however, we are very concerned with requiring ACOs to report two additional measures in such a short timeframe and in the same year the Web Interface and MIPS CQM reporting options are set to retire.

ACOs must make significant financial and people investments and implement workflow changes to adopt new measures using these new reporting types, which takes time, and many ACOs are still building and testing the framework needed for the new reporting requirements. For the three currently required eCQM measures, our national ACO estimates that we will have to aggregate, ingest and de-duplicate over 6 million QRDA1 files for all payers and patients in order to produce the required QRDA 3 file. This is new work that requires adding new resources that will not be dedicated to caring for patients.

Adding two additional measures will significantly increase the volume of QRDA1 files that ACOs have to manage, therefore, requiring additional resources that will have to be pulled away from other clinical and operational priorities. Adding two extra measures within a 6-month runway does not allow enough time to resource, build and test before the start of Performance Year 2025. **Trinity Health asks that CMS delay the new APP Plus quality measures until 2026. When adding additional eCQM measures, the required reporting year should be no earlier than one full performance year after the new measure is finalized in ruling. Additionally, we urge CMS to extend the Web Interface reporting option for one additional year to give organizations time to finish building and testing the necessary infrastructure needed for reporting eCQMs and prepare for the new APP Plus quality measure set.**

Reporting Types

Trinity Health was discouraged to see that CMS proposed to eliminate both the Web Interface and the MIPS CQM reporting types for PY2025 and subsequent years despite ACOs expressing numerous concerns and requests to delay the retirement of the Web Interface. This policy has eliminated over 40 small independent primary care practices from participating in our ACOs due to the financial and technical burden being placed on their practices for new quality reporting requirements. This policy change has resulted in a reduction in the number of Medicare patients in an accountable care relationship which is the opposite of CMS's strategy.

Our ACOs are made up of multiple clinically integrated networks containing over 2,000 independent affiliate providers, many of whom have relayed to us that they are being asked by their EHR vendor to pay anywhere from $200-500 per provider per instance of report that needs to be produced, which could end up costing our ACO and its providers over $600,000 each year. Additionally, some ACOs have been preparing or already reporting MIPS CQMs, so abruptly removing that reporting type option in such a short period of time could result in ACOs losing significant amounts of money that they have already invested. **Trinity Health strongly encourages CMS to consider extending all reporting types, including Web Interface for an additional year, and would ask that CMS instead focus efforts on the transition to digital quality measurement (dQM) as CMS has indicated that dQM is the gold standard collection type.**

Establishing a Complex Organization Adjustment & Extending the eCQM Reporting Incentive for Meeting the MSSP Quality Performance Standard

Trinity Health appreciates CMS's recognition of the challenges some APM Entities may face in reporting eCQMs and supports the addition of the Complex Organization Adjustment. During our eCQM transition work, we identified that our national ACO has over 100 different instances of EHRs and approximately 40,000 patients attributed to over 2,000 independent providers, which adds significant financial and operational complexity to successfully report eCQMs. We welcome the extension of the eCQM reporting incentive for meeting the MSSP Quality Performance Standard (QPS) and support the QPS calculation methodology. Providing the complex organizational adjustment and extension of the eCQM reporting incentive will help give ACOs confidence to move ahead with completing the eCQM reporting transition without having to also make allowances for a potential negative impact to shared savings. However, with such a short amount of time to prepare for an additional two measures, **we urge CMS to implement the QPS calculation methodology without the requirement of the two additional measures in the proposed APP Plus measure set. As a complex organization, we need these changes and fully appreciate and support the change in calculation of the QPS as well as the extension and addition of bonuses for reporting eCQMs for PY25 in the APP Plus measure set.**

We support the move to the universal measure set in the APP Plus reporting track, but given the complexities, the phase-in approach should start in performance year 2026. To further offset the struggles ACOs are facing and improve eCQM reporting, **we propose CMS make the following updates to the eCQM reporting requirements:**

- **Update the data completeness threshold for eCQMs to a threshold based on percentage of NPIs reporting vs. percentage of eligible patients in the measure denominator.**
- **Maintain the data completeness threshold at 75% based on the recommendation above.**
- **Remove non-primary care specialties from reporting on primary care specific measures.**

Additionally, we noted that in this proposed rule CMS did not reference the new requirement starting in 2025, which requires all APM participants to be on CEHRT, as well as the subsequent mandatory Promoting Interoperability (PI) reporting to meet the requirement regardless of QP status. This is a step backwards in being rewarded for participating in an Advanced APM and introduces significant new financial and business risk into model participation, which has providers questioning the value of participation in CMS APMs and investments they are making. Many of these providers have not had to report PI for long periods of time, and introducing this requirement while also requiring new quality reporting methods with eCQM or Medicare CQMs is resulting in providers having to be removed from the program due to inability to meet all of the new requirements. Our MSSP ACO has already removed 44 ACO Participant TINs amounting to about 90 providers and over 1,300 beneficiaries, who will be unable to meet this requirement, and we expect to remove more before the CMS

application deadline. Having to remove ACO participating practices and therefore losing beneficiaries directly contradicts CMS' goal of getting more lives under an accountable relationship. **We remain opposed to this policy and strongly advise CMS to reconsider this requirement.**

Financial Methodology

Anomalous and Highly Suspect Billing & Reopening ACO Payment Determinations

We applaud CMS for taking action to develop the framework for identifying and removing anomalous billings from both performance year and benchmark calculations for Performance Year 2024 and future years. This policy fairly protects ACOs and ensures they are not held accountable for fraudulent billing that is occurring outside of their control; however, this should also apply to non-catheter anomalous billing identified in 2023. The 2023 catheter spending is not the only instance of ACOs reporting suspected fraudulent billing.

We ask that CMS address the other areas of SAHS billing and provide additional details to support longer term strategies to address anomalous spending. According to a recent press release, the Justice Department announced the 2024 National Heath Care Fraud Enforcement Action, which resulted in criminal charges in connection with amniotic wound grafts, laboratory fraud, telemedicine as well as other areas. **We ask CMS to take a similar approach for other codes and categories deemed SAHS in 2023.**

Health Equity Benchmark Adjustment (HEBA)

Trinity Health supports the HEBA proposal despite the estimate that relatively few current ACOs are expected to benefit from the HEBA. Introducing this type of adjustment may increase MSSP participation among providers who care for higher-risk patients and who would likely not benefit initially from the two existing adjustments. To continue to make MSSP more appealing to providers who provide care to historically underserved beneficiaries, we propose that the HEBA should be in addition to the current adjustments rather than in place of the other two adjustments.

Additionally, we encourage CMS to expand the beneficiaries included in the HEBA calculation, to include beneficiaries who obtained Medicare coverage due to disability, as well as beneficiaries that live in an area with a high ADI. Overall, this policy aligns with CMS's health equity goals and your strategy to have all Medicare beneficiaries in accountable care relationships by 2030. While this proposal is a step in the right direction, **we continue to urge CMS to do more for successful ACOs, like us, who have earned savings in multiple years and are affected by the "rachet effect" on our benchmarks.** This issue threatens the sustainability of the MSSP program by de-incentivizing established ACOs from continuing to participate in the program.

Prepaid Shared Savings Option

Trinity Health supports the option for ACOs to receive quarterly, prepared shared savings because it provides ACOs with an upfront cash flow to invest in staffing, infrastructure and other population health initiatives used to further the purpose of the MSSP and provide additional benefits to our beneficiaries. However, we recommend CMS not implement the prescriptive requirements to spend at least 50% of the prepaid shared savings on direct beneficiary services.

Currently, ACOs and ACO Participants are not mandated to spend earned shared savings in a specific manner, so putting parameters around how the dollars must be spent will likely decrease participation in this offering. Today, we are investing our shared savings in a wide variety of activities that benefit traditional Medicare beneficiaries, clinicians, and practices. Allowing ACOs to retain full flexibility in how to use the prepaid shared savings, including providing the funds directly to the providers who are caring for the beneficiaries, and letting

them decide how to utilize the dollars based on their patients' needs would be the best use of the upfront cash flow.

Additionally, the requirement to submit a spend plan and publicly report the spend plan as well as the actual use of the prepaid shared savings is administratively burdensome to providers and ACOs. CMS has expressed disappointment in the past that ACOs have not participated in other flexibilities offered, and that is because the administrative burden is so much greater than the potential benefits. This will likely be the same if CMS does not allow more flexibility for the ACO to determine the best use of the dollars for their attributed population and participating network. To lessen the administrative burden on ACOs and increase the likelihood that ACOs take advantage of this offering, **we recommend that CMS only require ACOs to publicly report if they elected to receive the prepaid shared savings and report how they utilized the dollars at an aggregate level rather than an itemized breakdown.**

Beneficiary Assignment

Voluntary Alignment

CMS has proposed to revise current MSSP voluntary alignment regulations to broaden the existing exception to also include models which employ a claims-based assignment methodology using both primary care and non-primary care services. While the proposed revision to current voluntary alignment policy is expected to have a very minimal impact, it is our position that if a patient voluntarily aligns themselves to their primary clinician, that should take precedence over claims-based attribution. Furthermore, pulling patients out of MSSP and putting them into a time-limited model goes against the principles of accountable care by carving up accountability and works against the growth efforts for MSSP. ACOs have accountability for total cost of care and outcomes across the continuum, so alignment policy should preserve populations alignment to ACOs. **Instead, we propose that CMS focus on reducing current operational challenges ACOs and beneficiaries face with voluntary alignment in MSSP and make enhancements to the current MSSP voluntary alignment policy.**

Operational challenges with voluntary alignment and how the process is managed by CMS can create confusion for beneficiaries and practices. CMS' factsheet for beneficiaries on how to choose a primary clinician may be misleading, as it indicates beneficiaries are aligning to an individual clinician who they believe is responsible for managing their overall care. Operationally, CMS aligns beneficiaries to a practice location, not a specific clinician. When an individual clinician leaves a particular practice location, the beneficiaries that follow the clinician to a new location will still align to the previous practice location. This results in beneficiaries being attributed to ACOs they are no longer receiving care through, or not being attributed to an ACO provider from which they are receiving primary care services, because voluntary alignment takes precedence over claims-based alignment. In MSSP, beneficiaries must also use the MyMedicare.gov website to select their primary clinician, but many beneficiaries may not have access to the internet or be able to navigate the website to make this selection. Paper-based voluntary alignment is being tested in the ACO REACH Model and increases voluntary alignment. However, the ACO REACH Model has limitations in alignment; home-based primary care providers have no ability to conduct voluntary alignment because it may not be discussed in the patient's home even when that is the site of care. This challenge has been particularly significant for High Needs ACOs in the REACH Model, which serve more homebound patients.

Improvements to how voluntary alignment is operationalized would better engage beneficiaries in primary care, increase transparency, and enable providers to understand and manage their attributed populations. To do this, **CMS should: Improve voluntary alignment such that patients align to an individual clinician versus a practice location.** For example, allowing TIN-NPI participation would ensure beneficiaries are aligning to the

provider of their choice, rather than to a practice location. Provide information to beneficiaries on how to select a primary care provider when they enroll in Medicare and explain why this is beneficial to their care. Provide information on how beneficiaries can access a patient navigator who can help to connect them with a primary care provider. Provide ACOs with information on which individual providers their assigned patients are attributed to and provide an exception to allow for home-based primary care providers to discuss voluntary alignment with their patients. **We strongly urge CMS to consider these recommendations to improve voluntary alignment so that we can grow our ACO population and help achieve CMS's 2030 goals**.

Eligibility Requirements and Application Procedures

Monitoring Compliance with 5,000 Beneficiary Threshold

Trinity Health supports the proposal to sunset the requirement that CMS must terminate the participation agreement if the ACO does not have at least 5,000 beneficiaries assigned at the end of the performance year. Compared to when MSSP was first developed, MA is growing at a much faster rate and the current limitation is leading to more growth in convener-led consolidation. In order to preserve independent provider participation in the MSSP, ACOs should have the flexibility to use the remaining performance years to work on increasing attribution rather than being required to exit MSSP.

Revising Antitrust Language in Application Procedures

Trinity Health supports the proposal to remove the reference to the Antitrust Enforcement Policy Statement, aligning with the Antitrust Agencies' decision to withdraw the Antitrust Enforcement Policy Statement. However, we encourage CMS to work with other agencies to provide further clarity on the antitrust treatment and integration standards for ACOs related to MSSP participation, as well as their activities in the commercial space.

Beneficiary Notifications

Modifying Requirements for Timing of Follow-up Communication

Trinity Health appreciates CMS reevaluating the timing requirements and providing clarity of the follow-up communication, and we support the proposed change as this will help reduce some of the operational complexity of complying with the follow-up communication. However, even with the proposed change, the beneficiary notification and follow-up communication are overly burdensome to ACOs financially and administratively, and direct feedback from our beneficiary focus groups indicates that the additional communication is confusing and does not improve comprehension of the ACO objectives. **Trinity Health once again urges CMS to remove the follow-up requirement all together as it causes undue beneficiary confusion and frustration and takes away valuable resources that would otherwise be used to contribute towards ACO goals and objectives, and instead allow ACOs to develop and tailor content that's more meaningful to their population's needs.**

III. QUALITY PAYMENT PROGRAM

Performance Threshold and Data Completeness Criteria

Trinity Health appreciates CMS for proposing to maintain current performance threshold polices and supports this proposal. With all the changes occurring with quality reporting that providers and ACOs will be focused on, this is a fair proposal.

MIPS Value Pathways (MVPs)

Trinity Health supports the streamlined MIPS reporting pathways like MPVs and introducing MVPs specific to select specialties. We welcome more options to report MIPS, especially for unique groups of clinicians. **However, we are opposed to making MVPs mandatory in the future with the sunsetting of traditional**

MIPS reporting as currently proposed as this takes away flexibility for reporting options for providers required to report MIPs or non-APM quality. CMS should also fix disincentives for specialists' participation in APMs.

APMs like the MSSP model have encouraged removal of specialist providers due to complex quality reporting requirements and QP threshold issues with keeping them in the program. While MVPs give specialist providers, who would otherwise have to report MIPs, more flexibility and specialty focus, it does not fix the underlying issue of reporting challenges in APMs. If MVPs are designed to evolve the providers for APM participation MVPs do not solve this.

Requests for Information

Establishing Higher Risk and Potential Reward under the ENHANCED Track

Trinity is pleased to see CMS is still exploring the opportunity to establish a higher risk track than ENHANCED. We have advocated for a model that builds off the success of the Next Gen ACO model and could provide a bridge or alternative to ACO REACH. **Here are some recommendations for CMS to consider as the model is built:**

- The higher risk track should be in addition to the current A-E and ENHANCED tracks and should not replace the current ENHANCED track.
- CMS should give ACOs a choice between full risk with a discount and 85-90 percent shared savings rate. This should be similar to how ACO REACH and Next Gen offered options for percent savings, variable discounts, and caps on savings and losses rates between 5-15%
- In prior models, ACOs had the ability to participate in alternative payment arrangements, including infrastructure payments and population-based payment. The infrastructure payment provided an upfront payment that is recouped against savings or in addition to losses. When Trinity participated in the Next Gen model, we used this payment structure to fund investment in population health for independent practices to participate in full risk by providing investment funding before shared savings. Even established ACOs can benefit from this structure as we are always developing new programs and looking to add new practices who need the investment. In the population-based payment arrangement, certain ACO providers agree to receive reductions to their FFS reimbursements from CMS. Many then successfully used this option to negotiate payment arrangements with Skilled Nursing Facilities, laboratory service providers, and other entities to improve population health for their patients and drive value in their local communities. We encourage CMS to retain these options for organizations participating in the full risk offering.
- CMS allowed Next Gen providers to reduce or eliminate cost sharing for certain Part B services for attributed beneficiaries. The goal of this benefit has been to allow ACOs to reduce financial barriers for beneficiaries, encouraging better adherence to treatment plans. CMS gave Next Gens the flexibility to identify certain beneficiaries to receive these benefits. This waiver, and the flexibility for the ACO to determine how to implement the benefit, are features of the model that should be added to MSSP and future full-risk models for ACOs taking on performance-based risk.
- CMS should consider non-financial incentives in a full-risk model to entice participants to move towards higher levels or risk. Examples of these could be NPI level participation, an option for population-based payments, lower attribution thresholds for participation, Primary Care Capitation, Advanced Payment Options, more waivers and flexibilities, and improved voluntary alignment strategies used in ACO REACH.
- This full-risk option should include better reporting and access to data than currently offered in MSSP. Managing populations requires access to data to understand your patients and your performance. The

new model should provide access to data and dashboards that existed under Next Gen. Specifically, Trinity requests that CMS consider adding the Quarterly Benchmark, Claims Lag, and Monthly Expenditure Reports to the reporting package of the MSSP program. These reports added transparency, predictability and supported our efforts to reduce the overall cost of care.

- The higher risk track should also have a streamlined set of quality, EHR and patient experience metrics. Burden reduction is a key benefit for providers who participate in accountable care models, particularly two-sided risk models. Consistent with that approach, the ACO REACH model includes a streamlined set of claims-based quality measures, which are calculated by CMS, and an attestation approach to electronic health records certification. In contrast, for example, CMS recently finalized a requirement that participants in the Medicare Shared Savings Program report the MIPS promoting interoperability performance category measures instead of the attestation requirement. This requirement adds, rather than reduces, burden for APM participants. We request that the Innovation Center retain the streamlined requirements for ACO participants whether in MSSP or a future Innovation Center model.

Guiding Principles for Patient-Reported Outcome Measures in Federal Models, Quality Reporting and Payment Programs

Patient Reported Outcome Measures (PROMs) are very promising for getting closer to the beneficiaries' experience of care and outcomes that matter to them. **Because PROMs are still in development, including with commercial payers, CMS should take a stepwise approach that first establishes a PROM infrastructure with input from providers, then supports reporting and testing in a transparent process sharing data along the way, and then holds providers accountable for performance.** 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. Efforts to advance the use of PROMs should include looking at ways to improve the timeliness of collection and analysis of data and taking action to address issues raised**.**

Advanced Primary Care Hybrid Payment

Because of the prevalence and success of ACOs today and the many efforts and incentives in place to grow ACO participation to meet CMS' stated goals, CMS should "first do no harm" to ACOs. **CMS should not create new payment models that conflict with keeping primary care within and aligned to ACO models.** CMS' own evaluations show that primary care practices within an ACO model outperform those in primary care models alone.

Conclusion

We welcome the opportunity to inform any future policy and are happy to partner with CMS. If you have any questions on our comments, please feel free to contact Jennifer Nading at jennifer.nading@trinity-health.org.

Sincerely,

/s/

Jennifer Nading
Director, Medicare and Medicaid Policy and Regulatory Affairs